PRECEDIUM *drafting assistance*

REVIEWER READ

SAMPLE · Reviewer read: 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

89	2	4	4
summaries compared	items to look at	kinds of testing	standards

ABOUT THIS DOCUMENT

- SAMPLE of the Pre-filing reviewer read, From $1,000. Get yours at precedium.com/services/reviewer-read/
- 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. 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 product code QAS. Its only input from Northbridge Imaging (synthetic) is the list of tests and standards they gave, printed as given; no test report was read.
- Not regulatory advice. This read lists where the client's testing set differs from what cleared summaries in the code reported. A gap is a question for the client's engineers, not a finding that testing is insufficient, and nothing here states what the FDA will ask or decide.

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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 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.[1][2]

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
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

03 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)?

04 Element by element: the client beside the closest cleared devices

For each of the thirteen elements: where the client's documents stand, how many of the 85 AI-device summaries in QAS state it, and how the cleared devices closest to the client's indications (K213886, K233968, K200873) stated it in their own summaries.

VALIDATION SAMPLE SIZE

The client: not reviewed. **The code:** 74 of 85 summaries state it.

K213886 BriefCase: "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."[13]

K233968 CINA-iPE: "Avicenna.AI conducted a retrospective, multicenter, multinational and blinded study with the CINA-iPE application with the primary endpoint to evaluate the software's performance in identifying incidental pulmonary embolisms (iPE) on contrast-enhanced CT images performed for another clinical indication than for pulmonary embolism (PE) evaluation (i.e. not dedicated CTPA protocol), in 381 clinical anonymized cases. The dataset included 53.5% Male and 46.7% Female. Mean +/- SD age of patients included in the study was 64.5 +/- 15.8 yo (range: 18 - 99 yo)."[14]

AGE OF THE COHORT

The client: not reviewed. **The code:** 55 of 85 summaries state it.

K213886 BriefCase: "- 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."[15]

K233968 CINA-iPE: "The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communicating suspected positive findings for incidental Pulmonary Embolism (iPE). The device is indicated for adults and transitional adolescents (18 to 21 years old but treated as adults). CINA-iPE uses an artificial intelligence algorithm to analyze images and highlight cases with detected incidental PE on a standalone application in parallel to the ongoing standard of care image interpretation."[16]

SEX OF THE COHORT

The client: not reviewed. **The code:** 50 of 85 summaries state it.

K233968 CINA-iPE: "Avicenna.AI conducted a retrospective, multicenter, multinational and blinded study with the CINA-iPE application with the primary endpoint to evaluate the software's performance in identifying incidental pulmonary embolisms (iPE) on contrast-enhanced CT images performed for another clinical indication than for pulmonary embolism (PE) evaluation (i.e. not dedicated CTPA protocol), in 381 clinical anonymized cases. The dataset included 53.5% Male and 46.7% Female. Mean +/- SD age of patients included in the study was 64.5 +/- 15.8 yo (range: 18 - 99 yo)."[17]

RACE OR ETHNICITY OF THE COHORT

The client: not reviewed. **The code:** 12 of 85 summaries state it.

None of the closest devices' summaries states it.

STUDY DESIGN

The client: not reviewed. **The code:** 80 of 85 summaries state it.

K213886 BriefCase: "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)."[18]

K233968 CINA-iPE: "Avicenna.AI conducted a retrospective, multicenter, multinational and blinded study with the CINA-iPE application with the primary endpoint to evaluate the software's performance in identifying incidental pulmonary embolisms (iPE) on contrast-enhanced CT images performed for another clinical indication than for pulmonary embolism (PE) evaluation (i.e."[19]

SENSITIVITY

The client: not reviewed. **The code:** 82 of 85 summaries state it.

K213886 BriefCase: "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%)."[20]

K233968 CINA-iPE: "The data was acquired primarily by 4 different scanner makers (GE-31.5%, Philips-28.3%, Siemens- 26%, and Canon-13.9%) and 39 different scanner models. Device Sensitivity [95% CI] and Specificity [95% CI] were computed against the groundtruth established by consensus of three US-board-certified expert radiologists."[21]

SPECIFICITY

The client: not reviewed. **The code:** 82 of 85 summaries state it.

K213886 BriefCase: "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%)."[22]

K233968 CINA-iPE: "The data was acquired primarily by 4 different scanner makers (GE-31.5%, Philips-28.3%, Siemens- 26%, and Canon-13.9%) and 39 different scanner models. Device Sensitivity [95% CI] and Specificity [95% CI] were computed against the groundtruth established by consensus of three US-board-certified expert radiologists."[23]

AUC

The client: not reviewed. **The code:** 28 of 85 summaries state it.

K200873 HALO: "For the primary endpoint: calculation of the performance of the HALO algorithm showed a sensitivity and specificity for LVO detection of respectively 91.1% (95% CI, 86.0%-94.8%) and 87.0% (95% CI, 81.2%- 91.5%). The area under the curve (AUC) is 0.97. For the secondary endpoints the median notification time for the detected LVO cases was 4 minutes 31 seconds, with a minimum of 3:47 and maximal 7:12."[24]

REFERENCE STANDARD

The client: not reviewed. **The code:** 70 of 85 summaries state it.

K233968 CINA-iPE: "The data was acquired primarily by 4 different scanner makers (GE-31.5%, Philips-28.3%, Siemens- 26%, and Canon-13.9%) and 39 different scanner models. Device Sensitivity [95% CI] and Specificity [95% CI] were computed against the groundtruth established by consensus of three US-board-certified expert radiologists. As a primary endpoint, the global Sensitivity and Specificity were found to be 87.8% [95%CI: 82.2% - 92.2%] and 92.0% [95%CI: 87.3% - 95.4%], respectively."[25]

K200873 HALO: "Three hundred forty-eight CTA scans of the brain were collected. After exclusion, 364 patients were included for further analyses. Ground truth was established by an expert panel consisting of 3 neuro radiologists. For the primary endpoint: calculation of the performance of the HALO algorithm showed a sensitivity and specificity for LVO detection of respectively 91.1% (95% CI, 86.0%-94.8%) and 87.0% (95% CI, 81.2%- 91.5%)."[26]

COMPARATOR

The client: not reviewed. **The code:** 77 of 85 summaries state it.

K213886 BriefCase: "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%)."[27]

K233968 CINA-iPE: "As a primary endpoint, the global Sensitivity and Specificity were found to be 87.8% [95%CI: 82.2% - 92.2%] and 92.0% [95%CI: 87.3% - 95.4%], respectively. These findings achieved the 80% performance goal of the study and are similar to the results reported for the predicate BriefCase device (Aidoc Medical) which demonstrated Sensitivity and Specificity of 89.7% [95%CI: 80.8% - 95.5%] and 90.1% [95%CI: 81.5% - 95.6%], respectively."[28]

MULTIPLE SITES

The client: not reviewed. **The code:** 74 of 85 summaries state it.

K213886 BriefCase: "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)."[29]

K233968 CINA-iPE: "Avicenna.AI conducted a retrospective, multicenter, multinational and blinded study with the CINA-iPE application with the primary endpoint to evaluate the software's performance in identifying incidental pulmonary embolisms (iPE) on contrast-enhanced CT images performed for another clinical indication than for pulmonary embolism (PE) evaluation (i.e."[30]

PROSPECTIVE COLLECTION

The client: not reviewed. **The code:** 1 of 85 summaries state it.

None of the closest devices' summaries states it.

PATIENT OUTCOMES

The client: not reviewed. **The code:** 1 of 85 summaries state it.

None of the closest devices' summaries states it.

The devices' own sentences, quoted to whole sentences from their summaries. Where the client's documents do not state an element most of the code states, a reviewer may ask about it; whether it applies is the client's judgement.

05 Where the client's set differs from the record

2 items are reported by at least a quarter of the summaries in this code and are not in what the client gave, most common first. A reviewer comparing the file with its predicates may ask about each; whether it applies to the device is the client's engineering judgement.

Performance comparator: reported by 77 of 85 AI-device summaries in this code (91%); not in the client's study[31]

AUC: reported by 28 of 85 AI-device summaries in this code (33%); not in the client's study[31]

Each line is a passage in a cleared summary that reports this kind of testing for the device itself: a statement that it was tested, or the standard it meets as listed in the summary. Testing the summary attributes to the predicate, another device or an earlier submission, or reports as not performed, is left out (every line read against its page twice, D-095 to D-098). A share counts summaries that report the kind; a summary can leave out testing that was done, so each share is a floor: 'at least this many report it', never 'only this many did'.

06 Performance evidence, beside the code's AI devices

What the 85 AI-list summaries in QAS report about how performance was shown, element by element, beside what the client's study reports.[31]

Evidence element	AI-device summaries reporting it	The client's study
Sensitivity	82 of 85 (96%)	reported
Specificity	82 of 85 (96%)	reported
Study design	80 of 85 (94%)	reported
Performance comparator	77 of 85 (91%)	**not reported**
Validation sample size	74 of 85 (87%)	reported
Multiple collection sites	74 of 85 (87%)	reported
Reference standard	70 of 85 (82%)	reported
Age distribution	55 of 85 (65%)	reported
Sex breakdown	50 of 85 (59%)	reported
AUC	28 of 85 (33%)	**not reported**
Race or ethnicity breakdown	12 of 85 (14%)	not reported
Prospective collection	1 of 85 (1%)	not reported

Evidence element	AI-device summaries reporting it	The client's study
Patient outcomes	1 of 85 (1%)	not reported

The client's column is what they told us their study reports. An element most peers report and the client's study does not is a question a reviewer may ask; whether it applies to this device is the client's judgement.

07 By kind of testing

Kind	Summaries reporting it	The client's set
Software	at least 33 of 89[31]	in the set
Usability / human factors	at least 10 of 89[31]	in the set
Bench / non-clinical performance	at least 3 of 89[31]	not in the set
Clinical data	at least 1 of 89[31]	in the set

08 By standard

Standard	Summaries	The client's set
IEC 62304	14 of 89[31]	in the set
IEC 62366	9 of 89[31]	not in the set
ISO 62304	5 of 89[31]	not in the set
IEC 62366-1	1 of 89[31]	not in the set

09 The client's set as given

Kinds: clinical, software, usability. Standards: IEC 62304, ISO 14971.[32]

10 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.

11 Get this pre-filing reviewer read for your device

This is a sample pre-filing reviewer read 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/reviewer-read/ 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 K213886, 510(k) summary (FDA) (page 7).
14 K233968, 510(k) summary (FDA) (page 6).
15 K213886, 510(k) summary (FDA) (page 7).
16 K233968, 510(k) summary (FDA) (page 6).
17 K233968, 510(k) summary (FDA) (page 6).
18 K213886, 510(k) summary (FDA) (page 7).
19 K233968, 510(k) summary (FDA) (page 6).
20 K213886, 510(k) summary (FDA) (page 7).
21 K233968, 510(k) summary (FDA) (page 7).
22 K213886, 510(k) summary (FDA) (page 7).
23 K233968, 510(k) summary (FDA) (page 7).
24 K200873, 510(k) summary (FDA) (page 7).
25 K233968, 510(k) summary (FDA) (page 7).
26 K200873, 510(k) summary (FDA) (page 7).
27 K213886, 510(k) summary (FDA) (page 7).
28 K233968, 510(k) summary (FDA) (page 7).
29 K213886, 510(k) summary (FDA) (page 7).
30 K233968, 510(k) summary (FDA) (page 6).
31 Device Evidence, the verified FDA record (register, confirmed predicate links, indications, testing as each summary reports it, openFDA recalls) (read 2026-11-15).
32 The client's testing set, entered on the unit step.

Appendix: attachments index

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