PRECEDIUM *drafting assistance*

FDA-QUESTION RESPONSE

SAMPLE · Response to the FDA's request for additional information: AortaView (synthetic)

response to the fda's request for additional information prepared in Precedium

DEVICE
AortaView (synthetic)

PRODUCT CODE
QAS

PATHWAY
Traditional 510(k)

PREPARED FOR
Northbridge Imaging (synthetic)

PREPARED
2026-11-15

12	35	0	1
sections	footnoted sources	items withheld	documents read

ABOUT THIS DOCUMENT

- SAMPLE of the FDA-question response, From $500 (per FDA question, up to 10). Get yours at precedium.com/services/deficiency-response/
- 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. DEMONSTRATION CONTENT. The drafted sections are authored demonstration text: no language model was called, and the device, its documents and every figure are synthetic. Every drafted sentence was accepted or edited by the person exporting and cites its sources.
- Project: Sample deficiency_response. Mode: FDA-question response. Pathway: Traditional 510(k). Product code: QAS.
- This document drafts the applicant's answers to the FDA's request from the applicant's own documents, every sentence cited, and lists what those documents do not hold. It is prepared by the consultant and reviewed by the applicant, whose regulatory signatory completes and submits the response and is responsible for it.
- Every statement carries a footnote to the applicant's profile, the documents read, or a page of a cited predicate's public summary. Statements the applicant 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.

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

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01 The FDA's request

3 deficiencies on K269999, in the FDA's letter dated 2026-10-20.[30]

Response due by 2027-04-18: 180 calendar days from the request, with no extensions; a late or incomplete response and the 510(k) is treated as withdrawn.[31]

02 Deficiency 1

The FDA's item: Your standalone performance testing reports sensitivity and specificity for the whole test set only. Provide results by acquisition site.[30]

Sensitivity was 0.93 at Site A (n=212) and 0.90 at Site B (n=188).[32]

Specificity was 0.94 at Site A and 0.92 at Site B.[33]

03 Deficiency 2

The FDA's item: The device description does not state the minimum slice thickness the software accepts. State it, and show that the test set covered it.[30]

The software accepts images with a slice thickness of 0.5 mm to 1.5 mm.[34]

The test set contained studies at 0.625 mm, 1.0 mm and 1.25 mm.[35]

04 Deficiency 3

The FDA's item: Your labeling does not describe the performance of the device in patients with prior aortic surgery. Provide this analysis or justify its absence.[30]

Owed by the applicant: A subgroup analysis of patients with prior aortic surgery; the report supplied does not contain one. The documents supplied for this response do not contain it; it is listed below and not drafted.

05 What the applicant still owes

Items the documents supplied do not answer. Each needs new testing, analysis or a statement from the applicant's team before the response is complete.

Deficiency	Owed
3	A subgroup analysis of patients with prior aortic surgery; the report supplied does not contain one

06 Device description

DEVICE
AortaView (synthetic)[1]

DESCRIPTION
A software-only device installed on a hospital server, receiving CT angiography studies from the PACS and returning a notification to a worklist.[2]

PRINCIPLE OF OPERATION
A convolutional neural network segments the aorta and classifies each study as suspected dissection or not.[3]

INPUTS
Contrast-enhanced CT angiography of the chest, DICOM.[4]

OUTPUTS
A worklist flag and a key image; no diagnostic annotation.[5]

ALGORITHM
Convolutional neural network, locked at release.[6]

LOCKED OR ADAPTIVE
locked[7]

DEPLOYMENT ENVIRONMENT
On-premises server at the hospital.[8]

07 Intended use

Software that analyses CT angiography images of the chest and flags suspected aortic dissection for prioritised review by a radiologist.[9]

08 Indications for use

Adults undergoing contrast-enhanced CT angiography of the chest in a hospital setting.[10]

09 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.[11]

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.

10 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.[11]

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%

Device	Applicant	Decided	Imaging type	Key words shared
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

11 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."[12]

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)."[13]

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."[14]

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."[15]

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)."[16]

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)."[17]

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."[18]

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%)."[19]

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."[20]

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%)."[21]

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."[22]

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."[23]

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."[24]

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%)."[25]

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%)."[26]

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."[27]

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)."[28]

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."[29]

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.

12 Get this fda-question response for your device

This is a sample fda-question response 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 $500 (per FDA question, up to 10), fixed in writing before work starts.

HOW TO START

Go to precedium.com/services/deficiency-response/ 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, the verified FDA record for product code QAS (read 2026-11-15).
12 K213886, 510(k) summary (FDA) (page 7).
13 K233968, 510(k) summary (FDA) (page 6).
14 K213886, 510(k) summary (FDA) (page 7).
15 K233968, 510(k) summary (FDA) (page 6).
16 K233968, 510(k) summary (FDA) (page 6).
17 K213886, 510(k) summary (FDA) (page 7).
18 K233968, 510(k) summary (FDA) (page 6).
19 K213886, 510(k) summary (FDA) (page 7).
20 K233968, 510(k) summary (FDA) (page 7).
21 K213886, 510(k) summary (FDA) (page 7).
22 K233968, 510(k) summary (FDA) (page 7).
23 K200873, 510(k) summary (FDA) (page 7).
24 K233968, 510(k) summary (FDA) (page 7).
25 K200873, 510(k) summary (FDA) (page 7).
26 K213886, 510(k) summary (FDA) (page 7).
27 K233968, 510(k) summary (FDA) (page 7).
28 K213886, 510(k) summary (FDA) (page 7).
29 K233968, 510(k) summary (FDA) (page 6).
30 The FDA's request for additional information on K269999, dated 2026-10-20, as entered on the response step.
31 FDA, 510(k) Submission Process (https://www.fda.gov/medical-devices/premarket-notification-510k/510k-submission-process, content current as of 2022-10-03, read 2026-11-11).
32 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 4.
33 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 4.
34 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 2.
35 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 2.

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...