PRECEDIUM *drafting assistance*

PREDICATE SHORTLIST

SAMPLE · Predicate shortlist: QAS

QAS · Radiological Computer-Assisted Triage And Notification Software

PRODUCT CODE
QAS

DEVICE TYPE
Radiological Computer-Assisted Triage And Notification Software

CLASS / REGULATION
Class II · 21 CFR 892.2080

PREPARED FOR
Northbridge Imaging (synthetic)

RECORD READ
2026-11-15

90	5	5	0
candidates in the pool	shortlisted	in the same code	recalls listed

ABOUT THIS DOCUMENT

- SAMPLE of the Predicate shortlist, $499. Get yours at precedium.com/services/predicate-shortlist/
- SAMPLE DELIVERABLE. The client (Northbridge Imaging), its device (AortaView), its documents, its FDA correspondence and every figure in them are synthetic, made up for this sample. Every FDA record, summary, guidance and list cited is real and checked.
- Made from the FDA's public record as Device Evidence publishes it (read 2026-11-15): the FDA register, 510(k) summaries read and checked page by page, and openFDA's recall data. A language model chose the order of the five; it wrote no sentence here.
- Every figure is traced to that record, and every passage to the page of the FDA summary it is quoted from; the sources appendix lists each one.
- It covers product code QAS. Its only input from Northbridge Imaging (synthetic) is the device's name and indications for use, as they gave them. The five were ranked by a language model (claude-opus-5-5) from candidates the record supplied; every fact under each comes from the FDA record, not from the model.
- Not regulatory advice, not a recommendation and not a determination of substantial equivalence. Measured on 1,500 decided devices, the predicate the company actually cited was among the five for about half of them. The list is a starting point for the client's regulatory team to review; the choice of predicate is theirs and the FDA decides.

Prepared 2026-11-15. The person exporting it is responsible for its contents; the FDA decides.

Contents

01 Review time in QAS, by submission type ... 3
02 What the 85 AI devices in QAS state ... 3
03 The cleared devices in QAS most like the client's ... 4
04 Where predicates in QAS come from ... 6
05 Changing a cleared device in QAS: the precedent ... 6
06 The leading applicants in QAS ... 7
07 Clinical uses in QAS ... 7
08 Questions the record for QAS raises ... 8
09 The shortlist ... 9
10 The candidates side by side ... 9
11 Candidate 1: K251406 ... 10
12 Candidate 2: K210237 ... 14
13 Candidate 3: K222329 ... 18
14 Candidate 4: K201020 ... 21
15 Candidate 5: K213886 ... 25
16 The other candidates reviewed ... 30
17 Sources and method ... 31
18 Get this predicate shortlist for your device ... 32

Appendix: sources ... 33
Appendix: attachments index ... 36

01 Review time in QAS, by submission type

510(k)s decided in QAS in the last ten years, by the submission type the FDA records. All 510(k)s in the code: median 103 days, one in four over 155, one in ten over 224.[1][2]

Submission type	510(k)s	Median days	75th percentile
Traditional	75	112	160
Special	14	29	29

Calendar days from receipt to decision, including time on hold. A description of past reviews, not an estimate for this one.

02 What the 85 AI devices in QAS state

How many of the code's AI-device summaries state each kind of evidence. An element most of the code states and the client's file does not is a question a reviewer may ask.[1][2]

Evidence element	Code's AI devices stating it	Share
Sensitivity	82 of 85	96%
Specificity	82 of 85	96%
Study design	80 of 85	94%
Performance comparator	77 of 85	91%
Validation sample size	74 of 85	87%
Multiple collection sites	74 of 85	87%
Reference standard	70 of 85	82%
Age distribution	55 of 85	65%
Sex breakdown	50 of 85	59%
AUC	28 of 85	33%
Race or ethnicity breakdown	12 of 85	14%
Prospective collection	1 of 85	1%
Patient outcomes	1 of 85	1%

Counts are floors: a summary can omit what its submission held.

HOW IT HAS CHANGED OVER TIME

The share of the code's AI-device summaries stating each element, by when the device was decided (summaries: 2016-2020 19, 2021-2023 31, 2024 on 35). A rising share is what reviewers now see most often.

Evidence element	2016-2020	2021-2023	2024 on
Validation sample size	79%	87%	91%
Age distribution	26%	68%	83%
Sex breakdown	11%	65%	80%
Race or ethnicity breakdown	0%	13%	23%
Study design	95%	87%	100%
Sensitivity	95%	94%	100%
Specificity	95%	94%	100%
AUC	26%	29%	40%
Reference standard	58%	77%	100%
Performance comparator	89%	90%	91%
Multiple collection sites	84%	87%	89%
Prospective collection	0%	0%	3%
Patient outcomes	0%	0%	3%

03 The cleared devices in QAS most like the client's

Ranked by how many key words of the client's indications appear in each device's own indications statement; a device whose summary names only a different imaging type counts at half weight. A word count, not a judgement of equivalence.[12]

Device	Applicant	Decided	Imaging type	Key words shared
K213886 BriefCase	Aidoc Medical , Ltd.	2022-04-26	CT	56%
K233968 CINA-iPE	Avicenna.Ai	2024-03-13	CT	56%
K200873 HALO	Nico-Lab B.V.	2020-11-20	CT	44%
K201020 BriefCase	Aidoc Medical , Ltd.	2020-08-26	CT	44%

Device	Applicant	Decided	Imaging type	Key words shared
K222329 BriefCase	Aidoc Medical , Ltd.	2022-09-28	CT	44%
K251195 BriefCase-Triage	Aidoc Medical , Ltd.	2026-01-27	CT	44%
K251406 BriefCase-Triage	Aidoc Medical , Ltd.	2025-05-30	CT	44%
K250248 BriefCase-Triage	Aidoc Medical , Ltd.	2025-02-14	not stated	44%
K182875 DeepCT	Deep01 Limited	2019-07-10	CT	33%
K193658 Viz ICH	Viz. Ai, Inc.	2020-03-18	CT	33%

Device	Sample size	Sites	Prospective	Reference standard	Design	Performance
K213886 BriefCase	p. 7	p. 7	-	-	p. 7	p. 7
K233968 CINA-iPE	p. 6	p. 6	-	p. 7	p. 6	p. 7
K200873 HALO	p. 7	p. 7	-	p. 7	p. 7	p. 7
K201020 BriefCase	p. 8	p. 8	-	-	p. 8	p. 8
K222329 BriefCase	p. 7	p. 7	-	p. 8	p. 5	p. 7
K251195 BriefCase-Triage	p. 10	p. 9	-	p. 10	p. 9	p. 10
K251406 BriefCase-Triage	p. 10	p. 9	-	p. 10	p. 9	p. 10
K250248 BriefCase-Triage	p. 8	p. 8	-	p. 8	p. 8	p. 8
K182875 DeepCT	p. 6	p. 9	-	-	p. 6	p. 9
K193658 Viz ICH	-	p. 7	-	p. 7	p. 7	p. 7

04 Where predicates in QAS come from

68 summaries in QAS cite a confirmed predicate (76 links). 100% point to a device in QAS. A predicate was a median 1.8 years old when cited.[12]

Most cited predicate	Applicant	Decided	Cited by
K180647 BriefCase	Aidoc Medical , Ltd.	2018-08-01	10
DEN170073 ContaCT	Viz.AI, Inc.	2018-02-13	7
K203508 BriefCase	Aidoc Medical , Ltd.	2020-12-29	7
K190072 BriefCase	Aidoc Medical , Ltd.	2019-04-15	4
K222884 Rapid NCCT Stroke	Ischemaview, Inc.	2023-03-02	4
K193298 BriefCase	Aidoc Medical , Ltd.	2020-06-19	3
K182177 Accipiolx	Maxq-AI , Ltd.	2018-10-26	2
K190896 BriefCase	Aidoc Medical , Ltd.	2019-05-31	2

05 Changing a cleared device in QAS: the precedent

14 Special 510(k)s were decided in QAS in the last ten years, a median of 29 days against 112 for a Traditional (n=75). A Special 510(k) is for a change to the submitter's own cleared device.[12]

4 devices in QAS have an FDA-authorized predetermined change control plan:[13]

Number	Device	Company	Decided
K260906	A2Z-ABDO-TRIAGE	A2Z RADIOLOGY AI INC.	2026-09-16
K261085	RAPID VESSEL OCCLUSION (RAPID VO)	ISCHEMAVIEW	2026-07-13
K252366	A2Z-UNIFIED-TRIAGE	A2Z RADIOLOGY AI INC.	2025-11-24
K253265	BRIEFCASE-TRIAGE	AIDOC MEDICAL, LTD.	2025-11-06

06 The leading applicants in QAS

The 10 most frequent applicants: when they filed, how long their 510(k)s took, and the predicates their own summaries cite most.[12]

Company	Decisions	First / latest	Median days	On AI list	Predicates they cite most
Aidoc Medical , Ltd.	25	2018-08-01 / 2026-05-14	57	25	K203508 (7); K180647 (5); DEN170073 (2)
Ischemaview, Inc.	11	2020-03-31 / 2026-10-09	94	9	K193087 (2); K200941 (2); K221456 (2)
Ever Fortune.Ai, Co., Ltd.	6	2023-10-04 / 2026-10-30	158	5	K192167 (1); K193298 (1); K221248 (1)
Avicenna.Ai	5	2020-06-24 / 2024-09-12	111	5	K180647 (1); K190072 (1); K190896 (1)
Annalise-Ai Pty , Ltd.	4	2023-04-03 / 2023-09-22	133	4	K193351 (1); K211179 (1); K221314 (1)
Brainomix Limited	4	2023-07-27 / 2025-08-26	96	4	K222884 (1); K232496 (1)
JLK, Inc.	4	2024-09-27 / 2026-03-24	126	4	K222884 (1)
Viz. Ai, Inc.	4	2020-03-18 / 2022-10-21	79	4	DEN170073 (2); K180647 (1)
Siemens Medical Solutions USA, Inc.	3	2022-01-28 / 2025-04-10	224	3	K182177 (1); K203260 (1); K232431 (1)
A2z Radiology Ai, Inc.	2	2025-11-24 / 2026-09-16	181	1	K223240 (1); K252366 (1)

07 Clinical uses in QAS

What the 69 indications statements held for QAS are for. A keyword grouping, labelled as such: a device can fall in several groups, and 1 fall in none.[12]

Body area	Devices	Share
Brain and head	50	72%
Blood vessels	25	36%
Lung and chest	13	19%
Bone, joint and spine	7	10%
Abdomen and pelvis	3	4%
Heart	1	1%

Task	Devices	Share
Triage and notification	68	99%
Viewing and communication	62	90%
Detection	59	86%
Image enhancement	2	3%
Planning and guidance	2	3%
Segmentation and measurement	2	3%

08 Questions the record for QAS raises

Drawn from the figures in this report, for a Pre-Submission meeting or the team. Questions only: the record describes past filings, and the FDA decides.

1. Only 1 of the 85 AI-device summaries in QAS states prospective collection. What does the FDA expect a submission for this device to show on it?

2. Only 12 of the 85 AI-device summaries in QAS state race or ethnicity breakdown. What does the FDA expect a submission for this device to show on it?

3. 14 Special 510(k)s in QAS took a median of 29 days. For later changes to this device, which kinds of modification would fit a Special 510(k)?

09 The shortlist

Five devices already on the market that a company preparing a 510(k) for AortaView would be likely to consider as its predicate, chosen from 90 candidates in the public record.[14]

Measured limit (2026-11-14, 1,500 decided devices): the predicate the company actually cited was among these five for about half of devices (54.9%; about a third for dental devices). This is a starting list for the regulatory team to review, not a recommendation and not a determination of substantial equivalence.

The order is the order the model gave (claude-opus-5-5); the facts under each device come from the FDA record, not from the model.

10 The candidates side by side

	K251406 BriefCase-Triage	K210237 CINA CHEST	K222329 BriefCase	K201020 BriefCase	K213886 BriefCase
Applicant	Aidoc Medical , Ltd.	Avicenna.Ai	Aidoc Medical , Ltd.	Aidoc Medical , Ltd.	Aidoc Medical , Ltd.
Product code	QAS	QAS	QAS	QAS	QAS
Decided	2025-05-30 (1.5 y ago)	2021-05-19 (5.5 y ago)	2022-09-28 (4.1 y ago)	2020-08-26 (6.2 y ago)	2022-04-26 (4.6 y ago)
510(k) review	24 days, Special	111 days, Traditional	57 days, Traditional	131 days, Traditional	134 days, Traditional
Code median review	103 days	103 days	103 days	103 days	103 days
AI evidence elements stated	9 of 13	7 of 13	9 of 13	7 of 13	7 of 13
Indications held	yes, quoted below	yes, quoted below	yes, quoted below	yes, quoted below	yes, quoted below
Generations of predicates traced	1	4	5	4	4
Later summaries citing it	2	1	1	1	1
FDA recalls listed	0	0	0	0	0

	K251406 BriefCase-Triage	K210237 CINA CHEST	K222329 BriefCase	K201020 BriefCase	K213886 BriefCase
Authorized change-control plan	no	no	no	no	no

Each column is read from the FDA's record of that device; the sections below give the passages and pages.

11 Candidate 1: K251406

Shortlist position 1. Product code QAS (the same as the client's). Cited as a predicate by 2 later summaries (confirmed links); 2 of them are in this pool.[14]

K251406 · BriefCase-Triage · Aidoc Medical , Ltd. · 510(k) decided 2025-05-30 · product code QAS[14]

Decided 2025-05-30: 1.5 years before this report.[14]

Its Special 510(k) took 24 days from receipt to decision; the median in QAS is 103 days (n=89).

ITS INDICATIONS FOR USE

"BriefCase-Triage is a radiological computer aided triage and notification software indicated for use in the analysis of CT chest, abdomen, or chest/abdomen exams with contrast (CTA and CT with contrast) in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected positive findings of Aortic Dissection (AD) pathology. BriefCase-Triage uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of BriefCase-Triage are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/ prioritization."[15] (FDA Form 3881)

ITS INDICATIONS BESIDE YOURS

The predicate's statement	Yours, as given
The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected positive findings of Aortic Dissection (AD) pathology. BriefCase-Triage uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for	AortaView is a radiological computer-aided triage and notification software indicated for use in the analysis of contrast-enhanced CT angiography of the chest in adults. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communicating suspected positive findings of acute aortic dissection. AortaView uses an artificial intelligence algorithm to analyze images and flag cases with suspected aortic dissection in parallel to the standard of care image interpretation. Notifications include compressed preview images that are for informational purposes only and not intended for diagnostic use. The

The predicate's statement	Yours, as given
diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device.[16]	device does not alter the original medical image and is not intended to be used as a diagnostic device.[17]

Aspect	The predicate's statement	Yours	Compared
Imaging type	CT	CT	same
Body area	Lung and chest, Abdomen and pelvis, Blood vessels	Lung and chest, Blood vessels	**differs**
Task	Triage and notification, Detection, Viewing and communication	Triage and notification, Viewing and communication	**differs**
Population	adults, children	adults	**differs**
Intended user	hospital networks	radiologists, hospital networks	**differs**
Output	notification or flag, marked or annotated images	notification or flag	**differs**

33 of the 40 key words in your statement appear in the predicate's. Words in yours that the predicate's does not use: acute, angiography, aortaview, communicating, enhanced, flag, radiologists.

A keyword reading of the two statements to show where they differ, not a judgement of equivalence. Every difference in intended use, target population or output is for the submitter to explain and the FDA to judge.

ITS PERFORMANCE EVIDENCE, AS ITS SUMMARY REPORTS IT (9 OF 13 ELEMENTS)

Evidence element	In its summary	Page	QAS AI devices stating it
Validation sample size	"contrast (CTA and CT with contrast) in 509 cases from 5 US-based clinical sites. The study compared the software's performance to the ground truth, as determined by three senior board-certified radiologists."[18]	10	74 of 85
Age distribution	"Slice thickness 0.5 mm - 5.0 mm Exclusion Criteria ? All studies that have an inadequate field of view Inclusion Criteria ? Scans performed on adults/transitional adolescents >= 18 years of age."[19]	9	55 of 85
Sex breakdown	"As can be seen in Table 3 the mean age of patients whose scans were reviewed for AD was 60.1 years, with a standard deviation of 17.3 years. Gender distribution was 50.9% male, and 49.1% female (Table 4). Scanner distribution can also be found in Table 5 below. Table 3.[20]	11	50 of 85
Race or ethnicity breakdown	*Not reported*	-	12 of 85

Evidence element	In its summary	Page	QAS AI devices stating it
Study design	"Performance Data Pivotal Study Summary Aidoc conducted a retrospective, blinded, multicenter study with the Briefcase-Triage software to evaluate the software's performance in..."[21]	9	80 of 85
Sensitivity	"Test pivotal study data was sequestered from algorithm development activities, and use of the data is managed by appropriate Quality Management System procedures. Primary endpoints were sensitivity and specificity with an 80% performance goal. Secondary endpoints were Briefcase-Triage time-to-notification compared to the predicate device."[22]	10	82 of 85
Specificity	The same passage as Sensitivity.[23]	10	82 of 85
AUC	*Not reported*	-	28 of 85
Reference standard	"contrast) in 509 cases from 5 US-based clinical sites. The study compared the software's performance to the ground truth, as determined by three senior board-certified radiologists. The cases collected for the pivotal dataset were all distinct in time or center from the cases used to train the algorithm, as was used for the most recent clearance (K222329)."[24]	10	70 of 85
Performance comparator	"Primary endpoints were sensitivity and specificity with an 80% performance goal. Secondary endpoints were Briefcase-Triage time-to-notification compared to the predicate device. Positive Predictive Value (PPV), Negative Predictive Value (NPV), Positive Likelihood Ratio (PLR), and Negative Likelihood Ratio (NLR) were also assessed."[25]	10	77 of 85
Multiple collection sites	"Aidoc conducted a retrospective, blinded, multicenter study with the Briefcase-Triage software to evaluate the software's performance in identifying CT chest,"[26]	9	74 of 85
Prospective collection	*Not reported*	-	1 of 85
Patient outcomes	*Not reported*	-	1 of 85

The thirteen elements Device Evidence reads in every AI-device summary. "Not reported" means the reading found no statement of it in the summary; it is not a statement about what the company did.

STANDARDS AND TEST TYPES NAMED IN ITS SUMMARY

No standards-based testing (software, electrical safety, biocompatibility and the like) passed the reading rules for this summary. Its performance study is set out in the table above.

Testing: lines read from the summary by rules and confirmed against their own sentence by an independent check; no wrong line on 760 hand-read summaries (2026-11-14). About half of the testing a summary reports passes both, so a test not listed may still have been done.

WHERE IT COMES FROM: ITS OWN PREDICATES

Generation 1

K251406: the record of predicates ends here - its summary is held, but none of its predicates has passed verification yet (in the review queue).[14]

LATER DEVICES THAT CITED IT

2 later summaries cite it as a predicate (confirmed links only), newest first.[14]

Device	Applicant	Decided	Code	Type	Review days	AI list
K253578 BriefCase-Triage: CARE Multi-Tri...	Aidoc Medical , Ltd.	2026-02-26	QAS	Traditional	101	yes
K252970 BriefCase-Triage: CARE Multi-tri...	Aidoc Medical , Ltd.	2026-01-07	QAS	Traditional	112	yes

HOW LATER DEVICES ARGUED EQUIVALENCE TO IT

The opening of each later device's own technological-characteristics or substantial-equivalence section, quoted from its 510(k) summary with the page: how others set themselves beside this predicate.

K253578 BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation device (2026-02-26): "BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax; Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation device is substantially equivalent to BriefCase-Triage for Aortic Dissection (AD) (K251406). As explained in more detail below, BriefCase-Triage device has the same intended use and similar indications for use, technological characteristics, and principles of operation as the previously cleared predicate BriefCase-Triage for AD (K251406). While the specific clinical indications differ, each indication remains independently time-sensitive. Additionally, both devices have modules fine tuned from a locked foundation model."[27]

K252970 BriefCase-Triage: CARE Multi-triage CT Body (2026-01-07): "BriefCase-Triage: CARE Multi-triage CT Body device is substantially equivalent to BriefCase-Triage for Aortic Dissection (AD) (K251406). As explained in more detail below, BriefCase-Triage: CARE Multi-triage CT Body device has the same intended use and similar indications for use, technological characteristics, and principles of operation as the previously cleared predicate BriefCase-Triage for AD (K251406). While the specific clinical indications differ, each indication remains independently time-sensitive. Additionally, both devices have modules fine tuned from a locked foundation model."[28]

RECALLS THE FDA LISTS AGAINST IT

No recall in openFDA's device recall data lists this number.[14]

12 Candidate 2: K210237

Shortlist position 2. Product code QAS (the same as the client's). Cited as a predicate by 1 later summary (confirmed links); 1 of it is in this pool.[14]

K210237 · CINA CHEST · Avicenna.Ai · 510(k) decided 2021-05-19 · product code QAS[14]

Decided 2021-05-19: 5.5 years before this report.[14]

Its Traditional 510(k) took 111 days from receipt to decision; the median in QAS is 103 days (n=89).

ITS INDICATIONS FOR USE

"CINA CHEST is a radiological computer aided triage and notification software indicated for use in the analysis of Chest and Thoraco-abdominal CT angiography. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communicating suspected positive findings of (1) Chest CT angiography for Pulmonary Embolism (PE) and (2) Chest or Thoraco-abdominal CT angiography for Aortic Dissection (AD). CINA CHEST uses an artificial intelligence algorithm to analyze images and highlight cases with detected PE and AD on a standalone Web application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected PE or AD findings. Notifications include compressed preview images that are meant for informational purposes only, and are not intended for diagnostic use beyond notification. The device does not alter the original medical image, and it is not intended to be used as a diagnostic device. The results of CINA CHEST are intended to be used in conjunction with other patient information and based on professional judgment to assist with triage/prioritization of medical images. Notified clinicians are ultimately responsible for reviewing full images per the standard of care."[29] (FDA Form 3881)

ITS INDICATIONS BESIDE YOURS

The predicate's statement	Yours, as given
The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communicating suspected positive findings of (1) Chest CT angiography for Pulmonary Embolism (PE) and (2) Chest or Thoraco-abdominal CT angiography for Aortic Dissection (AD). CINA CHEST uses an artificial intelligence algorithm to analyze images and highlight cases with detected PE and AD on a standalone Web application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected PE or AD findings. Notifications include compressed preview images that are meant for informational purposes only, and are not intended for diagnostic use beyond notification. The device does not alter the original medical image, and it is not intended to be used as a diagnostic device.[30]	AortaView is a radiological computer-aided triage and notification software indicated for use in the analysis of contrast-enhanced CT angiography of the chest in adults. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communicating suspected positive findings of acute aortic dissection. AortaView uses an artificial intelligence algorithm to analyze images and flag cases with suspected aortic dissection in parallel to the standard of care image interpretation. Notifications include compressed preview images that are for informational purposes only and not intended for diagnostic use. The device does not alter the original medical image and is not intended to be used as a diagnostic device.[31]

Aspect	The predicate's statement	Yours	Compared
Imaging type	CT	CT	same
Body area	Lung and chest, Abdomen and pelvis, Blood vessels	Lung and chest, Blood vessels	**differs**
Task	Triage and notification, Detection, Viewing and communication	Triage and notification, Viewing and communication	**differs**
Population	not stated	adults	only yours states it
Intended user	radiologists, clinicians, hospital networks	radiologists, hospital networks	**differs**
Output	notification or flag, marked or annotated images	notification or flag	**differs**

34 of the 40 key words in your statement appear in the predicate's. Words in yours that the predicate's does not use: acute, adults, aortaview, contrast, enhanced, flag.

A keyword reading of the two statements to show where they differ, not a judgement of equivalence. Every difference in intended use, target population or output is for the submitter to explain and the FDA to judge.

ITS PERFORMANCE EVIDENCE, AS ITS SUMMARY REPORTS IT (7 OF 13 ELEMENTS)

Evidence element	In its summary	Page	QAS AI devices stating it
Validation sample size	"Avicenna.AI conducted a retrospective, multicenter and blinded study with the CINA CHEST software with the primary endpoint to evaluate the software's performance in 1) Chest CT angiography (CTA) images pertaining to patient with suspected Pulmonary Embolism (PE) findings and 2) Chest or Thoraco-abdominal CT angiography (CTA) images series pertaining to patient with suspected Aortic Dissection (AD) findings, in 396 and 298 clinical anonymized cases, respectively. The data was provided from multiple US clinical sites: 230 and 200 US cities, for PE and AD, respectively.[82]	7	74 of 85
Age distribution	*Not reported*	-	55 of 85
Sex breakdown	*Not reported*	-	50 of 85
Race or ethnicity breakdown	*Not reported*	-	12 of 85
Study design	"Avicenna.AI conducted a retrospective, multicenter and blinded study with the CINA CHEST software with the primary endpoint to evaluate the software's performance in 1) Chest CT angiography (CTA) images pertaining to patient with suspected Pulmonary Embolism (PE) findings and 2) Chest or Thoraco-abdominal CT angiography (CTA) images series	7	80 of 85

Evidence element	In its summary	Page	QAS AI devices stating it
	pertaining to patient with suspected Aortic Dissection (AD) findings, in 396 and 298 clinical anonymized cases, respectively."[63]		
Sensitivity	"Device sensitivities and specificities were compared to ground truth established by concurrence of several US-board-certified radiologist readers. Sensitivity and Specificity for the "PE" prioritization and triage application were found to be 91.1% [95% CI: 86.1% - 94.7 %] and 91.8% [95% CI: 87.1% - 95.1%], respectively. Regarding the "AD" prioritization and triage application, Sensitivity and Specificity of 96.4% [95% CI: 91.7% - 98.8%] and 97.5% [95% CI: 93.8% - 99.3%], respectively, were obtained."[34]	7	82 of 85
Specificity	The same passage as Sensitivity.[35]	7	82 of 85
AUC	*Not reported*	-	28 of 85
Reference standard	"There were 190 (48%) positive PE (images with PE) cases and 137 (46%) positive AD (images with AD) cases included in the analyses. Device sensitivities and specificities were compared to ground truth established by concurrence of several US-board-certified radiologist readers. Sensitivity and Specificity for the "PE" prioritization and triage application were found to be 91.1% [95% CI: 86.1% - 94.7 %] and 91.8% [95% CI: 87.1% - 95.1%], respectively."[66]	7	70 of 85
Performance comparator	The same passage as Reference standard.[37]	7	77 of 85
Multiple collection sites	The same passage as Study design.[38]	7	74 of 85
Prospective collection	*Not reported*	-	1 of 85
Patient outcomes	*Not reported*	-	1 of 85

The thirteen elements Device Evidence reads in every AI-device summary. "Not reported" means the reading found no statement of it in the summary; it is not a statement about what the company did.

STANDARDS AND TEST TYPES NAMED IN ITS SUMMARY

Area	Standards named	Where
Software	-	p. 7: "Software Verification and Validation Testing The CINA CHEST device has been evaluated and verified in accordance with software specifications and applicable performance standards through a Software..."[39]

Testing: lines read from the summary by rules and confirmed against their own sentence by an independent check; no wrong line on 760 hand-read summaries (2026-11-14). About half of the testing a summary reports passes both, so a test not listed may still have been done.

WHERE IT COMES FROM: ITS OWN PREDICATES

Generation 1

K210237 cites K190072 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-04-15 · product code QAS[14] (K210237 summary, page 4)[40]

Generation 2

K190072 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[14] (K190072 summary, page 4)[41]

Generation 3

K180647 cites DEN170073 · ContaCT · Viz.AI, Inc. · De Novo decided 2018-02-13 · product code QAS[14] (K180647 summary, page 4)[42]

Generation 4

DEN170073: the record of predicates ends here - it is a De Novo authorization; predicates are a 510(k) concept.[14]

LATER DEVICES THAT CITED IT

1 later summary cites it as a predicate (confirmed links only), newest first.[14]

Device	Applicant	Decided	Code	Type	Review days	AI list
K222329 BriefCase	Aidoc Medical , Ltd.	2022-09-28	QAS	Traditional	57	yes

HOW LATER DEVICES ARGUED EQUIVALENCE TO IT

The opening of each later device's own technological-characteristics or substantial-equivalence section, quoted from its 510(k) summary with the page: how others set themselves beside this predicate.

K222329 BriefCase (2022-09-28): "The subject BriefCase and primary predicate CINA CHEST triage (K210237) are very similar, as explained below. Both devices are radiological computer-aided triage and notification software programs. Both devices are artificial intelligence, deep-learning algorithms incorporating software packages for use with DICOM 3.0 compliant scanners, PACS, and radiology workstations. The predicate CINA CHEST evaluates images from CT scanners as does the proposed Briefcase. The predicate and subject devices differ in the fact that the subject device runs also on CT exams with contrast (CTA and CT with contrast) that include the chest. All image types were included in the standalone performance study."[43]

RECALLS THE FDA LISTS AGAINST IT

No recall in openFDA's device recall data lists this number.[14]

QUESTIONS THE RECORD RAISES ABOUT THIS PREDICATE

Drawn from the figures above, for your team or a Pre-Submission meeting. Questions only: the FDA decides.

1. Its summary does not state age distribution and sex breakdown, which most of the 85 AI devices in QAS do. What will your submission show where the predicate is silent?

2. Its line of predicates ends at a De Novo (above). Does your device stay within the special controls that

De Novo set?

13 Candidate 3: K222329

Shortlist position 3. Product code QAS (the same as the client's). Cited as a predicate by 1 later summary (confirmed links); 1 of it is in this pool.[14]

K222329 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2022-09-28 · product code QAS[14]

Decided 2022-09-28: 4.1 years before this report.[14]

Its Traditional 510(k) took 57 days from receipt to decision; the median in QAS is 103 days (n=89).

ITS INDICATIONS FOR USE

"BriefCase is a radiological computer-aided triage and notification software indicated for use in the analysis of CT exams with contrast (CTA and CT with contrast) that include the chest in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive cases of aortic dissection (AD) pathology. BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of BriefCase are intended to be used in conjunction with other patient information and based on the user's professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care."[44] (FDA Form 3881)

ITS INDICATIONS BESIDE YOURS

The predicate's statement	Yours, as given
The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communicating suspected positive cases of aortic dissection (AD) pathology. BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device.[45]	AortaView is a radiological computer-aided triage and notification software indicated for use in the analysis of contrast-enhanced CT angiography of the chest in adults. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communicating suspected positive findings of acute aortic dissection. AortaView uses an artificial intelligence algorithm to analyze images and flag cases with suspected aortic dissection in parallel to the standard of care image interpretation. Notifications include compressed preview images that are for informational purposes only and not intended for diagnostic use. The device does not alter the original medical image and is not intended to be used as a diagnostic device.[46]

Aspect	The predicate's statement	Yours	Compared
Imaging type	CT	CT	same
Body area	Lung and chest, Blood vessels	Lung and chest, Blood vessels	same
Task	Triage and notification, Detection, Viewing and communication	Triage and notification, Viewing and communication	**differs**
Population	adults, children	adults	**differs**
Intended user	clinicians, hospital networks	radiologists, hospital networks	**differs**
Output	notification or flag, marked or annotated images	notification or flag	**differs**

34 of the 40 key words in your statement appear in the predicate's. Words in yours that the predicate's does not use: acute, angiography, aortaview, enhanced, flag, radiologists.

A keyword reading of the two statements to show where they differ, not a judgement of equivalence. Every difference in intended use, target population or output is for the submitter to explain and the FDA to judge.

ITS PERFORMANCE EVIDENCE, AS ITS SUMMARY REPORTS IT (9 OF 13 ELEMENTS)

Evidence element	In its summary	Page	QAS AI devices stating it
Validation sample size	"Aidoc conducted a retrospective, blinded, multicenter, study with the BriefCase software to evaluate the software's performance in identifying aortic dissection in CT images in 499 cases. The cases were collected from 5 medical centers in the US and are distinct datasets from the ones used to train the algorithm."[47]	7	74 of 85
Age distribution	"As can be seen in Table 3 the mean age of patients whose scans were reviewed for AD was 60.02 years, with a standard deviation of 17.19 years. Gender distribution was 51.9% male, and 47.9% female (Table 4)."[48]	8	55 of 85
Sex breakdown	"As can be seen in Table 3 the mean age of patients whose scans were reviewed for AD was 60.02 years, with a standard deviation of 17.19 years. Gender distribution was 51.9% male, and 47.9% female (Table 4). Scanner distribution can also be found in Table 5 below. Table 3.[49]	8	50 of 85
Race or ethnicity breakdown	*Not reported*	-	12 of 85
Study design	"The proposed device for aortic dissection has very similar technology and design as the predicate device, and similar indications for use, i.e., both devices are intended to aid in prioritization and triage of time-critical radiological images."[50]	5	80 of 85
Sensitivity	"Sensitivity and specificity exceeded the 80% performance goal. Sensitivity was 93.23% (95% CI: 88.70% - 96.35%) and	7	82 of 85

Evidence element	In its summary	Page	QAS AI devices stating it
	specificity was 92.83% (95% CI: 89.35% - 95.45%)."[51]		
Specificity	The same passage as Sensitivity.[52]	7	82 of 85
AUC	*Not reported*	-	28 of 85
Reference standard	"Table 4. Frequency Distribution of Gender Ground Truth Results Gender All Male Female N % N % N % Positive 129 25.9 63 12.6 192 38.6 Negative 130 26.1 176 35.3 306 61.4 All 239 48.0 259 52.0 498* 100.0 * 1 case had gender unknown."[53]	8	70 of 85
Performance comparator	"Secondary endpoints were BriefCase time-to-notification compared to the predicate device. Positive Predictive Value (PPV), Negative Predictive Value (NPV), Positive Likelihood Ratio (PLR), and Negative Likelihood Ratio (NLR) were also assessed."[54]	7	77 of 85
Multiple collection sites	"Aidoc conducted a retrospective, blinded, multicenter, study with the BriefCase software to evaluate the software's performance in identifying aortic dissection in CT images in 499 cases."[55]	7	74 of 85
Prospective collection	*Not reported*	-	1 of 85
Patient outcomes	*Not reported*	-	1 of 85

The thirteen elements Device Evidence reads in every AI-device summary. "Not reported" means the reading found no statement of it in the summary; it is not a statement about what the company did.

STANDARDS AND TEST TYPES NAMED IN ITS SUMMARY

No standards-based testing (software, electrical safety, biocompatibility and the like) passed the reading rules for this summary. Its performance study is set out in the table above.

Testing: lines read from the summary by rules and confirmed against their own sentence by an independent check; no wrong line on 760 hand-read summaries (2026-11-14). About half of the testing a summary reports passes both, so a test not listed may still have been done.

WHERE IT COMES FROM: ITS OWN PREDICATES

Generation 1

K222329 cites K210237 · CINA CHEST · Avicenna.Ai · 510(k) decided 2021-05-19 · product code QAS[14] (K222329 summary, page 4)[56]

Generation 2

K210237 cites K190072 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-04-15 · product code QAS[14] (K210237 summary, page 4)[57]

Generation 3

K190072 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[14] (K190072 summary, page 4)[58]

Generation 4

K180647 cites DEN170073 · ContaCT · Viz.AI, Inc. · De Novo decided 2018-02-13 · product code QAS[14] (K180647 summary, page 4)[59]

Generation 5

DEN170073: the record of predicates ends here - it is a De Novo authorization; predicates are a 510(k) concept.[14]

LATER DEVICES THAT CITED IT

1 later summary cites it as a predicate (confirmed links only), newest first.[14]

Device	Applicant	Decided	Code	Type	Review days	AI list
K240291 EFAI CARDIOSUITE CTA ACUTE AORTI...	Ever Fortune.Ai, Co., Ltd.	2024-04-08	QAS	Traditional	67	yes

HOW LATER DEVICES ARGUED EQUIVALENCE TO IT

The opening of each later device's own technological-characteristics or substantial-equivalence section, quoted from its 510(k) summary with the page: how others set themselves beside this predicate.

K240291 EFAI CARDIOSUITE CTA ACUTE AORTIC SYNDROME ASSESSMENT SYSTEM (2024-04-08): "Feature/ Function Proposed Device: EFAI AASCTA (K240291) Predicate Device: BriefCase (K222329) Intended Use/Indication for Use EFAI CARDIOSUITE CTA ACUTE AORTIC SYNDROME ASSESSMENT SYSTEM (EFAI BriefCase is a radiological computer-aided triage and notification software indicated for use in the analysis EFAI AASCTA Traditional 510(k) 2 EVER F9RTUNE.[60]

RECALLS THE FDA LISTS AGAINST IT

No recall in openFDA's device recall data lists this number.[14]

QUESTIONS THE RECORD RAISES ABOUT THIS PREDICATE

Drawn from the figures above, for your team or a Pre-Submission meeting. Questions only: the FDA decides.

1. Its line of predicates ends at a De Novo (above). Does your device stay within the special controls that De Novo set?

14 Candidate 4: K201020

Shortlist position 4. Product code QAS (the same as the client's). Cited as a predicate by 1 later summary (confirmed links); 1 of it is in this pool.[14]

K201020 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2020-08-26 · product code QAS[14]

Decided 2020-08-26: 6.2 years before this report.[14]

Its Traditional 510(k) took 131 days from receipt to decision; the median in QAS is 103 days (n=89).

ITS INDICATIONS FOR USE

"BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of contrast enhanced chest CT images (but not dedicated CTPA protocol) CT. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive cases of Incidental Pulmonary Embolism (iPE) pathologies. For the iPE pathology, the software is only intended to be used on single- energy exams. The device is intended to work with GE and Siemens scanners only. BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of BriefCase are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care."[61] (FDA Form 3881)

ITS INDICATIONS BESIDE YOURS

The predicate's statement	Yours, as given
The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive cases of Incidental Pulmonary Embolism (iPE) pathologies. For the iPE pathology, the software is only intended to be used on single- energy exams. The device is intended to work with GE and Siemens scanners only. BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification.[62]	AortaView is a radiological computer-aided triage and notification software indicated for use in the analysis of contrast-enhanced CT angiography of the chest in adults. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communicating suspected positive findings of acute aortic dissection. AortaView uses an artificial intelligence algorithm to analyze images and flag cases with suspected aortic dissection in parallel to the standard of care image interpretation. Notifications include compressed preview images that are for informational purposes only and not intended for diagnostic use. The device does not alter the original medical image and is not intended to be used as a diagnostic device.[63]

Aspect	The predicate's statement	Yours	Compared
Imaging type	CT	CT	same
Body area	Lung and chest	Lung and chest, Blood vessels	**differs**
Task	Triage and notification, Detection, Viewing and communication	Triage and notification, Viewing and communication	**differs**
Population	not stated	adults	only yours states it
Intended user	radiologists, clinicians, hospital networks	radiologists, hospital networks	**differs**

Aspect	The predicate's statement	Yours	Compared
Output	notification or flag, marked or annotated images	notification or flag	**differs**

32 of the 40 key words in your statement appear in the predicate's. Words in yours that the predicate's does not use: acute, adults, angiography, aortaview, aortic, communicating, dissection, flag.

A keyword reading of the two statements to show where they differ, not a judgement of equivalence. Every difference in intended use, target population or output is for the submitter to explain and the FDA to judge.

ITS PERFORMANCE EVIDENCE, AS ITS SUMMARY REPORTS IT (7 OF 13 ELEMENTS)

Evidence element	In its summary	Page	QAS AI devices stating it
Validation sample size	"Aidoc conducted a retrospective, blinded, multicenter study with the BriefCase software with the primary endpoint to evaluate the software's performance in identifying Contrast-enhanced chest CTs (but not dedicated CTPA protocol), containing Incidental Pulmonary Embolism in 268 cases from 2 clinical study sites in the US. There were 74 positive cases and 194 negative cases (images with iPE versus without iPE) included in the analysis."[64]	8	74 of 85
Age distribution	"- Scans performed with 64- slice scanner or greater number of detectors. - Scans performed on adults/transitional adults >= 18 years of age. - Slice thickness 0.5 - 3.0 mm axial. Exclusion Criteria - All studies that are technically inadequate, including studies with motion artifacts, severe metal artifacts, sub-optimal bolus or inadequate field of view."[65]	7	55 of 85
Sex breakdown	*Not reported*	-	50 of 85
Race or ethnicity breakdown	*Not reported*	-	12 of 85
Study design	"Aidoc conducted a retrospective, blinded, multicenter study with the BriefCase software with the primary endpoint to evaluate the software's performance in	8	80 of 85

Evidence element	In its summary	Page	QAS AI devices stating it
	identifying Contrast-enhanced chest CTs (but not dedicated CTPA protocol), containing Incidental Pulmonary Embolism in 268 cases from 2 clinical study sites in the US."[66]		
Sensitivity	"There were 74 positive cases and 194 negative cases (images with iPE versus without iPE) included in the analysis. Sensitivity and specificity exceeded the 80% performance goal. Specifically, sensitivity was 90.5% (95% CI: 81.4%, 96.2%) and specificity was 88.7% (95% CI: 83.3%, 92.8%)."[67]	8	82 of 85
Specificity	The same passage as Sensitivity.[68]	8	82 of 85
AUC	*Not reported*	-	28 of 85
Reference standard	*Not reported*	-	70 of 85
Performance comparator	The same passage as Sensitivity.[69]	8	77 of 85
Multiple collection sites	The same passage as Study design.[70]	8	74 of 85
Prospective collection	*Not reported*	-	1 of 85
Patient outcomes	*Not reported*	-	1 of 85

The thirteen elements Device Evidence reads in every AI-device summary. "Not reported" means the reading found no statement of it in the summary; it is not a statement about what the company did.

STANDARDS AND TEST TYPES NAMED IN ITS SUMMARY

No standards-based testing (software, electrical safety, biocompatibility and the like) passed the reading rules for this summary. Its performance study is set out in the table above.

Testing: lines read from the summary by rules and confirmed against their own sentence by an independent check; no wrong line on 760 hand-read summaries (2026-11-14). About half of the testing a summary reports passes both, so a test not listed may still have been done.

WHERE IT COMES FROM: ITS OWN PREDICATES

Generation 1

K201020 cites K190072 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-04-15 · product code QAS[14] (K201020 summary, page 4)[71]

Generation 2

K190072 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code

QAS[14] (K190072 summary, page 4)[72]

Generation 3

K180647 cites DEN170073 · ContaCT · Viz.AI, Inc. · De Novo decided 2018-02-13 · product code QAS[14] (K180647 summary, page 4)[73]

Generation 4

DEN170073: the record of predicates ends here - it is a De Novo authorization; predicates are a 510(k) concept.[14]

LATER DEVICES THAT CITED IT

1 later summary cites it as a predicate (confirmed links only), newest first.[14]

Device	Applicant	Decided	Code	Type	Review days	AI list
K203508 BriefCase	Aidoc Medical , Ltd.	2020-12-29	QAS	Special	29	yes

HOW LATER DEVICES ARGUED EQUIVALENCE TO IT

The opening of each later device's own technological-characteristics or substantial-equivalence section, quoted from its 510(k) summary with the page: how others set themselves beside this predicate.

K203508 BriefCase (2020-12-29): "The subject and predicate devices have an identical intended use, technological characteristics, and principles of operation. The only difference is that the subject device has a broadened intended use population of appropriately trained medical specialists, whereas the predicate device is indicated for use by radiologists. Both devices are intended to provide the users with notifications and unannotated preview images of suspect studies for the purpose of preemptive triage, and are therefore substantially equivalent. A table comparing the key features of the subject and predicate devices is provided below. Table 1."[74]

RECALLS THE FDA LISTS AGAINST IT

No recall in openFDA's device recall data lists this number.[14]

QUESTIONS THE RECORD RAISES ABOUT THIS PREDICATE

Drawn from the figures above, for your team or a Pre-Submission meeting. Questions only: the FDA decides.

1. Its summary does not state sex breakdown and reference standard, which most of the 85 AI devices in QAS do. What will your submission show where the predicate is silent?

2. Its line of predicates ends at a De Novo (above). Does your device stay within the special controls that De Novo set?

15 Candidate 5: K213886

Shortlist position 5. Product code QAS (the same as the client's). Cited as a predicate by 1 later summary (confirmed links); 1 of it is in this pool.[14]

K213886 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2022-04-26 · product code QAS[14]

Decided 2022-04-26: 4.6 years before this report.[14]

Its Traditional 510(k) took 134 days from receipt to decision; the median in QAS is 103 days (n=89).

ITS INDICATIONS FOR USE

"BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of contrast-enhanced chest CTs (not dedicated CTPA protocol) in adults or transitional adolescents age 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspect cases of incidental Pulmonary Embolism (iPE) pathologies. The device is intended to be used on single- energy exams only. BriefCase uses an artificial intelligence algorithm to analyze images and flag suspect cases on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for suspect cases. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of BriefCase are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care."[75] (FDA Form 3881)

ITS INDICATIONS BESIDE YOURS

The predicate's statement	Yours, as given
The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspect cases of incidental Pulmonary Embolism (iPE) pathologies. The device is intended to be used on single- energy exams only. BriefCase uses an artificial intelligence algorithm to analyze images and flag suspect cases on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for suspect cases. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device.[76]	AortaView is a radiological computer-aided triage and notification software indicated for use in the analysis of contrast-enhanced CT angiography of the chest in adults. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communicating suspected positive findings of acute aortic dissection. AortaView uses an artificial intelligence algorithm to analyze images and flag cases with suspected aortic dissection in parallel to the standard of care image interpretation. Notifications include compressed preview images that are for informational purposes only and not intended for diagnostic use. The device does not alter the original medical image and is not intended to be used as a diagnostic device.[77]

Aspect	The predicate's statement	Yours	Compared
Imaging type	CT	CT	same
Body area	Lung and chest	Lung and chest, Blood vessels	**differs**
Task	Triage and notification, Viewing and communication	Triage and notification, Viewing and communication	same
Population	adults, children	adults	**differs**
Intended user	clinicians, hospital networks	radiologists, hospital networks	**differs**

Aspect	The predicate's statement	Yours	Compared
Output	notification or flag	notification or flag	same

30 of the 40 key words in your statement appear in the predicate's. Words in yours that the predicate's does not use: acute, angiography, aortaview, aortic, communicating, dissection, findings, positive, radiologists, suspected.

A keyword reading of the two statements to show where they differ, not a judgement of equivalence. Every difference in intended use, target population or output is for the submitter to explain and the FDA to judge.

ITS PERFORMANCE EVIDENCE, AS ITS SUMMARY REPORTS IT (7 OF 13 ELEMENTS)

Evidence element	In its summary	Page	QAS AI devices stating it
Validation sample size	"Aidoc conducted a retrospective, blinded, multicenter study with the BriefCase software with the primary endpoint to evaluate the software's performance in identifying Contrast-enhanced chest CTs (not dedicated CTPA protocol, acquired through Philips and Toshiba scanners), containing Incidental Pulmonary Embolism in 159 cases from 3 clinical study sites (2 in the US, 1 OUS). There were 78 positive cases and 81 negative cases (images with iPE versus without iPE) included in the analysis."[78]	7	74 of 85
Age distribution	"- Scans performed with a 64 slice or greater number of detectors. - Scans performed on adults/transitional adults >= 18 years of age. - Slice thickness; 0.5 - 2.0 mm axial. Exclusion Criteria All studies that are technically inadequate, including studies with motion artifacts, severe metal artifacts, or inadequate field of view."[79]	7	55 of 85
Sex breakdown	*Not reported*	-	50 of 85
Race or ethnicity breakdown	*Not reported*	-	12 of 85
Study design	"Aidoc conducted a retrospective, blinded, multicenter study with the BriefCase software with the primary endpoint to evaluate the	7	80 of 85

Evidence element	In its summary	Page	QAS AI devices stating it
	software's performance in identifying Contrast-enhanced chest CTs (not dedicated CTPA protocol, acquired through Philips and Toshiba scanners), containing Incidental Pulmonary Embolism in 159 cases from 3 clinical study sites (2 in the US, 1 OUS)."[80]		
Sensitivity	"Sensitivity and specificity exceeded the 80% performance goal. Specifically, sensitivity was 89.7 % (95% CI: 80.8%, 95.5%) and specificity was 90.1% (95% CI: 81.5%, 95.6%)."[81]	7	82 of 85
Specificity	The same passage as Sensitivity.[82]	7	82 of 85
AUC	*Not reported*	-	28 of 85
Reference standard	*Not reported*	-	70 of 85
Performance comparator	The same passage as Sensitivity.[83]	7	77 of 85
Multiple collection sites	The same passage as Study design.[84]	7	74 of 85
Prospective collection	*Not reported*	-	1 of 85
Patient outcomes	*Not reported*	-	1 of 85

The thirteen elements Device Evidence reads in every AI-device summary. "Not reported" means the reading found no statement of it in the summary; it is not a statement about what the company did.

STANDARDS AND TEST TYPES NAMED IN ITS SUMMARY

No standards-based testing (software, electrical safety, biocompatibility and the like) passed the reading rules for this summary. Its performance study is set out in the table above.

Testing: lines read from the summary by rules and confirmed against their own sentence by an independent check; no wrong line on 760 hand-read summaries (2026-11-14). About half of the testing a summary reports passes both, so a test not listed may still have been done.

WHERE IT COMES FROM: ITS OWN PREDICATES

Generation 1

K213886 cites K203508 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2020-12-29 · product code QAS[14] (K213886 summary, page 4)[85]

Generation 2

K203508 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[14] (K203508 summary, page 13)[86]

K203508 cites K190072 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-04-15 · product code QAS[14] (K203508 summary, page 17)[87]

K203508 cites K190896 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-05-31 · product code QAS[14] (K203508 summary, page 9)[88]

K203508 cites K192383 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-12-20 · product code QAS[14] (K203508 summary, page 30)[89]

K203508 cites K193298 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2020-06-19 · product code QAS[14] (K203508 summary, page 21)[90]

K203508 cites K201020 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2020-08-26 · product code QAS[14] (K203508 summary, page 25)[91]

Generation 3

K180647 cites DEN170073 · ContaCT · Viz.AI, Inc. · De Novo decided 2018-02-13 · product code QAS[14] (K180647 summary, page 4)[92]

K190072 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[14] (K190072 summary, page 4)[93]

K190896 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[14] (K190896 summary, page 4)[94]

K192383 cites DEN170073 · ContaCT · Viz.AI, Inc. · De Novo decided 2018-02-13 · product code QAS[14] (K192383 summary, page 4)[95]

K192383 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[14] (K192383 summary, page 4)[96]

K193298 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[14] (K193298 summary, page 4)[97]

K201020 cites K190072 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-04-15 · product code QAS[14] (K201020 summary, page 4)[98]

Generation 4

DEN170073: the record of predicates ends here - it is a De Novo authorization; predicates are a 510(k) concept.[14]

LATER DEVICES THAT CITED IT

1 later summary cites it as a predicate (confirmed links only), newest first.[14]

Device	Applicant	Decided	Code	Type	Review days	AI list
K233968 CINA-iPE	Avicenna.Ai	2024-03-13	QAS	Traditional	89	yes

HOW LATER DEVICES ARGUED EQUIVALENCE TO IT

The opening of each later device's own technological-characteristics or substantial-equivalence section, quoted from its 510(k) summary with the page: how others set themselves beside this predicate.

K233968 CINA-iPE (2024-03-13): "The subject CINA-iPE and the predicate BriefCase device are both

intended to aid in prioritization and triage of radiological images of time sensitive findings for patient detection and diagnosis (i.e., incidental Pulmonary Embolism) based on the analysis of medical images acquired from radiological signal acquisition systems. The CINA device provides the CINA Platform in which the subject CINA- iPE prioritization and triage application can be integrated, deployed and used. The labeling of the subject and the predicate devices clearly states that the devices are not for diagnostic use."[99]

RECALLS THE FDA LISTS AGAINST IT

No recall in openFDA's device recall data lists this number.[14]

QUESTIONS THE RECORD RAISES ABOUT THIS PREDICATE

Drawn from the figures above, for your team or a Pre-Submission meeting. Questions only: the FDA decides.

1. Its summary does not state sex breakdown and reference standard, which most of the 85 AI devices in QAS do. What will your submission show where the predicate is silent?

2. Its line of predicates ends at a De Novo (above). Does your device stay within the special controls that De Novo set?

16 The other candidates reviewed

The rest of the 40 the shortlist was chosen from, closest indications first.

K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[14]

K203508 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2020-12-29 · product code QAS[14]

K193298 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2020-06-19 · product code QAS[14]

K221456 · Rapid ICH · Ischemaview, Inc. · 510(k) decided 2022-09-12 · product code QAS[14]

K200855 · CINA · Avicenna.Ai · 510(k) decided 2020-06-24 · product code QAS[14]

K190072 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-04-15 · product code QAS[14]

K193087 · Rapid ICH · Ischemaview Incorporated · 510(k) decided 2020-03-31 · product code QAS[14]

K251195 · BriefCase-Triage · Aidoc Medical , Ltd. · 510(k) decided 2026-01-27 · product code QAS[14]

K221716 · CINA · Avicenna.Ai · 510(k) decided 2022-11-22 · product code QAS[14]

K222884 · Rapid NCCT Stroke · Ischemaview, Inc. · 510(k) decided 2023-03-02 · product code QAS[14]

K192383 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-12-20 · product code QAS[14]

K241727 · BriefCase-Triage · Aidoc Medical , Ltd. · 510(k) decided 2024-07-12 · product code QAS[14]

K190896 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-05-31 · product code QAS[14]

K221240 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2022-05-17 · product code QAS[14]

K221248 · Rapid LVO · Ischemaview, Inc. · 510(k) decided 2022-05-31 · product code QAS[14]

K222277 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2022-08-26 · product code QAS[14]

K213721 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2022-03-21 · product code QAS[14]

K250248 · BriefCase-Triage · Aidoc Medical , Ltd. · 510(k) decided 2025-02-14 · product code QAS[14]

K200921 · qER · Qure.Ai Technologies · 510(k) decided 2020-06-17 · product code QAS[14]

K220709 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2022-10-07 · product code QAS[14]

K221314 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2022-06-03 · product code QAS[14]

K220499 · Rapid PE Triage and Notification (PETN) · Ischemaview, Inc. · 510(k) decided 2022-05-17 · product code QAS[14]

K250685 · Methinks NCCT Stroke · Methinks Software, S.L · 510(k) decided 2025-06-16 · product code QAS[14]

K251151 · Rapid CTA 360 · Ischemaview · 510(k) decided 2025-07-16 · product code QAS[14]

K242837 · BriefCase-Triage · Aidoc Medical , Ltd. · 510(k) decided 2024-10-18 · product code QAS[14]

K211179 · InferRead CT Stroke.AI · Infervision Medical Technology Co., Ltd. · 510(k) decided 2021-08-12 · product code QAS[14]

K233968 · CINA-iPE · Avicenna.Ai · 510(k) decided 2024-03-13 · product code QAS[14]

K200941 · Rapid LVO · Ischemaview, Inc. · 510(k) decided 2020-07-09 · product code QAS[14]

K240942 · CINA-CSpine · Avicenna.Ai · 510(k) decided 2024-09-12 · product code QAS[14]

K232436 · Rapid SDH · Ischemaview, Inc. · 510(k) decided 2023-10-25 · product code QAS[14]

K212261 · StrokeSENS LVO · Circle Neurovascular Imaging, Inc. · 510(k) decided 2021-10-14 · product code QAS[14]

K221330 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2022-11-18 · product code QAS[14]

K251533 · Rapid Obstructive Hydrocephalus, Rapid OH · Ischemaview, Inc. · 510(k) decided 2025-09-04 · product code QAS[14]

K262301 · Rapid ICH (v4.0) · Ischemaview, Inc. · 510(k) decided 2026-10-09 · product code QAS[14]

K241719 · NeuroICH · Neurocareai, Inc. · 510(k) decided 2024-11-07 · product code QAS[14]

17 Sources and method

Register: openFDA 510(k) and PMA data and the FDA's De Novo pages, as published by Device Evidence.

Predicate links: 510(k) summaries decided 2016 onwards, read and checked against the FDA register (existence, decision order, device name); only links that passed every check are used (Device Evidence D-071).

Indications: the summary's FDA Form 3881 box, or its Indications for Use heading, quoted verbatim.

Testing: lines read from the summary by rules and confirmed against their own sentence by an

independent check; no wrong line on 760 hand-read summaries (2026-11-14). About half of the testing a summary reports passes both, so a test not listed may still have been done.

Recalls: openFDA device recall and enforcement data, joined on the submission number.

18 Get this predicate shortlist for your device

This is a sample predicate shortlist for a synthetic client; the FDA record it cites is real.

For your own predicate: the same report, built from the FDA's record for it. $499, .

HOW TO START

Go to precedium.com/services/predicate-shortlist/ and send an enquiry, or email hello@precedium.com. A person replies within one working day.

Not sure which service fits? Send one document for a free first read (precedium.com/first-read/): a one-page reply in two working days, with a fixed quote.

Consultants: any service at 20% off, delivered under your firm's name. Precedium prepares content; the FDA decides.

Appendix: sources

Every footnote number in this document resolves to one line below.

1 Applicant's device profile: Device name.
2 Applicant's device profile: Device description.
3 Applicant's device profile: Principle of operation.
4 Applicant's device profile: Inputs.
5 Applicant's device profile: Outputs.
6 Applicant's device profile: Algorithm type.
7 Applicant's device profile: Locked or adaptive.
8 Applicant's device profile: Deployment environment.
9 Applicant's device profile: Intended use.
10 Applicant's device profile: Indications for use.
11 Device Evidence public exposure file (product-code base rates), QAS (capture 2026-09-10).
12 Device Evidence, the verified FDA record for product code QAS (read 2026-11-15).
13 FDA, Predetermined Change Control Plans: List of Authorized Devices with PCCPs, content current as of 2026-10-20, captured 2026-10-26.
14 Device Evidence, the verified FDA record (register, confirmed predicate links, indications, testing as each summary reports it, openFDA recalls) (read 2026-11-15).
15 K251406, 510(k) summary (FDA) (page 4).
16 K251406, 510(k) summary (FDA) (page 4).
17 The client's indications for use, as given.
18 K251406, 510(k) summary (FDA) (page 10).
19 K251406, 510(k) summary (FDA) (page 9).
20 K251406, 510(k) summary (FDA) (page 11).
21 K251406, 510(k) summary (FDA) (page 9).
22 K251406, 510(k) summary (FDA) (page 10).
23 K251406, 510(k) summary (FDA) (page 10).
24 K251406, 510(k) summary (FDA) (page 10).
25 K251406, 510(k) summary (FDA) (page 10).
26 K251406, 510(k) summary (FDA) (page 9).
27 K253578, 510(k) summary (FDA) (page 6).
28 K252970, 510(k) summary (FDA) (page 7).
29 K210237, 510(k) summary (FDA) (page 3).
30 K210237, 510(k) summary (FDA) (page 3).
31 The client's indications for use, as given.
32 K210237, 510(k) summary (FDA) (page 7).
33 K210237, 510(k) summary (FDA) (page 7).
34 K210237, 510(k) summary (FDA) (page 7).
35 K210237, 510(k) summary (FDA) (page 7).
36 K210237, 510(k) summary (FDA) (page 7).
37 K210237, 510(k) summary (FDA) (page 7).

38	K210237, 510(k) summary (FDA) (page 7).
39	K210237, 510(k) summary (FDA) (page 7).
40	K210237, 510(k) summary (FDA) (page 4).
41	K190072, 510(k) summary (FDA) (page 4).
42	K180647, 510(k) summary (FDA) (page 4).
43	K222329, 510(k) summary (FDA) (page 5).
44	K222329, 510(k) summary (FDA) (page 3).
45	K222329, 510(k) summary (FDA) (page 3).
46	The client's indications for use, as given.
47	K222329, 510(k) summary (FDA) (page 7).
48	K222329, 510(k) summary (FDA) (page 8).
49	K222329, 510(k) summary (FDA) (page 8).
50	K222329, 510(k) summary (FDA) (page 5).
51	K222329, 510(k) summary (FDA) (page 7).
52	K222329, 510(k) summary (FDA) (page 7).
53	K222329, 510(k) summary (FDA) (page 8).
54	K222329, 510(k) summary (FDA) (page 7).
55	K222329, 510(k) summary (FDA) (page 7).
56	K222329, 510(k) summary (FDA) (page 4).
57	K210237, 510(k) summary (FDA) (page 4).
58	K190072, 510(k) summary (FDA) (page 4).
59	K180647, 510(k) summary (FDA) (page 4).
60	K240291, 510(k) summary (FDA) (page 5).
61	K201020, 510(k) summary (FDA) (page 3).
62	K201020, 510(k) summary (FDA) (page 3).
63	The client's indications for use, as given.
64	K201020, 510(k) summary (FDA) (page 8).
65	K201020, 510(k) summary (FDA) (page 7).
66	K201020, 510(k) summary (FDA) (page 8).
67	K201020, 510(k) summary (FDA) (page 8).
68	K201020, 510(k) summary (FDA) (page 8).
69	K201020, 510(k) summary (FDA) (page 8).
70	K201020, 510(k) summary (FDA) (page 8).
71	K201020, 510(k) summary (FDA) (page 4).
72	K190072, 510(k) summary (FDA) (page 4).
73	K180647, 510(k) summary (FDA) (page 4).
74	K203508, 510(k) summary (FDA) (page 10).
75	K213886, 510(k) summary (FDA) (page 3).
76	K213886, 510(k) summary (FDA) (page 3).
77	The client's indications for use, as given.
78	K213886, 510(k) summary (FDA) (page 7).
79	K213886, 510(k) summary (FDA) (page 7).
80	K213886, 510(k) summary (FDA) (page 7).

81 K213886, 510(k) summary (FDA) (page 7).

82 K213886, 510(k) summary (FDA) (page 7).

83 K213886, 510(k) summary (FDA) (page 7).

84 K213886, 510(k) summary (FDA) (page 7).

85 K213886, 510(k) summary (FDA) (page 4).

86 K203508, 510(k) summary (FDA) (page 13).

87 K203508, 510(k) summary (FDA) (page 17).

88 K203508, 510(k) summary (FDA) (page 9).

89 K203508, 510(k) summary (FDA) (page 30).

90 K203508, 510(k) summary (FDA) (page 21).

91 K203508, 510(k) summary (FDA) (page 25).

92 K180647, 510(k) summary (FDA) (page 4).

93 K190072, 510(k) summary (FDA) (page 4).

94 K190896, 510(k) summary (FDA) (page 4).

95 K192383, 510(k) summary (FDA) (page 4).

96 K192383, 510(k) summary (FDA) (page 4).

97 K193298, 510(k) summary (FDA) (page 4).

98 K201020, 510(k) summary (FDA) (page 4).

99 K233968, 510(k) summary (FDA) (page 8).

Appendix: attachments index

Document	Kind	Pages	Passages	Added	SHA-256
AortaView standalone performance report v3 (synthetic)	PDF	12	0	2026-11-15	0000000000000000...