**PRECEDIUM** *drafting assistance*

CHANGE ASSESSMENT

# SAMPLE · Modification 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**

| 13 | 29 | 0 | 1 |
|---|---|---|---|
| sections | footnoted sources | items withheld | documents read |

## ABOUT THIS DOCUMENT

- SAMPLE of the Modification package, Quoted. Get yours at precedium.com/services/modification-package/
- 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, or the parent's exposure file at a named capture. 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.

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## 01 The change

Version 2.2 redesigns the notification panel (larger preview image, case age shown) and adds a second worklist integration (HL7 to a second PACS vendor). The algorithm, its outputs, the indications and the labeling claims are unchanged (synthetic).[16]

Version marketed: 2.1.0. Version after the change: 2.2.0.[16]

## 02 The general change guidance, Flowcharts A-D, answered

Each question is the FDA's, copied from the guidance and asked in the order of its flowcharts; every applicable chart is followed (PDF p. 14). 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 2026-11-14.

| Question | Answer | Reason | Guidance |
|---|---|---|---|
| **Is the change made with intent to significantly improve the safety or effectiveness of the device?** | No | The release notes state the purpose is easier reading of notifications and a second worklist integration, not better detection (synthetic release plan, p. 1).[16] | PDF p. 13[17] |
| **B1 Is the device an in vitro diagnostic device?** | No | AortaView is not an in vitro diagnostic device.[16] | PDF p. 26[18] |
| **B2 Is it a control mechanism, operating principle, or energy type change?** | No | The algorithm, its operating principle and its outputs are unchanged; only the notification panel and an integration change (synthetic design change record DCR-031).[16] | PDF p. 26[19] |
| **B3 Is it a change in sterilization, cleaning, or disinfection?** | No | Software only: no sterilization, cleaning or disinfection.[16] | PDF p. 27[20] |
| **B4 Is there a change in packaging or expiration dating?** | No | Software only: no packaging or expiration dating.[16] | PDF p. 28[21] |
| **B5 Is it any other change in design (e.g., dimensions, performance specifications, wireless communication, components or accessories, or the patient/user interface)?** | Yes | The patient/user interface changes: the notification panel is redesigned, and notifications can also be sent to a second worklist system (synthetic DCR-031).[16] | PDF p. 29[22] |
| **B5.1 Does the change significantly affect the use of the device?** | No | Users still receive the same notification for the same studies; the summative usability test found no change in how the device is used (synthetic usability | PDF p. 30[23] |

| Question | Answer | Reason | Guidance |
|---|---|---|---|
| | | report UR-12, p. 3).[16] | |
| **B5.2 Does a risk-based assessment of the changed device identify any new risks or significantly modified existing risks?** | No | The risk file review found no new hazard and no change in the severity or probability of existing ones (synthetic risk file RF-7, rev. 4, section 6).[16] | PDF p. 31[24] |
| **B5.3 Are clinical data necessary to evaluate safety or effectiveness for purposes of design validation?** | No | No: the change does not touch the algorithm; bench verification of the integration is sufficient (synthetic verification plan VP-31).[16] | PDF p. 32[25] |
| **B5.4 Do design verification and/or validation activities produce any unexpected issues of safety or effectiveness?** | No | Verification and validation passed with no unexpected issue (synthetic test report TR-31, p. 2).[16] | PDF p. 32[26] |

## 03 Where the guidance points

### The guidance does not point to a new 510(k)

The FDA's flowcharts do not lead to a new 510(k) for this change as answered. Record the assessment, its rationale and the verification and validation in the design history file. If either guidance leads to a new 510(k) on any other aspect of the change, that conclusion governs.[2728]

General guidance: Technology, engineering or performance change: B1 -> B2 -> B3 -> B4 -> B5 -> B5.1 -> B5.2 -> B5.3 -> B5.4. 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 |

| Submission | Device | Company | Decided |
|---|---|---|---|
| **K253265** | BRIEFCASE-TRIAGE | AIDOC MEDICAL, LTD. | 2025-11-06 |

4 authorizations with a PCCP in product code QAS.[29]

## 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 of the chest and notifies a radiologist of a suspected aortic dissection for prioritised review.[9]

## 07 Indications for use

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

## 08 Base rates for product code QAS

86 devices on the FDA AI list under QAS, 85 with a readable clearance summary; those summaries state a mean of 8.16 of thirteen evidence elements, against 4.43 across the whole list.[11]

28 applicants hold a clearance in the code; 15 of them cleared a device in the two years before the capture.

Past 510(k) reviews of AI-list devices in QAS ran a median of 104 days from receipt to decision (middle half 69-156 days; n=85, from openFDA). This describes past filings and is not a statement about any submission.

No device in the code on the AI list is named in an FDA recall record at this capture.

1 summary in the code states a predetermined change control plan.

What the record cannot settle: whether any submission will clear or how long it will take; whether a device works in a setting its summary does not describe; anything about cost, reimbursement or outcomes, which clearance summaries almost never state.

## 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.[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 |

## 10 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.[14]

| 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 |
| **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 |

## 11 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.[14]

| 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; |

| Family | Applicant | Clearances | Each: number, type, decided |
|---|---|---|---|
| | | | 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 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 |

| Family | Applicant | Clearances | Each: number, type, decided |
|---|---|---|---|
| **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 |

## 12 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."[15]

## 13 Get this modification package for your device

This is a sample modification package 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. Quoted for your device, fixed in writing before work starts.

HOW TO START

**Go to precedium.com/services/modification-package/ 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 for product code QAS (read 2026-11-15).

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

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

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 13, read 2026-11-14).

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, PDF page 26, read 2026-11-14).

19 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 26, read 2026-11-14).

20 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 27, read 2026-11-14).

21 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 28, read 2026-11-14).

22 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 29, read 2026-11-14).

23 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 30, read 2026-11-14).

24 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 31, read 2026-11-14).

25 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 32, read 2026-11-14).

26 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 32, read 2026-11-14).

27 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).

28 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).

29 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... |