PRECEDIUM *drafting assistance*

PREDICATE CHECK

Predicate check: K180647, K193087

K180647 · BriefCase; K193087 · Rapid ICH

PREDICATES
K180647, K193087

DEVICE
BriefCase; Rapid ICH

PREPARED FOR
Example report

RECORD READ
2026-11-17

2	14	12	0
predicates checked	AI evidence elements	later citing summaries	recalls listed

ABOUT THIS DOCUMENT

- REAL EXAMPLE of the Predicate check, $149 (per predicate, or $349 for up to 3). Get yours at precedium.com/services/predicate-check/
- Made from the FDA's public record as Device Evidence publishes it (read 2026-11-17): the FDA register, 510(k) summaries read and checked page by page, and openFDA's recall data. No language model wrote any part of it.
- 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 K180647, K193087. It uses no document from Example report and makes no statement about any particular device of theirs.
- Not regulatory advice and not a determination of substantial equivalence. This check states what the FDA's public record says about each predicate named. Whether a device is substantially equivalent to it is for the submitter to argue and the FDA to decide.

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01 Your candidates side by side

	K180647 BriefCase	K193087 Rapid ICH
Applicant	Aidoc Medical , Ltd.	Ischemaview Incorporated
Product code	QAS	QAS
Decided	2018-08-01 (8.3 y ago)	2020-03-31 (6.6 y ago)
510(k) review	142 days, Traditional	146 days, Traditional
Code median review	103 days	103 days
AI evidence elements stated	7 of 13	7 of 13
Indications held	yes, quoted below	yes, quoted below
Generations of predicates traced	2	3
Later summaries citing it	10	2
FDA recalls listed	0	0
Authorized change-control plan	no	no

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

02 At a glance

K180647, BriefCase (Aidoc Medical , Ltd.): 510(k) decided 2018-08-01, 8.3 years ago; indications quoted from its summary; 7 of 13 AI evidence elements reported; 2 generations of predicates traced; cited by 10 later summaries; no FDA recall listed against it.

K193087, Rapid ICH (Ischemaview Incorporated): 510(k) decided 2020-03-31, 6.6 years ago; indications quoted from its summary; 7 of 13 AI evidence elements reported; 3 generations of predicates traced; cited by 2 later summaries; no FDA recall listed against it.

03 Predicate K180647

K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[1]

Decided 2018-08-01: 8.3 years before this report.[1]

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."[2] (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.[3]	An artificial intelligence triage and notification software that analyzes non-contrast head CT images of adults and flags suspected acute intracranial hemorrhage, so that trained radiologists can prioritize their review. It works in parallel to the standard of care and does not provide a diagnosis.[4]

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

13 of the 19 key words in your statement appear in the predicate's. Words in yours that the predicate's does not use: acute, adults, contrast, diagnosis, flags, prioritize.

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."[5]	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 intracranial hemorrhage (ICH) findings in 198 cases from 3 clinical sites (2 US and 1 OUS)."[6]	7	80 of 85
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%)."[7]	7	82 of 85

Evidence element	In its summary	Page	QAS AI devices stating it
Specificity	The same passage as Sensitivity.[8]	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)."[9]	8	70 of 85
Performance comparator	The same passage as Sensitivity.[10]	7	77 of 85
Multiple collection sites	The same passage as Study design.[11]	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[1] (K180647 summary, page 4)[12]

Generation 2

DEN170073: the record of predicates ends here - it is a De Novo authorization; predicates are a 510(k) concept.[1]

LATER DEVICES THAT CITED IT

10 later summaries cite it as a predicate (confirmed links only), newest first.[1]

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."[13]

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."[14]

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."[15]

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."[16]

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."[17]

RECALLS THE FDA LISTS AGAINST IT

No recall in openFDA's device recall data lists this number.[1]

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?

04 Predicate K193087

K193087 · Rapid ICH · Ischemaview Incorporated · 510(k) decided 2020-03-31 · product code QAS[1]

Decided 2020-03-31: 6.6 years before this report.[1]

Its Traditional 510(k) took 146 days from receipt to decision; the median in QAS is 103 days (n=89).

ITS INDICATIONS FOR USE

"RAPID ICH 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). RAPID ICH uses an artificial intelligence algorithm to analyze images and highlight cases with detected ICH on a server or 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 RAPID ICH 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."[18] (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). RAPID ICH uses an artificial intelligence algorithm to analyze images and highlight cases with detected ICH on a server or 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.[19]	An artificial intelligence triage and notification software that analyzes non-contrast head CT images of adults and flags suspected acute intracranial hemorrhage, so that trained radiologists can prioritize their review. It works in parallel to the standard of care and does not provide a diagnosis.[20]

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

13 of the 19 key words in your statement appear in the predicate's. Words in yours that the predicate's does not use: acute, adults, contrast, diagnosis, flags, prioritize.

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	"iSchemaView conducted a retrospective, blinded, multicenter, multinational	10	74 of 85

Evidence element	In its summary	Page	QAS AI devices stating it
	study with the RAPID ICH software with the primary endpoint to evaluate the software's performance in identifying noncontrast CT head images containing intracranial hemorrhage (ICH) findings in 336 cases from US (4 Sites and 1 Multisite Study) and OUS sites (1 site, 1 multisite). There were approximately an equal number of positive and negative cases (images with ICH versus without ICH) included in the analysis."[21]		
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	"iSchemaView conducted a retrospective, blinded, multicenter, multinational study with the RAPID ICH software with the primary endpoint to evaluate the software's performance in identifying noncontrast CT head images containing intracranial hemorrhage (ICH) findings in 336 cases from US (4 Sites and 1 Multisite Study) and OUS sites (1 site, 1 multisite)."[22]	10	80 of 85
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 Se: 0.899 (95% CI: 0.847 - 0.935) and Sp: 0.943 (95% CI: 0.895 - 0.970)."[23]	10	82 of 85

Evidence element	In its summary	Page	QAS AI devices stating it
Specificity	The same passage as Sensitivity.[24]	10	82 of 85
AUC	*Not reported*	-	28 of 85
Reference standard	"The RAPID ICH performance has been validated through the use of phantoms and retrospective case data and through the use of reader truthing of the data. Conclusion: In conclusion, iSchemaView's RAPID ICH is substantially equivalent in technological characteristics, safety, and performance characteristics to the legally marketed predicate device, BriefCase (K180647); the two devices vary slightly in the notification pathway, the subject device has a mobile interface to allow messaging."[25]	11	70 of 85
Performance comparator	The same passage as Sensitivity.[26]	10	77 of 85
Multiple collection sites	The same passage as Study design.[27]	10	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	IEC 62304:2015, ISO 62304:2015	p. 10: "RAPID ICH has been developed in conformance with the following standards, as applicable: EN ISO 14971:2012 Application of Risk Management to Medical Devices IEC 62304:2015 Medical device software -..."[28]

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

K193087 cites K180647 · BriefCase · Aidoc Medical , Ltd. · 510(k) decided 2018-08-01 · product code QAS[1] (K193087 summary, page 4)[29]

Generation 2

K180647 cites DEN170073 · ContaCT · Viz.AI, Inc. · De Novo decided 2018-02-13 · product code QAS[1] (K180647 summary, page 4)[30]

Generation 3

DEN170073: the record of predicates ends here - it is a De Novo authorization; predicates are a 510(k) concept.[1]

LATER DEVICES THAT CITED IT

2 later summaries cite it as a predicate (confirmed links only), newest first.[1]

Device	Applicant	Decided	Code	Type	Review days	AI list
K221456 Rapid ICH	Ischemaview, Inc.	2022-09-12	QAS	Traditional	116	yes
K200941 Rapid LVO	Ischemaview, Inc.	2020-07-09	QAS	Traditional	92	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.

K221456 Rapid ICH (2022-09-12): "Rapid ICH does not raise new questions of safety or effectiveness compared to the previously cleared Rapid ICH (K193087). Both devices are radiological computer-aided triage and notification software applications for use with non-contrast CT input. The minor change causing this filing, is the use of additional data for training and validation; there are no further differences. Thus, the Rapid ICH software is substantially equivalent. The following table summarizes and compares data on the Rapid ICH (K193087) to the subject device of this Traditional 510(k) submission. A table comparing the key features of the subject and predicate devices is provided below."[31]

K200941 Rapid LVO (2020-07-09): "Rapid Platform performs the following functions in support of Rapid LVO: • processes DICOM images from multiple sources to provide visualization of changes of tissue perfusion, diffusion and change."[32]

RECALLS THE FDA LISTS AGAINST IT

No recall in openFDA's device recall data lists this number.[1]

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?

05 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.[33]

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.

06 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.[33]

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%

07 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.[33]

Device	Applicant	Decided	Imaging type	Key words shared
K250685 Methinks NCCT Stroke	Methinks Software, S.L	2025-06-16	CT	75%
K200921 qER	Qure.Ai Technologies	2020-06-17	CT	69%
K221240 BriefCase	Aidoc Medical , Ltd.	2022-05-17	CT	69%
K222884 Rapid NCCT Stroke	Ischemaview, Inc.	2023-03-02	CT	69%

Device	Applicant	Decided	Imaging type	Key words shared
K241719 NeuroICH	Neurocareai, Inc.	2024-11-07	CT	69%
K180647 BriefCase	Aidoc Medical , Ltd.	2018-08-01	CT	63%
K190072 BriefCase	Aidoc Medical , Ltd.	2019-04-15	CT	63%
K193087 Rapid ICH	Ischemaview Incorporated	2020-03-31	CT	63%
K200855 CINA	Avicenna.Ai	2020-06-24	CT	63%
K211179 InferRead CT Stroke.AI	Infervision Medical Technology Co., Ltd.	2021-08-12	CT	63%

Device	Sample size	Sites	Prospective	Reference standard	Design	Performance
K250685 Methinks NCCT Stroke	p. 9	p. 8	-	p. 14	p. 8	p. 9
K200921 qER	p. 10	p. 10	-	p. 10	p. 10	p. 10
K221240 BriefCase	p. 7	p. 7	-	-	p. 7	p. 7
K222884 Rapid NCCT Stroke	p. 10	p. 9	-	p. 11	p. 9	p. 9
K241719 NeuroICH	p. 9	-	-	p. 9	p. 9	p. 9
K180647 BriefCase	p. 7	p. 7	-	p. 8	p. 7	p. 7
K190072 BriefCase	p. 7	p. 7	-	p. 7	p. 7	p. 7
K193087 Rapid ICH	p. 10	p. 10	-	p. 11	p. 10	p. 10
K200855 CINA	p. 7	p. 7	-	p. 7	p. 7	p. 7
K211179 InferRead CT Stroke.AI	p. 10	p. 10	-	p. 10	p. 10	p. 10

08 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.[33]

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

09 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.[33]

4 devices in QAS have an FDA-authorized predetermined change control plan:[34]

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

10 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.[33]

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)

11 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.[33]

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%

12 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)?

13 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.

14 Get this predicate check for your device

This is a real predicate check, made from the FDA's record exactly as a buyer receives it.

For your own predicate: the same report, built from the FDA's record for it. $149 (per predicate, or $349 for up to 3), within one working day of your enquiry.

HOW TO START

Go to precedium.com/services/predicate-check/ 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 Device Evidence, the verified FDA record (register, confirmed predicate links, indications, testing as each summary reports it, openFDA recalls) (read 2026-11-17).

2 K180647, 510(k) summary (FDA) (page 3).

3 K180647, 510(k) summary (FDA) (page 3).

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

5 K180647, 510(k) summary (FDA) (page 7).

6 K180647, 510(k) summary (FDA) (page 7).

7 K180647, 510(k) summary (FDA) (page 7).

8 K180647, 510(k) summary (FDA) (page 7).

9 K180647, 510(k) summary (FDA) (page 8).

10 K180647, 510(k) summary (FDA) (page 7).

11 K180647, 510(k) summary (FDA) (page 7).

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

13 K203508, 510(k) summary (FDA) (page 10).

14 K200855, 510(k) summary (FDA) (page 6).

15 K193298, 510(k) summary (FDA) (page 5).

16 K200921, 510(k) summary (FDA) (page 5).

17 K193087, 510(k) summary (FDA) (page 7).

18 K193087, 510(k) summary (FDA) (page 3).

19 K193087, 510(k) summary (FDA) (page 3).

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

21 K193087, 510(k) summary (FDA) (page 10).

22 K193087, 510(k) summary (FDA) (page 10).

23 K193087, 510(k) summary (FDA) (page 10).

24 K193087, 510(k) summary (FDA) (page 10).

25 K193087, 510(k) summary (FDA) (page 11).

26 K193087, 510(k) summary (FDA) (page 10).

27 K193087, 510(k) summary (FDA) (page 10).

28 K193087, 510(k) summary (FDA) (page 10).

29 K193087, 510(k) summary (FDA) (page 4).

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

31 K221456, 510(k) summary (FDA) (page 5).

32 K200941, 510(k) summary (FDA) (page 5).

33 Device Evidence, the verified FDA record for product code QAS (read 2026-11-17).

34 FDA, Predetermined Change Control Plans: List of Authorized Devices with PCCPs, content current as of 2026-10-20, captured 2026-10-26.