PRECEDIUM *drafting assistance*

SUBMISSION DRAFTING

SAMPLE · Predetermined change control plan: AortaView (synthetic)

Traditional 510(k) - submission content prepared in Precedium

DEVICE
AortaView (synthetic)

PRODUCT CODE
QAS

PATHWAY
Traditional 510(k)

PREPARED FOR
Northbridge Imaging (synthetic)

PREPARED
2026-11-15

9	115	0	1
sections	footnoted sources	items withheld	documents read

ABOUT THIS DOCUMENT

- SAMPLE of the Change-control plan (PCCP) section, From $6,000. Get yours at precedium.com/services/pccp/
- 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 submission. Mode: Submission drafting. Pathway: Traditional 510(k). Product code: QAS.
- This document organises the applicant's own statements and readings of the public record. It is reviewed, edited and approved by the submitter, who is responsible for its contents. A person pastes it into the FDA's eSTAR; nothing here fills or validates that form.
- Every statement carries a footnote to the applicant'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 applicant did not make are printed as "not stated by the applicant" and listed in the not-exported appendix.
- Acceptance checklist: Refuse to Accept Policy for 510(k)s - Appendix A, Acceptance Checklist for Traditional 510(k)s, issued 2022-04-21, read 2026-09-06.
- 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.

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01 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]

02 Intended use

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

03 Indications for use

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

04 Predetermined change control plan: the applicant's answers

MODIFICATIONS PLANNED

Three planned modifications, all within the current indications for use: (M1) retraining the dissection model on additional CT angiography studies from new clinical sites, to keep performance stable across scanner models; (M2) extending compatibility to CT scanners from a manufacturer not in the original test set, after site-level verification; (M3) re-tuning the operating threshold within a pre-specified range (0.40 to 0.60) to hold sensitivity at or above the cleared value. Out of scope: any change to the target condition, the patient population, the input modality, the output or the intended user (synthetic).[20]

MODIFICATION PROTOCOL: DATA MANAGEMENT

Training and test data are kept apart by patient and by site. Each new site contributes at least 300 studies for training; a sequestered test set of 600 studies from at least three sites never used in training, enriched to 30% positives with type A and type B dissections in proportion, is locked before any retraining and refreshed only under change control. Reference standard: consensus of two board-certified radiologists, a third on disagreement (synthetic).[21]

MODIFICATION PROTOCOL: RETRAINING

At most two retrained releases a year. The architecture, the pre-processing and the input specification are unchanged; only weights and the operating threshold (M3, within its range) may change. Each retraining run is logged with its data manifest, code version and random seed (synthetic).[22]

MODIFICATION PROTOCOL: PERFORMANCE EVALUATION

Acceptance criteria, all on the locked test set: sensitivity at least 0.90 with a lower 95% confidence bound of at least 0.85; specificity at least 0.90 with a lower bound of at least 0.85; no subgroup by site, scanner manufacturer, sex or age band (18-44, 45-64, 65+) with sensitivity more than 5 points below the overall value; time-to-notification median under 5 minutes. A release failing any criterion is not deployed (synthetic).[23]

MODIFICATION PROTOCOL: UPDATE PROCEDURES

A release is deployed only after the evaluation report passes every acceptance criterion and is signed by the Head of Regulatory and the Clinical Lead. Sites are updated in a staged rollout (one site for two weeks, then all); the previous version can be restored within 24 hours (synthetic).[24]

IMPACT ASSESSMENT

Each modification was assessed against the risk file (RF-7). Main risks: a missed dissection delaying review (mitigated by the sensitivity criteria and the subgroup floor); an unexpected drop on one scanner manufacturer (mitigated by per-manufacturer reporting and the site-level verification in M2). No modification introduces a new hazard or changes the device's role in parallel to the standard of care (synthetic).[25]

PERFORMANCE MONITORING AFTER DEPLOYMENT

Monthly audit at each site: 50 randomly sampled flagged and 50 unflagged studies read by a radiologist; sensitivity below 0.85 at any site triggers investigation and, if confirmed, rollback (synthetic).[26]

COMMUNICATION OF CHANGES

Every release carries release notes stating the modification, the evaluation results and the version; the labeling states the current version and that the device is updated under an authorized PCCP. Users are notified at least 14 days before deployment (synthetic).[27]

AUTHORIZED PCCPS IN THE PRODUCT CODE

The FDA lists 4 authorized PCCPs whose primary product code is QAS: K260906 (A2Z-ABDO-TRIAGE, 2026-09-16); K261085 (RAPID VESSEL OCCLUSION (RAPID VO), 2026-07-13); K252366 (A2Z-UNIFIED-TRIAGE, 2025-11-24); K253265 (BRIEFCASE-TRIAGE, 2025-11-06).[28]

05 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.[41]

4 devices in QAS have an FDA-authorized predetermined change control plan:[42]

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

06 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.[114]

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

Number	Device	Applicant	Decided	Review days
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

07 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.[114]

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 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;

Family	Applicant	Clearances	Each: number, type, decided
			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

08 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."[115]

09 Get this change-control plan (pccp) section for your device

This is a sample change-control plan (pccp) section 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 $6,000, fixed in writing before work starts.

HOW TO START

Go to precedium.com/services/pccp/ 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 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 4.
12 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 6.
13 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 6.
14 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 3.
15 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 7.
16 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 7.
17 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 5.
18 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 4.
19 Applicant's device profile: Software documentation level.
20 Applicant's device profile: Modifications planned.
21 Applicant's device profile: Modification protocol: data management.
22 Applicant's device profile: Modification protocol: retraining.
23 Applicant's device profile: Modification protocol: performance evaluation.
24 Applicant's device profile: Modification protocol: update procedures.
25 Applicant's device profile: Impact assessment.
26 Applicant's device profile: Performance monitoring after deployment.
27 Applicant's device profile: Communication of changes.
28 FDA, Predetermined Change Control Plans: List of Authorized Devices with PCCPs (content current as of 2026-10-20; captured 2026-10-26; https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/predetermined-change-control-plans).
29 Applicant's device profile: Training data summary.
30 Applicant's device profile: Performance claims.
31 Applicant's device profile: Labeling summary.
32 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 4.
33 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 6.
34 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 6.
35 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 3.
36 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 7.

37 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 7.

38 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 5.

39 Applicant's document "AortaView standalone performance report v3 (synthetic)", page 4.

40 Device Evidence public exposure file (product-code base rates), QAS (capture 2026-09-10).

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

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

43 Device Evidence, the verified FDA record (register, confirmed predicate links, indications, testing as each summary reports it, openFDA recalls) (read 2026-11-15).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

61 DEN170073, De Novo decision summary (FDA) (page 8).

62 DEN170073, De Novo decision summary (FDA) (page 5).

63 DEN170073, De Novo decision summary (FDA) (page 9).

64 DEN170073, De Novo decision summary (FDA) (page 9).

65 DEN170073, De Novo decision summary (FDA) (page 5).

66 DEN170073, De Novo decision summary (FDA) (page 8).

67 DEN170073, De Novo decision summary (FDA) (page 9).

68 DEN170073, De Novo decision summary (FDA) (page 8).

69 K251590, 510(k) summary (FDA) (page 6).

70 K223042, 510(k) summary (FDA) (page 6).

71 K193658, 510(k) summary (FDA) (page 5).

72 K192383, 510(k) summary (FDA) (page 5).

73 K182875, 510(k) summary (FDA) (page 8).

74 K203508, 510(k) summary (FDA) (page 3).

75 K203508, 510(k) summary (FDA) (page 3).

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

77 K203508, 510(k) summary (FDA) (page 27).

78 K203508, 510(k) summary (FDA) (page 13).
79 K203508, 510(k) summary (FDA) (page 17).
80 K203508, 510(k) summary (FDA) (page 9).
81 K203508, 510(k) summary (FDA) (page 30).
82 K203508, 510(k) summary (FDA) (page 21).
83 K203508, 510(k) summary (FDA) (page 25).
84 K180647, 510(k) summary (FDA) (page 4).
85 K190072, 510(k) summary (FDA) (page 4).
86 K190896, 510(k) summary (FDA) (page 4).
87 K192383, 510(k) summary (FDA) (page 4).
88 K192383, 510(k) summary (FDA) (page 4).
89 K193298, 510(k) summary (FDA) (page 4).
90 K201020, 510(k) summary (FDA) (page 4).
91 K221330, 510(k) summary (FDA) (page 5).
92 K220709, 510(k) summary (FDA) (page 5).
93 K222277, 510(k) summary (FDA) (page 5).
94 K221314, 510(k) summary (FDA) (page 5).
95 K221240, 510(k) summary (FDA) (page 5).
96 K213886, 510(k) summary (FDA) (page 7).
97 K233968, 510(k) summary (FDA) (page 6).
98 K213886, 510(k) summary (FDA) (page 7).
99 K233968, 510(k) summary (FDA) (page 6).
100 K233968, 510(k) summary (FDA) (page 6).
101 K213886, 510(k) summary (FDA) (page 7).
102 K233968, 510(k) summary (FDA) (page 6).
103 K213886, 510(k) summary (FDA) (page 7).
104 K233968, 510(k) summary (FDA) (page 7).
105 K213886, 510(k) summary (FDA) (page 7).
106 K233968, 510(k) summary (FDA) (page 7).
107 K200873, 510(k) summary (FDA) (page 7).
108 K233968, 510(k) summary (FDA) (page 7).
109 K200873, 510(k) summary (FDA) (page 7).
110 K213886, 510(k) summary (FDA) (page 7).
111 K233968, 510(k) summary (FDA) (page 7).
112 K213886, 510(k) summary (FDA) (page 7).
113 K233968, 510(k) summary (FDA) (page 6).
114 Device Evidence, the verified FDA record for product code QAS (read 2026-11-15).
115 K252366, 510(k) summary (FDA) (page 13).

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...