PRECEDIUM *drafting assistance*

PRE-SUB MINUTES AND FEEDBACK MAP

SAMPLE · Pre-Submission meeting minutes (draft): AortaView (synthetic)

pre-submission meeting minutes (draft) prepared in Precedium

DEVICE
AortaView (synthetic)

PRODUCT CODE
QAS

PATHWAY
Traditional 510(k)

PREPARED FOR
Northbridge Imaging (synthetic)

PREPARED
2026-11-15

19	71	0	1
sections	footnoted sources	items withheld	documents read

ABOUT THIS DOCUMENT

- SAMPLE of the Pre-Sub minutes and feedback map, From $1,000. Get yours at precedium.com/services/presub-minutes/
- 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.
- Prepared with drafting assistance in Precedium (Device Evidence), 2026-11-15. No language model was used in this document.
- Project: Sample presub_minutes. Mode: Pre-Sub minutes and feedback map. Pathway: Traditional 510(k). Product code: QAS.
- This document organises the client's own statements and documents beside the public record of the product code, and states the gaps as questions. It is prepared by the consultant and reviewed by the client, whose regulatory lead is responsible for any decision taken on it.
- Every statement carries a footnote to the sponsor's profile, the documents read, or a page of a cited predicate's public summary, or the parent's exposure file at a named capture. Statements the sponsor did not make are printed as "not stated by the applicant" and listed in the not-exported appendix.
- Prepared for Northbridge Imaging (synthetic) by the consultant, on documents the client supplied under a confidentiality agreement signed 2026-11-01, received 2026-11-02, to be deleted by 2027-11-01. The client agreed that passages may be sent to the model provider named above under its API terms.

Contents

01 Meeting minutes 3
02 Discussion 3
03 Decisions made and agreements reached 4
04 Action items 4
05 Feedback map: what each response changes 5
06 Dates 5
07 Review time in QAS, by submission type 5
08 What the 85 AI devices in QAS state 5
09 The cleared devices in QAS most like the client's 7
10 Where predicates in QAS come from 8
11 Changing a cleared device in QAS: the precedent 9
12 The leading applicants in QAS 9
13 Clinical uses in QAS 10
14 Questions the record for QAS raises 11
15 The leading predicate candidates side by side 11
16 Candidate K180647 in detail 12
17 Candidate DEN170073 in detail 17
18 Candidate K203508 in detail 20
19 Get this pre-sub minutes and feedback map for your device 25

Appendix: sources 26
Appendix: not exported 28
Appendix: attachments index 29

01 Meeting minutes

Laid out in the FDA's example format for Q-Submission meeting minutes; the format is optional.[69]

Item	Detail
Submission number	Q269991 (synthetic)[68]
Submission type	Pre-Sub Meeting[68]
Product name	AortaView (synthetic)[68]
Submitter	Northbridge Imaging (synthetic)[68]
Meeting date	2026-11-05[68]
Meeting format	Virtual[68]
Date FDA feedback was sent	2026-10-31[68]
FDA attendees	Lead reviewer and branch chief, Division of Radiological Imaging Devices (synthetic)[68]
Company attendees	CEO, Head of Regulatory, Clinical Lead, Biostatistician (synthetic)[68]

02 Discussion

Question 1

Does the FDA agree that a triage and notification device in product code QAS cleared for CT angiography of the chest and abdomen (BriefCase-Triage, 2025) is an appropriate predicate for AortaView?[68]

FDA Response to Question 1

We agree a computer-aided triage device in product code QAS cleared for CT angiography of the chest may be an appropriate predicate. Your submission should explain any differences in the target finding and show they do not raise different questions of safety and effectiveness.[67]

Meeting Discussion for Question 1

The FDA confirmed the predicate is acceptable in principle. The team will add a table of differences in target condition (synthetic).[68]

Outcome: Agreed.

Question 2

Is a retrospective test set of 600 studies from three US sites, with a two-radiologist consensus reference standard, adequate for the standalone performance study?[68]

FDA Response to Question 2

The proposed design appears reasonable. Please ensure the test set is enriched for type A and type B dissections in proportions you justify, and report results by site and by scanner manufacturer.[67]

Meeting Discussion for Question 2

The FDA asked for subgroup results by site and scanner vendor. The statistician will extend the analysis plan (synthetic).[68]

Outcome: Follow-up needed.

Question 3

Does the FDA agree that a time-to-notification analysis is sufficient to support the triage claim, without a reader study?[68]

FDA Response to Question 3

A time-to-notification analysis comparing device notification time with standard-of-care time-to-open is consistent with other devices in this product code. A multi-reader study is not expected for a triage claim of this kind.[67]

Meeting Discussion for Question 3

Agreed; no reader study is planned (synthetic).[68]

Outcome: Agreed.

03 Decisions made and agreements reached

The predicate approach and the absence of a reader study were agreed. Subgroup reporting by site and scanner manufacturer will be added (synthetic).[68]

04 Action items

Who	What	By
The submitter	Send the revised statistical analysis plan with subgroup reporting by site and scanner vendor[68]	2026-11-30
The submitter	Submit the meeting minutes to the FDA within 15 days of the meeting[68]	2026-11-20

05 Feedback map: what each response changes

Plan item or submission section	FDA responses
Predicate / substantial equivalence comparison	1[68]
Performance testing - clinical	2[68]
Test plan (not yet a section)	2, 3[68]

06 Dates

Draft minutes due to the FDA by 2026-11-20, 15 days after the meeting.[70]

If the FDA edits the draft, it intends to send the revised minutes within 30 days; if it has no edits, the minutes are considered final.[71]

07 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.[12]

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.

08 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.[12]

Evidence element	Code's AI devices stating it	Share
Sensitivity	82 of 85	96%

Evidence element	Code's AI devices stating it	Share
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%

Evidence element	2016-2020	2021-2023	2024 on
Multiple collection sites	84%	87%	89%
Prospective collection	0%	0%	3%
Patient outcomes	0%	0%	3%

09 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%
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

Device	Sample size	Sites	Prospective	Reference standard	Design	Performance
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

10 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

Most cited predicate	Applicant	Decided	Cited by
K190896 BriefCase	Aidoc Medical , Ltd.	2019-05-31	2

11 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

12 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)

Company	Decisions	First / latest	Median days	On AI list	Predicates they cite most
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)

13 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%

Task	Devices	Share
Planning and guidance	2	3%
Segmentation and measurement	2	3%

14 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)?

15 The leading predicate candidates side by side

	K180647 BriefCase	DEN170073 ContaCT	K203508 BriefCase
Applicant	Aidoc Medical , Ltd.	Viz.AI, Inc.	Aidoc Medical , Ltd.
Product code	QAS	QAS	QAS
Decided	2018-08-01 (8.3 y ago)	2018-02-13 (8.8 y ago)	2020-12-29 (5.9 y ago)
510(k) review	142 days, Traditional	-	29 days, Special
Code median review	103 days	103 days	103 days
AI evidence elements stated	7 of 13	8 of 13	1 of 13
Indications held	yes, quoted below	no	yes, quoted below
Generations of predicates traced	2	1	3
Later summaries citing it	10	8	7
FDA recalls listed	0	0	0

	K180647 BriefCase	DEN170073 ContaCT	K203508 BriefCase
Authorized change-control plan	no	no	no

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

16 Candidate K180647 in detail

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

Decided 2018-08-01: 8.3 years before this report.[14]

Its Traditional 510(k) took 142 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 non-enhanced head CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of pathologies in head CT images, namely Intracranial Hemorrhage (ICH) . BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected ICH 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 ICH 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 professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care."[15] (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 findings of pathologies in head CT images, namely Intracranial Hemorrhage (ICH) . BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected ICH 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 ICH 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.[16]	Adults undergoing contrast-enhanced CT angiography of the chest in a hospital emergency setting.[17]

Aspect	The predicate's statement	Yours	Compared
Imaging type	CT	CT	same

Aspect	The predicate's statement	Yours	Compared
Body area	Brain and head	Lung and chest	**differs**
Task	Triage and notification, Detection, Viewing and communication	not stated	only the predicate's states it
Population	not stated	adults	only yours states it
Intended user	radiologists, clinicians, hospital networks	not stated	only the predicate's states it
Output	notification or flag, marked or annotated images	not stated	only the predicate's states it

2 of the 9 key words in your statement appear in the predicate's. Words in yours that the predicate's does not use: adults, angiography, chest, contrast, emergency, setting, undergoing.

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, multinational study with the BriefCase software with the primary endpoint to evaluate the software's performance in identifying non- contrast CT head images containing intracranial hemorrhage (ICH) findings in 198 cases from 3 clinical sites (2 US and 1 OUS). There were approximately an equal number of positive and negative cases (images with ICH versus without ICH) included in the analysis."[18]	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	"Aidoc conducted a retrospective, blinded, multicenter, multinational study with the BriefCase software with the primary endpoint to evaluate the software's performance in identifying non- contrast CT head images containing	7	80 of 85

Evidence element	In its summary	Page	QAS AI devices stating it
	intracranial hemorrhage (ICH) findings in 198 cases from 3 clinical sites (2 US and 1 OUS)."[19]		
Sensitivity	"There were approximately an equal number of positive and negative cases (images with ICH versus without ICH) included in the analysis. Sensitivity and specificity exceeded the 80% performance goal. Specifically, sensitivity was observed to be 93.6% (95% CI: 86.6%-97.6%) and specificity was observed to be 92.3% (95% CI: 85.4%-96.6%)."[20]	7	82 of 85
Specificity	The same passage as Sensitivity.[21]	7	82 of 85
AUC	*Not reported*	-	28 of 85
Reference standard	"Fifty-nine (59) cases have been identified as true positive (i.e., identified as positive by both the BriefCase and the ground truth) and the time-to-exam-open has been also collected for these cases. As shown in the table below, analysis demonstrated that standard of care time-to-exam-open (72.6 minutes: 95% CI 45.0-100.2) is significantly longer than the parallel time-to-notification of the BriefCase software (4.5 minutes: 95% CI 4.1-4.8)."[22]	8	70 of 85
Performance comparator	The same passage as Sensitivity.[23]	7	77 of 85
Multiple collection sites	The same passage as Study design.[24]	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

K180647 cites DEN170073 · ContaCT · Viz.AI, Inc. · De Novo decided 2018-02-13 · product code QAS[14] (K180647 summary, page 4)[25]

Generation 2

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

10 later summaries cite 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
K200855 CINA	Avicenna.Ai	2020-06-24	QAS	Traditional	85	yes
K193298 BriefCase	Aidoc Medical , Ltd.	2020-06-19	QAS	Traditional	205	yes
K200921 qER	Qure.Ai Technologies	2020-06-17	QAS	Traditional	72	yes
K193087 Rapid ICH	Ischemaview Incorporated	2020-03-31	QAS	Traditional	146	yes
K193658 Viz ICH	Viz. Ai, Inc.	2020-03-18	QAS	Traditional	79	yes
K192383 BriefCase	Aidoc Medical , Ltd.	2019-12-20	QAS	Traditional	112	yes
K182875 DeepCT	Deep01 Limited	2019-07-10	QAS	Traditional	271	yes
K190896 BriefCase	Aidoc Medical , Ltd.	2019-05-31	QAS	Traditional	56	yes
K190072 BriefCase	Aidoc Medical , Ltd.	2019-04-15	QAS	Traditional	90	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."[26]

K200855 CINA (2020-06-24): "CINA runs on a standard "off the shelf" server/workstation and is made of the following software components: • CINA Image Processing Applications including two applications: ICH and LVO; • CINA Platform server that includes the Worklist client application in which notifications from the CINA Image Processing applications (ICH and LVO) are received. Each of these components is briefly described below. VI.1. CINA Platform The CINA platform is the technical platform for integrating and deploying CINA image processing applications."[27]

K193298 BriefCase (2020-06-19): "The subject BriefCase for IFG triage and predicate device BriefCase for ICH triage (K180647) are identical in all aspects and defer only with respect to the training of the algorithm on IFG and ICH images, respectively. Both devices are radiological computer-aided triage and notification software programs. Both devices are artificial intelligence algorithms incorporated software packages for use with CT scanners, PACS, and radiology workstations. Both devices are intended to aid in triage and prioritization of radiological images."[28]

K200921 qER (2020-06-17): "The qER software consists of two major components: 1) a configurable gateway as an interface with the client systems such as the PACS and worklist; and 2) analysis module that hosts the pre-trained artificial intelligence algorithms. qER software can be deployed completely on client premises (on-premise) or on cloud servers (on- cloud). For on-cloud processing mode, an on-premise gateway is deployed that interfaces with the HIPAA- compliant cloud server(s) where the analysis is performed. Additionally, a configuration module allows control over triage settings and output formats. The deep learning analysis module underlying qER consists of a set of 4 independent algorithms."[29]

K193087 Rapid ICH (2020-03-31): "The subject and predicate devices are radiological computer-assisted triage and notification software programs. Both devices are artificial intelligence algorithms incorporated software packages for use with CT scanners, PACS, and workstations. Both devices process images intended to aid in prioritization and triage of radiological medical images. The subject and predicate device process NCCT images for ICH indication."[30]

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?

17 Candidate DEN170073 in detail

DEN170073 · ContaCT · Viz.AI, Inc. · De Novo decided 2018-02-13 · product code QAS[14]

Decided 2018-02-13: 8.8 years before this report.[14]

ITS INDICATIONS FOR USE

Not available: it is a De Novo authorization; predicates are a 510(k) concept.

ITS INDICATIONS BESIDE YOURS

The predicate's statement	Yours, as given
Not available	Adults undergoing contrast-enhanced CT angiography of the chest in a hospital emergency setting.[31]

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 (8 OF 13 ELEMENTS)

Evidence element	In its summary	Page	QAS AI devices stating it
Validation sample size	"• Series containing inconsistent pixel spacing; • Series containing slices thicker than 0.625mm; • Series containing improperly ordered slices (e.g. as a result of manual correction by an Imaging technician); and • Series containing an incomplete skull. b. Test Protocol All 300 studies were reviewed by neuro-radiologists to establish the Ground Truth; each study was reviewed to determine if the image contained image features consistent with an LVO, and thus required further review.[32]	8	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	"The following figure presents the ROC and performance curves of the algorithm in the standalone performance dataset. The estimated area under the curve (AUC) is .91; the fixed optimum threshold, 60mm, is marked with the vertical dashed line: 1.0 H."[33]	5	80 of 85
Sensitivity	"Each case was classified based on the following table: Device c. Endpoints Primary Analysis: Sensitivity and Specificity The sensitivity and specificity of the device performance were calculated using two- sided 95% Clopper-Pearson confidence	9	82 of 85

Evidence element	In its summary	Page	QAS AI devices stating it
	intervals and compared to pre-defined performance goals. Sensitivity was calculated as follows: TP / (TP+FN) Specificity was calculated as follows: TN / (TN+FP) Study endpoints and performance goals: (b) (4) Secondary Analysis: CTA-to-Notification Time As a secondary analysis, the company compared the Standard of Care CTA-to- notification time with the equivalent metric observed for ContaCT."[34]		
Specificity	The same passage as Sensitivity.[35]	9	82 of 85
AUC	"The following figure presents the ROC and performance curves of the algorithm in the standalone performance dataset. The estimated area under the curve (AUC) is .91; the fixed optimum threshold, 60mm, is marked with the vertical dashed line: 1.0 H. Standard/Guidance Document Referenced NEMA PS 3.1 - 3.20 (2016), Digital Imaging and Communications in Medicine (DICOM) set."[36]	5	28 of 85
Reference standard	"Viz.AI conducted a retrospective study to assess the sensitivity and specificity of the image analysis algorithm and notification functionality of ContaCT against a ground truth as established by trained neuro-radiologists in the detection of large vessel occlusions (LVO) in the brain, and to compare the Standard of Care with ContaCT on CTA-to- notification time."[37]	8	70 of 85
Performance comparator	"When ContaCT identified a suspected LVO in a test study, it sent a notification to the mobile application component recommending further review of the study. A log of notifications was maintained by the testing facility and compared with respect to the Ground Truth for each case. Each case was classified based on the following table: Device c. Endpoints Primary Analysis: Sensitivity and Specificity The sensitivity and specificity of the device performance were calculated using two- sided 95% Clopper-Pearson confidence intervals and compared to pre-defined performance goals."[38]	9	77 of 85
Multiple collection sites	"Data Characteristics (Special Control 1.ii.) Three hundred (300) CT angiogram (CTA) images (studies) were obtained from two clinical sites in the U.S. There were approximately equal numbers of positive and negative cases (images with LVO and without LVO, respectively) included in the analysis."[39]	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

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

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

Device	Applicant	Decided	Code	Type	Review days	AI list
K251590 Methinks CTA Stroke	Methinks Software, S.L	2025-08-20	QAS	Traditional	89	yes
K223042 Viz LVO ContaCT	Viz. Ai, Inc.	2022-10-21	QAS	Special	22	yes
K200873 HALO	Nico-Lab B.V.	2020-11-20	QAS	Traditional	233	yes
K193658 Viz ICH	Viz. Ai, Inc.	2020-03-18	QAS	Traditional	79	yes
K192383 BriefCase	Aidoc Medical , Ltd.	2019-12-20	QAS	Traditional	112	yes
K182875 DeepCT	Deep01 Limited	2019-07-10	QAS	Traditional	271	yes
K183285 cmTriage	Curemetrix, Inc.	2019-03-08	QFM	Traditional	102	yes
K180647 BriefCase	Aidoc Medical , Ltd.	2018-08-01	QAS	Traditional	142	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.

K251590 Methinks CTA Stroke (2025-08-20): "WITH THE PREDICATE DEVICE Methinks CTA Stroke does not raise new questions of safety or effectiveness compared to the previously cleared ContaCT (DEN170073). Both devices are radiological computer-aided triage and notification software applications for determining suspicion of Large Vessel Occlusion (LVO). Both devices use CT angiogram images for the identification of suspected LVO cases. Compared to the predicate device, the subject device identifies an additional type of occlusion MCA-M2 (the predicate identifies ICA and MCA-M1 only) which does not raise

a substantial difference in the indications for use nor different questions of safety and effectiveness."[40]

K223042 Viz LVO ContaCT (2022-10-21):"Both the subject and predicate device use the same artificial intelligence, machine learning (AI/ML) software algorithm to identify suspected large vessel occlusions (LVOs) on stroke-protocoled CTA imaging of head in the same regions of the large vessels. Additionally, the software algorithm for the subject device is hosted on the same architecture, automatically receives imaging in the same DICOM format, and uses the same mechanisms to identify applicable imaging for analysis as the predicate device."[41]

K193658 Viz ICH (2020-03-18): "Viz ICH and its primary predicate, ContaCT (DEN170073), use the same process of automatic data identification and transfer to send images from the local hospital network to..."[42]

K192383 BriefCase (2019-12-20): "The subject BriefCase for LVO triage and primary predicate BriefCase for ICH triage (K180647) are identical in all aspects and differ only with respect to the training of the algorithm on LVO and ICH images, respectively. The addition of a notification filter feature to the software platform design is considered a minor change which does not alter the safety and efficacy profile of the device. Both devices are radiological computer-aided triage and notification software programs. Both devices are artificial intelligence algorithms incorporated software packages for use with CT scanners, PACS, and radiology workstations."[43]

K182875 DeepCT (2019-07-10): "WITH THE PREDICATE DEVICE Similarities: Both ContaCT and DeepCT (Ver. 4.1.4): Are to identify and communicate CT images of specific patients to a specialist, independent of standard of care workflow. Use artificial intelligence algorithm to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation and recommends review of those images. Process images intended to aid in prioritization and triage of radiological medical images. Are not for diagnostic use beyond notification. Send notifications to a specialist."[44]

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?

18 Candidate K203508 in detail

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

Decided 2020-12-29: 5.9 years before this report.[14]

Its Special 510(k) took 29 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 cervical spine CT images. 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 linear lucencies in the cervical spine bone in patterns compatible with fractures. BriefCase uses an artificial intelligence algorithm to analyse 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."[45] (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 linear lucencies in the cervical spine bone in patterns compatible with fractures. BriefCase uses an artificial intelligence algorithm to analyse 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.[46]	Adults undergoing contrast-enhanced CT angiography of the chest in a hospital emergency setting.[47]

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

1 of the 9 key words in your statement appear in the predicate's. Words in yours that the predicate's does not use: adults, angiography, chest, contrast, emergency, enhanced, setting, undergoing.

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 (1 OF 13 ELEMENTS)

Evidence element	In its summary	Page	QAS AI devices stating it
Validation sample size	*Not reported*	-	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. Inclusion criteria - Contrast-enhanced chest CTs (but not dedicated CTPA protocol. - Single energy exams. - Scans performed with a 64 slice or greater number of detectors."[48]	27	55 of 85
Sex breakdown	*Not reported*	-	50 of 85
Race or ethnicity breakdown	*Not reported*	-	12 of 85
Study design	*Not reported*	-	80 of 85
Sensitivity	*Not reported*	-	82 of 85
Specificity	*Not reported*	-	82 of 85
AUC	*Not reported*	-	28 of 85
Reference standard	*Not reported*	-	70 of 85
Performance comparator	*Not reported*	-	77 of 85
Multiple collection sites	*Not reported*	-	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

K203508 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[14] (K203508 summary, page 13)[49]

K203508 cites K190072 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-04-15 · product code QAS[14] (K203508 summary, page 17)[50]

K203508 cites K190896 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-05-31 · product code QAS[14] (K203508 summary, page 9)[51]

K203508 cites K192383 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-12-20 · product code QAS[14] (K203508 summary, page 30)[52]

K203508 cites K193298 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2020-06-19 · product code QAS[14] (K203508 summary, page 21)[53]

K203508 cites K201020 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2020-08-26 · product code QAS[14] (K203508 summary, page 25)[54]

Generation 2

K180647 cites DEN170073 · ContaCT · Viz.AI, Inc. · De Novo decided 2018-02-13 · product code QAS[14] (K180647 summary, page 4)[55]

K190072 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[14] (K190072 summary, page 4)[56]

K190896 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[14] (K190896 summary, page 4)[57]

K192383 cites DEN170073 · ContaCT · Viz.AI, Inc. · De Novo decided 2018-02-13 · product code QAS[14] (K192383 summary, page 4)[58]

K192383 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[14] (K192383 summary, page 4)[59]

K193298 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[14] (K193298 summary, page 4)[60]

K201020 cites K190072 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2019-04-15 · product code QAS[14] (K201020 summary, page 4)[61]

Generation 3

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

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

Device	Applicant	Decided	Code	Type	Review days	AI list
K221330 BriefCase	Aidoc Medical , Ltd.	2022-11-18	QAS	Traditional	196	yes
K220709 BriefCase	Aidoc Medical , Ltd.	2022-10-07	QAS	Traditional	211	yes

Device	Applicant	Decided	Code	Type	Review days	AI list
K222277 BriefCase	Aidoc Medical , Ltd.	2022-08-26	QAS	Special	28	yes
K221314 BriefCase	Aidoc Medical , Ltd.	2022-06-03	QAS	Special	29	yes
K221240 BriefCase	Aidoc Medical , Ltd.	2022-05-17	QAS	Special	18	yes
K213886 BriefCase	Aidoc Medical , Ltd.	2022-04-26	QAS	Traditional	134	yes
K213721 BriefCase	Aidoc Medical , Ltd.	2022-03-21	QAS	Traditional	117	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.

K221330 BriefCase (2022-11-18): "The subject BriefCase for vertically malpositioned ETT in relation to the carina triage and primary predicate BriefCase for iPE triage (K203508) are identical in all aspects and defer only with respect to the training of the algorithm on vertically malpositioned ETT in relation to the carina vs iPE images. 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 x-ray scanners, PACS, and radiology workstations."[62]

K220709 BriefCase (2022-10-07): "The subject BriefCase for VO triage and primary predicate BriefCase for LVO triage (K203508) are identical in all aspects and defer only with respect to the training of the algorithm on VO vs LVO (M1) images. Both devices are radiological computer-aided triage and notification software programs. Both devices are artificial intelligence, deep-learning algorithms incorporated software packages for use with DICOM 3.0 compliant CT scanners, PACS, and radiology workstations. Both devices are intended to aid in triage and prioritization of radiological images and utilize the same design of deep learning algorithm trained on medical images."[63]

K222277 BriefCase (2022-08-26): "The subject BriefCase for PE triage and predicate BriefCase for PE triage (K203508) are identical in most aspects and differ with respect to their algorithm performance due to training the subject device on a larger data set, the addition of 2 operating points, and ability to process single and dual energy exams. Both the predicate and subject device are radiological computer-aided triage and notification software programs. Both devices are artificial intelligence, deep-learning algorithms that incorporate software packages for use with DICOM 3.0 compliant CT scanners, PACS, and radiology workstations."[64]

K221314 BriefCase (2022-06-03): "The subject BriefCase for M1-LVO triage and primary predicate BriefCase for LVO triage (K203508) are identical in most aspects and differ with respect to very specific changes in (1) indications for use, (2) user guide warnings, and (3) minor changes in User Interface. All these changes are added to the subject device with the intent to further clarify its intended use - as analyzing specifically M1 large vessels. Both the primary predicate and subject devices are radiological computer-aided triage and notification software programs."[65]

K221240 BriefCase (2022-05-17): "The subject BriefCase for ICH triage and primary predicate BriefCase for ICH triage (K203508) are identical in most aspects and differ with respect to their algorithm performance, due to training the subject device on a larger data set. Additional minor changes have been made to reflect software and the UI. Both the primary predicate and subject devices are radiological computer-aided triage and notification software programs. Both devices are artificial intelligence, deep-learning algorithms incorporated software packages for use with DICOM 3.0 compliant CT scanners, PACS, and radiology workstations."[66]

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 validation sample size, sex breakdown, study design, sensitivity, specificity, reference standard, performance comparator and multiple collection sites, 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?

19 Get this pre-sub minutes and feedback map for your device

This is a sample pre-sub minutes and feedback map for a synthetic client; the FDA record it cites is real.

For your own device: the same work on your documents, under a signed confidentiality agreement. From $1,000, fixed in writing before work starts.

HOW TO START

Go to precedium.com/services/presub-minutes/ 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 K180647, 510(k) summary (FDA) (page 3).
16 K180647, 510(k) summary (FDA) (page 3).
17 The client's indications for use, as given.
18 K180647, 510(k) summary (FDA) (page 7).
19 K180647, 510(k) summary (FDA) (page 7).
20 K180647, 510(k) summary (FDA) (page 7).
21 K180647, 510(k) summary (FDA) (page 7).
22 K180647, 510(k) summary (FDA) (page 8).
23 K180647, 510(k) summary (FDA) (page 7).
24 K180647, 510(k) summary (FDA) (page 7).
25 K180647, 510(k) summary (FDA) (page 4).
26 K203508, 510(k) summary (FDA) (page 10).
27 K200855, 510(k) summary (FDA) (page 6).
28 K193298, 510(k) summary (FDA) (page 5).
29 K200921, 510(k) summary (FDA) (page 5).
30 K193087, 510(k) summary (FDA) (page 7).
31 The client's indications for use, as given.
32 DEN170073, De Novo decision summary (FDA) (page 8).
33 DEN170073, De Novo decision summary (FDA) (page 5).
34 DEN170073, De Novo decision summary (FDA) (page 9).
35 DEN170073, De Novo decision summary (FDA) (page 9).
36 DEN170073, De Novo decision summary (FDA) (page 5).
37 DEN170073, De Novo decision summary (FDA) (page 8).

38 DEN170073, De Novo decision summary (FDA) (page 9).

39 DEN170073, De Novo decision summary (FDA) (page 8).

40 K251590, 510(k) summary (FDA) (page 6).

41 K223042, 510(k) summary (FDA) (page 6).

42 K193658, 510(k) summary (FDA) (page 5).

43 K192383, 510(k) summary (FDA) (page 5).

44 K182875, 510(k) summary (FDA) (page 8).

45 K203508, 510(k) summary (FDA) (page 3).

46 K203508, 510(k) summary (FDA) (page 3).

47 The client's indications for use, as given.

48 K203508, 510(k) summary (FDA) (page 27).

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

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

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

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

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

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

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

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

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

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

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

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

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

62 K221330, 510(k) summary (FDA) (page 5).

63 K220709, 510(k) summary (FDA) (page 5).

64 K222277, 510(k) summary (FDA) (page 5).

65 K221314, 510(k) summary (FDA) (page 5).

66 K221240, 510(k) summary (FDA) (page 5).

67 The FDA's written feedback for this Q-Submission, as pasted and split on the minutes step.

68 The sponsor's own record of the meeting, entered on the minutes step.

69 FDA, Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program (final guidance 2025-05, https://www.fda.gov/media/114034/download, PDF page 39, read 2026-11-14).

70 FDA, Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program (final guidance 2025-05, https://www.fda.gov/media/114034/download, PDF page 21, read 2026-11-14).

71 FDA, Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program (final guidance 2025-05, https://www.fda.gov/media/114034/download, PDF page 22, read 2026-11-14).

Appendix: not exported

Nothing was withheld.

Appendix: attachments index

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