PRECEDIUM *drafting assistance*

CHANGE ASSESSMENT

SAMPLE · Change assessment: AortaView (synthetic)

change assessment prepared in Precedium

DEVICE
AortaView (synthetic)

PRODUCT CODE
QAS

PATHWAY
Traditional 510(k)

PREPARED FOR
Northbridge Imaging (synthetic)

PREPARED
2026-11-15

12	20	0	1
sections	footnoted sources	items withheld	documents read

ABOUT THIS DOCUMENT

- SAMPLE of the Change assessment, From $2,500. Get yours at precedium.com/services/model-change/
- 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 model_change. Mode: Change assessment. Pathway: Traditional 510(k). Product code: QAS.
- This record applies the FDA's published guidance questions to one proposed change, as the client described it, with the reason for each answer. It is prepared by the consultant and reviewed by the client, whose regulatory lead decides whether a submission is made.
- Every statement carries a footnote to the client's profile, the documents read, or a page of a cited predicate's public summary. Statements the client 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. No passage of the client's documents was sent to a model provider.
- Not regulatory advice and not a determination. This record applies the FDA's published guidance questions to the change as the client described it; the answers are the client's and the consultant's. Whether a new submission is required is for the manufacturer to decide and the FDA to judge.

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

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01 The change

Version 2.1 retrains the dissection model on 3,800 additional studies from two new sites, with the aim of raising sensitivity for Stanford type B dissections. Inputs, outputs, labeling and the user interface are unchanged.[15]

Version marketed: 2.0.4. Version after the change: 2.1.0.[15]

02 The FDA's questions, answered

Each question is the FDA's, asked in the order of its flowchart. FDA, Deciding When to Submit a 510(k) for a Software Change to an Existing Device - Guidance for Industry and FDA Staff (issued 2017-10-25); read 2026-11-12. FDA, Deciding When to Submit a 510(k) for a Change to an Existing Device - Guidance for Industry and FDA Staff (issued 2017-10-25); read 2026-11-12. FDA, Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions - Guidance for Industry and FDA Staff (issued 2025-08-18); read 2026-11-11.

Question	Answer	Reason	Guidance
Does the device have an authorized Predetermined Change Control Plan?	No	[15]	-
Does the change alter the indications for use or the intended use - for example a new disease, condition or patient population, or a change from prescription to over-the-counter use?	No	The indications for use statement and the labeling are unchanged (synthetic labeling, section 1).[15]	PDF p. 17[16]
Is the change intended to significantly affect the device's safety or effectiveness - for example to significantly improve clinical outcomes or performance, or to mitigate a known risk or respond to adverse events?	Yes	The release plan states the purpose is higher sensitivity for type B dissections: a change intended to significantly affect effectiveness (synthetic release plan, p. 1).[15]	PDF p. 9[17]

03 Where the guidance points

The guidance points to a new 510(k)

Under the FDA's flowchart, submission of a new 510(k) is likely required for this change. Where the answer is close, a Pre-Submission asks the FDA directly; the guidances encourage discussing gray areas with the review division that cleared the device.[18][19]

Software path: indications -> intent. The flowcharts' wording, applied to the answers above; where any path points to a new 510(k), that governs. Whether a new submission is required is for the manufacturer to decide and the FDA to judge.

04 Change-control plans authorized in the code

Submission	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

4 authorizations with a PCCP in product code QAS.[20]

05 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]

06 Intended use

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

07 Indications for use

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

08 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.[11]

4 devices in QAS have an FDA-authorized predetermined change control plan:[12]

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

09 Modifications cleared in QAS: every Special 510(k)

14 Special 510(k)s in QAS, newest first. A Special 510(k) is a change to the submitter's own cleared device.[13]

Number	Device	Applicant	Decided	Review days
K261317	BriefCase-Triage	Aidoc Medical , Ltd.	2026-05-14	23
K253265	BriefCase-Triage	Aidoc Medical , Ltd.	2025-11-06	38
K251406	BriefCase-Triage	Aidoc Medical , Ltd.	2025-05-30	24

Number	Device	Applicant	Decided	Review days
K250248	BriefCase-Triage	Aidoc Medical , Ltd.	2025-02-14	18
K242837	BriefCase-Triage	Aidoc Medical , Ltd.	2024-10-18	29
K241727	BriefCase-Triage	Aidoc Medical , Ltd.	2024-07-12	28
K221716	CINA	Avicenna.Ai	2022-11-22	162
K223042	Viz LVO ContaCT	Viz. Ai, Inc.	2022-10-21	22
K222277	BriefCase	Aidoc Medical , Ltd.	2022-08-26	28
K221314	BriefCase	Aidoc Medical , Ltd.	2022-06-03	29
K221248	Rapid LVO	Ischemaview, Inc.	2022-05-31	29
K221240	BriefCase	Aidoc Medical , Ltd.	2022-05-17	18
K211788	HALO	Nicolab B.V.	2021-07-08	29
K203508	BriefCase	Aidoc Medical , Ltd.	2020-12-29	29

10 Device families in QAS cleared more than once

Devices one applicant has cleared more than once under a name beginning the same way: how often a device in QAS is changed and re-cleared, and by which route. Grouped by name, so a family can mix related products.[13]

Family	Applicant	Clearances	Each: number, type, decided
BriefCase-Triage	Aidoc Medical , Ltd.	25	K261317 Special 2026-05-14; K253578 Traditional 2026-02-26; K251195 Traditional 2026-01-27; K252970 Traditional 2026-01-07; K253265 Special 2025-11-06; K251406 Special 2025-05-30; K250248 Special 2025-02-14; K242837 Special 2024-10-18; K241727 Special 2024-07-12; K232751 Traditional 2023-10-30; K221330 Traditional 2022-11-18; K220709 Traditional 2022-10-07; K222329 Traditional 2022-09-28; K222277 Special 2022-08-26; K221314 Special 2022-06-03; K221240 Special 2022-05-17; K213886 Traditional 2022-04-26; K213721 Traditional 2022-03-21; K203508 Special 2020-12-29; K201020 Traditional 2020-08-26; K193298 Traditional 2020-06-19; K192383 Traditional 2019-12-20; K190896 Traditional 2019-05-31; K190072 Traditional 2019-04-15; K180647 Traditional 2018-08-01
Rapid ICH (v4.0)	Ischemaview, Inc.	11	K262301 Traditional 2026-10-09; K261085 Traditional 2026-07-13; K251533 Traditional 2025-09-04; K251151

Family	Applicant	Clearances	Each: number, type, decided
			Traditional 2025-07-16; K232436 Traditional 2023-10-25; K222884 Traditional 2023-03-02; K221456 Traditional 2022-09-12; K221248 Special 2022-05-31; K220499 Traditional 2022-05-17; K200941 Traditional 2020-07-09; K193087 Traditional 2020-03-31
EFAI NEUROSUITE CTA LVO ASSESSMENT SYS...	Ever Fortune.Ai, Co., Ltd.	6	K263109 Traditional 2026-10-30; K253163 Traditional 2026-04-22; K242821 Traditional 2025-02-20; K241923 Traditional 2024-12-06; K240291 Traditional 2024-04-08; K231025 Traditional 2023-10-04
CINA-CSpine	Avicenna.Ai	5	K240942 Traditional 2024-09-12; K233968 Traditional 2024-03-13; K221716 Special 2022-11-22; K210237 Traditional 2021-05-19; K200855 Traditional 2020-06-24
Brainomix 360 Triage Stroke	Brainomix Limited	4	K251983 Traditional 2025-08-26; K232496 Traditional 2023-11-21; K231837 Traditional 2023-09-28; K231195 Traditional 2023-07-27
Annalise Enterprise CTB Triage Trauma	Annalise-Ai Pty , Ltd.	4	K231384 Traditional 2023-09-22; K231767 Traditional 2023-09-22; K231094 Traditional 2023-08-15; K223240 Traditional 2023-04-03
Viz LVO ContaCT	Viz. Ai, Inc.	4	K223042 Special 2022-10-21; K220439 Traditional 2022-07-25; K210209 Traditional 2021-03-23; K193658 Traditional 2020-03-18
JLK-NCCT	JLK, Inc.	3	K252421 Traditional 2026-03-24; K243611 Traditional 2025-03-03; K243363 Traditional 2025-01-03
syngo.CT LVO Detection	Siemens Medical Solutions USA, Inc.	3	K243145 Traditional 2025-04-10; K232431 Traditional 2024-03-22; K203260 Traditional 2022-01-28
a2z-Abdo-Triage	A2z Radiology Ai, Inc.	2	K260906 Traditional 2026-09-16; K252366 Traditional 2025-11-24
qER-CTA (v1.0)	Qure.Ai Technologies	2	K251610 Traditional 2025-09-08; K200921 Traditional 2020-06-17
Methinks CTA Stroke	Methinks Software, S.L	2	K251590 Traditional 2025-08-20; K250685 Traditional 2025-06-16
Accipiolx	Maxq AL , Ltd.	2	K201310 Traditional 2020-08-07; K182177 Traditional 2018-10-26

11 How cleared devices in QAS describe their change-control plans

Each passage is the opening of the predetermined change control plan section in that device's own 510(k) summary, quoted to whole sentences with the page: what the FDA authorized the company to change, and how.

K252366 a2z-Unified-Triage (A2z Radiology Ai, Inc., 2025-11-24): "This submission contains a Predetermined Change Control Plan (PCCP). The PCCP does not include provisions for implementation of adaptive algorithms that will continuously learn in the field. All algorithm modifications will be trained, validated, and locked prior to release of the software to the field. A procedure has been established for updating device labeling to inform users about changes implemented under this PCCP, including a summary of the changes, characterization of algorithm performance, and compatibility information. The PCCP specifies possible modifications to a2z-Unified-Triage, as well as verification and valida- tion activities to implement changes in a controlled manner such that the modified device remains as safe and effective as the originally cleared device."[14]

12 Get this change assessment for your device

This is a sample change assessment 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 $2,500, fixed in writing before work starts.

HOW TO START

Go to precedium.com/services/model-change/ 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 FDA, Predetermined Change Control Plans: List of Authorized Devices with PCCPs, content current as of 2026-10-20, captured 2026-10-26.

13 Device Evidence, the verified FDA record for product code QAS (read 2026-11-15).

14 K252366, 510(k) summary (FDA) (page 13).

15 The client's description of the change and the answers recorded on the model-change step.

16 FDA, Deciding When to Submit a 510(k) for a Change to an Existing Device - Guidance for Industry and FDA Staff (issued 2017-10-25, https://www.fda.gov/media/99812/download, PDF page 17, read 2026-11-12).

17 FDA, Deciding When to Submit a 510(k) for a Change to an Existing Device - Guidance for Industry and FDA Staff (issued 2017-10-25, https://www.fda.gov/media/99812/download, PDF page 9, read 2026-11-12).

18 FDA, Deciding When to Submit a 510(k) for a Change to an Existing Device - Guidance for Industry and FDA Staff (issued 2017-10-25, https://www.fda.gov/media/99812/download, read 2026-11-12).

19 FDA, Deciding When to Submit a 510(k) for a Software Change to an Existing Device - Guidance for Industry and FDA Staff (issued 2017-10-25, https://www.fda.gov/media/99785/download, read 2026-11-12).

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

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...