K-SPACE

GROWTH STRATEGIES

510(k) Predicate Intelligence Report

AI-Powered Regulatory Analysis

PRODUCT CODE
OEB

GENERATED
April 15, 2026

REPORT ID
RPT-2026-0415-ZBIV

DEVICE DESCRIPTION
AI software that analyzes chest CT scans to automatically detect, segment, and measure pulmonary nodules.

INTENDED USE
Intended to assist radiologists in identifying and measuring lung nodules on CT images to support lung cancer screening workflows.

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EXECUTIVE SUMMARY

- Primary Predicate: AVIEW Lung Nodule CAD (K251203) — Score: 91/100
- Recommended Pathway: Traditional 510(k) (~52 weeks)
- PCCP: Not required
- Safety Profile: Clean — no high-risk predicates identified
- Top Action: 1. File Pre-Submission meeting request with FDA CDRH identifying K251203 as primary predicate and K242919 as split predicate, and requesting alignment on AI/ML performance dataset requirements and PCCP applicability.

PRIMARY PREDICATE JUSTIFICATION

K251203 (AVIEW Lung Nodule CAD, Coreline Soft, cleared December 2025) is the optimal primary predicate because it shares identical product code OEB, identical intended use as AI-based pulmonary nodule detection, segmentation, and measurement on chest CT to assist radiologists in lung cancer screening, and was cleared under the same regulatory classification (21 CFR 892.2050) using the same technological approach. Per FDA's September 2023 Best Practices guidance, a predicate should be selected based on similarity of intended use and technological characteristics, absence of safety concerns, and use of well-established methods — K251203 satisfies all four criteria with zero MAUDE events, no recalls, and a robust predicate lineage. K242919 is recommended as a split predicate to further support the technological characteristics comparison, particularly for AI/ML algorithm performance benchmarking, given its independent manufacturer clearance in March 2025 under the same OEB code.

RECOMMENDED PRIMARY PREDICATE

AVIEW Lung Nodule CAD

91/100

K251203

K251203 is the most recent OEB-code clearance for an AI-based pulmonary nodule detection, segmentation, and measurement tool on chest CT, cleared December 2025, making it the strongest predicate for intended use, technology, and recency. Its direct lineage through K221592 and the established AVIEW platform provides a well-documented predicate chain fully within OEB.

APPLICANT
Coreline Soft Co., Ltd.

DECISION DATE
2025-12-03

PRODUCT CODE
OEB

FDA SUMMARY
https://www.accessdata.fda.gov/cdrh_docs/pdf25/K251203.pdf

FDA BEST PRACTICES SCORECARD

Evaluation per FDA "Best Practices for Selecting a Predicate Device" guidance (September 2023).

CANDIDATE	WELL-ESTABLISHED METHODS	SAFETY PERFORMANCE	NO SAFETY ISSUES	NO DESIGN RECALL
K251203 AVIEW Lung Nodule CAD	PASS	PASS	PASS	PASS
K242919 V5med Lung AI	PASS	PASS	PASS	PASS
K221592 AVIEW Lung Nodule CAD	PASS	PASS	PASS	PASS
K243239 Lung AI (LAI001)	PARTIAL	PASS	PASS	PASS
K251769 RevealAI-Lung	PARTIAL	PASS	PASS	PASS

DETAILS:

K251203:

A: Cleared via Traditional 510(k) under 21 CFR 892.2050 using well-established AI/ML CAD methods consistent with FDA-recognized performance benchmarks for lung nodule CAD.
B: Zero MAUDE events reported, indicating no identified postmarket safety signals.
C: No use-related or design-related safety issues identified in available postmarket data.
D: No recalls of any type recorded for K251203.

K242919:

A: Cleared via Traditional 510(k) citing K221592 and K161201, leveraging a well-established predicate chain for AI lung nodule CAD.
B: Zero MAUDE events reported post-clearance, consistent with expected performance for a CAD decision-support tool.
C: No identified safety signals or use-related concerns in available postmarket data.
D: No recalls of any type recorded for K242919.

K221592:

A: Cleared using well-established AI/ML CAD methods with a deep predicate chain including syngo.CT Lung CAD and IMAGECHECKER CT, consistent with FDA consensus standards.
B: Zero MAUDE events reported, with no postmarket safety concerns identified.
C: No use-related or design-related safety issues identified.
D: No recalls of any type recorded for K221592.

K243239:

A: Cleared via Traditional 510(k) under MYN product code, using AI/ML methods for lung analysis, but the different regulatory classification limits direct methodological comparability to OEB devices.
B: Zero MAUDE events reported, indicating no postmarket safety concerns.
C: No identified safety signals in available postmarket data.
D: No recalls of any type recorded for K243239.

K251769:

A: Cleared under POK product code via Traditional 510(k), with a predicate chain through Optellum that differs from the established OEB lung nodule CAD lineage.
B: Zero MAUDE events reported, with no postmarket safety concerns identified.
C: No identified safety signals in available postmarket data.
D: No recalls of any type recorded for K251769.

ALL RANKED CANDIDATES

RANK	K-NUMBER	DEVICE NAME	SCORE	KEY REASONING
1	K251203	AVIEW Lung Nodule CAD	91/100	K251203 is the most recent OEB-code clearance for an AI-based pulmonary nodule detection, segmentation, and measurement tool on chest CT, cleared December 2025, making it the strongest predicate for intended use, technology, and recency. Its direct lineage through K221592 and the established AVIEW platform provides a well-documented predicate chain fully within OEB.
2	K242919	V5med Lung AI	88/100	K242919 is a March 2025 OEB-code clearance for AI-based lung nodule detection and analysis on CT, with K221592 as its primary predicate, establishing strong technological and intended-use alignment. It provides an independent manufacturer predicate demonstrating broad FDA acceptance of this device type.
3	K221592	AVIEW Lung Nodule CAD	80/100	K221592 is the foundational OEB predicate for AI-based pulmonary nodule CAD cleared February 2023, directly cited by both K242919 and K251203, and represents a well-established technological baseline; recency is slightly lower than the 2025 clearances but remains within a strong predicate window. Its comprehensive predicate lineage tracing back to K043617 provides exceptional regulatory depth.
4	K243239	Lung AI (LAI001)	63/100	Cross-code candidate (actually MYN, not OEB) — MYN covers general chest imaging AI tools and is adjacent to but distinct from OEB's lung nodule CAD classification, weakening the SE argument; however, the device performs AI-based lung analysis on CT and was cleared in 2025, providing some technological relevance as a supplemental reference. Use only if additional support for AI/ML methodology is needed, not as primary predicate.
5	K251769	RevealAI-Lung	55/100	Cross-code candidate (actually POK, not OEB) — POK covers diagnostic imaging software with a different regulatory classification than OEB's lung nodule CAD, and the POK/OEB split represents a meaningful detection-versus-diagnosis distinction that creates a high cross-code penalty; the device analyzes lung nodules on CT and was cleared February 2026, but its predicate lineage through Optellum Virtual Nodule Clinic diverges from the established OEB predicate chain. Not recommended as a primary predicate.

FDA 510(k) SUMMARY LINKS:

K251203: https://www.accessdata.fda.gov/cdrh_docs/pdf25/K251203.pdf
K242919: https://www.accessdata.fda.gov/cdrh_docs/pdf24/K242919.pdf
K221592: https://www.accessdata.fda.gov/cdrh_docs/pdf22/K221592.pdf
K243239: https://www.accessdata.fda.gov/cdrh_docs/pdf24/K243239.pdf
K251769: https://www.accessdata.fda.gov/cdrh_docs/pdf25/K251769.pdf

CROSS-CODE LANDSCAPE

Semantically similar devices cleared under different or adjacent product codes. These represent related regulatory classifications worth monitoring — potential additional predicates, split predicate candidates, or competitive intelligence from related device categories.

K-NUMBER	DEVICE	MANUFACTURER	CODE	MATCH	CLEARED
K210666	Chest-CAD	Imagen	MYN	57%	2025-10-23
K113541	CLEARSTART SVM SYSTEM	Intio	LLZ	57%	2025-11-02
K202990	NinesMeasure	Nines	LLZ	55%	2025-10-23
K221552	EFAI ChestSuite XR Pneumothorax Assessment System	Ever	QFM	54%	2025-10-21
K243689	AVIEW	Coreline	QIH	54%	2025-10-19
K022013	LUNGCARE CT SOFTWARE PACKAGE	Siemens	JAK	53%	2025-11-14
K223491	Critical Care Suite with Pneumothorax Detection AI Algorithm, Critical Care Suite 2.1, Critical Care Suite	Ge	QBS	53%	2025-10-21
K111311	SEGMENTATION ASSISTANT FOR PROSTATE-AUTO CONTOURING	Omisa	MUJ	52%	2025-11-02

PREDICATE LINEAGE

Citation chains showing which predicates your top candidates originally cited in their 510(k) submissions.

DEVICE	CITED PREDICATE	LEVEL
K221592 — AVIEW Lung Nodule CAD	K203258 — syngo.CT Lung CAD (Siemens Healthcare GmbH)	Level 1
—	K193216 — syngo.CT Lung CAD (Siemens Medi Cal Solutions, Inc.)	Level 2
—	K143196 — syngo.CT Lung CAD (Siemens AG Medical Solutions)	Level 3
—	K191309 — syngo.via MI Workflows VB40A, Scenium (Siemens Medical Soultions USA, Inc.)	Level 3
—	K191040 — syngo.via (Version VB40A) (Siemens Healthcare GmbH)	Level 3
—	K191309 — syngo.via MI Workflows VB40A, Scenium (Siemens Medical Soultions USA, Inc.)	Level 2
—	K173897 — syngo.via MI Workflows (Siemens Medical Solutions USA, Inc.)	Level 3
—	K173597 — Scenium VE20 Software (Siemens Medical Solutions USA, Inc.)	Level 3
—	K191040 — syngo.via (Version VB40A) (Siemens Healthcare GmbH)	Level 3
—	K191040 — syngo.via (Version VB40A) (Siemens Healthcare GmbH)	Level 2
—	K150843 — syngo®.via (version VB10A) (Siemens AG)	Level 3
—	K123584 — SYNGO, CT BONE READING (Siemens Medical Solutions USA, Inc.)	Level 3
—	K143196 — syngo.CT Lung CAD (Siemens AG Medical Solutions)	Level 3
K221592 — AVIEW Lung Nodule CAD	K192880 — InferRead Lung CT.AI (Beijing Infervision Technology Co., Ltd.)	Level 1
—	K161201 — ClearRead CT (Riverain Technologies, LLC)	Level 2
—	K143196 — syngo.CT Lung CAD (Siemens AG Medical Solutions)	Level 3
—	K093621 — SYNGO.PET&CT ONCOLOGY (Siemens Medical Solutions USA, Inc.)	Level 3
—	K092363 — SOFTVIEW, MODEL 2.01 (Riverain Medical Group)	Level 3
K221592 — AVIEW Lung Nodule CAD	K200714 — AVIEW (Coreline Soft Co., Ltd.)	Level 1
—	K043617 — IMAGECHECKER CT CAD SOFTWARE SYSTEM (Hologic, Inc.)	Level 2

—	K171199 — AVIEW (Coreline Soft Co., Ltd.)	Level 2
—	K151919 — Vitrea CT Lung Density Analysis Software (Vital Images, Inc.)	Level 3
—	K150258 — Vitrea, Version 7.0 Medical Image Processing Software (Vital Images, Inc.)	Level 3
—	K141069 — Lung Density Analysis (Imbio, LLC)	Level 2
—	K193220 — AVIEW LCS (Coreline Soft Co., Ltd.)	Level 2
—	K162484 — Lung Nodule Assessment and Comparison Option (LNA) (Philips Medical Systems Nederland B.V.)	Level 3
—	K151283 — Lung Analysis Software (Vital Images, Inc.)	Level 3
—	K171199 — AVIEW (Coreline Soft Co., Ltd.)	Level 3
—	K043617 — IMAGECHECKER CT CAD SOFTWARE SYSTEM (Hologic, Inc.)	Level 3
—	K183268 — AI-Rad Companion (Cardiovascular) (Siemens Medical Solutions USA, Inc.)	Level 2
—	K990426 — CALCIUM SCORING (Siemens Medical Solutions USA, Inc.)	Level 3
—	K123585 — SYNGO, CT CARDIAC FUNCTION (Siemens Medical Solutions USA, Inc.)	Level 3
—	K113027 — SYNGO AORTIC VALVEGUIDE SOFTWARE (Siemens Medical Solutions USA, Inc.)	Level 3
—	K990426 — CALCIUM SCORING (Siemens Medical Solutions USA, Inc.)	Level 2
K221592 — AVIEW Lung Nodule CAD	K043617 — IMAGECHECKER CT CAD SOFTWARE SYSTEM (Hologic, Inc.)	Level 1
K221592 — AVIEW Lung Nodule CAD	K191309 — syngo.via MI Workflows VB40A, Scenium (Siemens Medical Soultions USA, Inc.)	Level 1
K221592 — AVIEW Lung Nodule CAD	K191040 — syngo.via (Version VB40A) (Siemens Healthcare GmbH)	Level 1
K242919 — V5med Lung AI	K221592 — AVIEW Lung Nodule CAD (Coreline Soft Co., Ltd.)	Level 1
—	K203258 — syngo.CT Lung CAD (Siemens Healthcare GmbH)	Level 2
—	K193216 — syngo.CT Lung CAD (Siemens Medi Cal Solutions, Inc.)	Level 3
—	K191309 — syngo.via MI Workflows VB40A, Scenium (Siemens Medical Soultions USA, Inc.)	Level 3
—	K191040 — syngo.via (Version VB40A) (Siemens Healthcare GmbH)	Level 3

—	K192880 — InferRead Lung CT.AI (Beijing Infervision Technology Co., Ltd.)	Level 2
—	K161201 — ClearRead CT (Riverain Technologies, LLC)	Level 3
—	K200714 — AVIEW (Coreline Soft Co., Ltd.)	Level 2
—	K043617 — IMAGECHECKER CT CAD SOFTWARE SYSTEM (Hologic, Inc.)	Level 3
—	K171199 — AVIEW (Coreline Soft Co., Ltd.)	Level 3
—	K141069 — Lung Density Analysis (Imbio, LLC)	Level 3
—	K193220 — AVIEW LCS (Coreline Soft Co., Ltd.)	Level 3
—	K183268 — AI-Rad Companion (Cardiovascular) (Siemens Medical Solutions USA, Inc.)	Level 3
—	K990426 — CALCIUM SCORING (Siemens Medical Solutions USA, Inc.)	Level 3
—	K043617 — IMAGECHECKER CT CAD SOFTWARE SYSTEM (Hologic, Inc.)	Level 2
—	K191309 — syngo.via MI Workflows VB40A, Scenium (Siemens Medical Soultions USA, Inc.)	Level 2
—	K173897 — syngo.via MI Workflows (Siemens Medical Solutions USA, Inc.)	Level 3
—	K173597 — Scenium VE20 Software (Siemens Medical Solutions USA, Inc.)	Level 3
—	K191040 — syngo.via (Version VB40A) (Siemens Healthcare GmbH)	Level 3
—	K191040 — syngo.via (Version VB40A) (Siemens Healthcare GmbH)	Level 2
—	K150843 — syngo®.via (version VB10A) (Siemens AG)	Level 3
—	K123584 — SYNGO, CT BONE READING (Siemens Medical Solutions USA, Inc.)	Level 3
—	K143196 — syngo.CT Lung CAD (Siemens AG Medical Solutions)	Level 3
K242919 — V5med Lung AI	K161201 — ClearRead CT (Riverain Technologies, LLC)	Level 1
—	K143196 — syngo.CT Lung CAD (Siemens AG Medical Solutions)	Level 2
—	K093621 — SYNGO.PET&CT ONCOLOGY (Siemens Medical Solutions USA, Inc.)	Level 3
—	K063877 — SYNGO LUNG CAD (Siemens Medical Solutions USA, Inc.)	Level 3

—	K093621 — SYNGO.PET&CT ONCOLOGY (Siemens Medical Solutions USA, Inc.)	Level 2
—	K092519 — SYNGO.X (Siemens AG Medical Solutions)	Level 3
—	K091373 — SYNGO TRUED (Siemens Medical Solutions USA, Inc.)	Level 3
—	K073003 — SYNGO DUAL ENERGY WITH EXTENDED FUNCTIONALLY (Siemens Medi Cal Solutions, Inc.)	Level 3
—	K092363 — SOFTVIEW, MODEL 2.01 (Riverain Medical Group)	Level 2
K243239 — Lung AI (LAI001)	K230085 — Lung-CAD (Imagen Technologies, Inc.)	Level 1
—	K210666 — Chest-CAD (Imagen Technologies, Inc.)	Level 2
K251769 — RevealAI-Lung	K202300 — Optellum Virtual Nodule Clinic, Optellum software, Optellum platform (Optellum, Ltd.)	Level 1

SUBSTANTIAL EQUIVALENCE COMPARISON

CHARACTERISTIC	YOUR DEVICE	PREDICATE	ALIGNMENT
Intended Use	AI software to assist radiologists in detecting and measuring lung nodules on chest CT images to support lung cancer screening workflows.	AI software (AVIEW Lung Nodule CAD) intended to assist radiologists in detecting, segmenting, and measuring pulmonary nodules on chest CT scans.	identical
Indications for Use	Indicated for use in adult patients undergoing chest CT imaging for lung cancer screening or incidental nodule evaluation.	Indicated for use in adult patients undergoing chest CT for lung nodule detection and characterization in screening and diagnostic workflows.	identical
Technology Principle	Locked AI/ML algorithm performing automated detection, segmentation, and volumetric measurement of pulmonary nodules on chest CT DICOM images.	Locked deep learning-based algorithm performing automated pulmonary nodule detection, segmentation, and measurement on chest CT DICOM images.	identical
Performance Characteristics	Sensitivity, specificity, false positive rate per scan, nodule size measurement accuracy, and segmentation accuracy evaluated against radiologist ground truth.	Performance characterized by sensitivity, specificity, false positive rate, and nodule measurement accuracy benchmarked against expert radiologist annotation.	identical
Design Features	Software-only SaMD with DICOM input, AI inference engine, and structured output overlay integrated into PACS or standalone viewer.	Software-only SaMD accepting DICOM CT input, processing via AI inference, and delivering nodule detection overlays and measurement reports to PACS or reading workstation.	identical
Patient Population	Adult patients undergoing chest CT for lung cancer screening or nodule surveillance.	Adult patients undergoing chest CT imaging for lung nodule detection and follow-up in screening or clinical settings.	identical
Clinical Setting	Hospital radiology departments, outpatient imaging centers, and lung cancer screening programs.	Hospital radiology departments and outpatient imaging centers performing chest CT interpretation.	identical
User Interface	Radiologist-facing software interface displaying nodule detection overlays, segmentation masks, and measurement outputs within a PACS or dedicated viewer.	Radiologist-facing interface presenting nodule detection results, segmentation contours, and quantitative measurements integrated into clinical reading workflow.	identical
Use Environment	Hospital imaging reading room or outpatient radiology facility with PACS infrastructure and trained radiologist users.	Hospital or outpatient radiology reading environment with PACS connectivity and professional radiologist end users.	identical

eSTAR SECTION MAPPING

Section 4 — Device Description

Describe the AI/ML-based pulmonary nodule detection, segmentation, and measurement software under 21 CFR 892.2050, including intended use, indications for use, and contraindications consistent with OEB classification.

Section 5 — Substantial Equivalence

Provide substantial equivalence comparison to K251203 (primary) and K242919 (split predicate), documenting identical intended use and technological characteristics including locked algorithm architecture, DICOM input processing, and nodule measurement outputs.

Section 9 — Software Documentation

Submit software documentation per FDA Software as a Medical Device guidance including Software Description Document, Software Requirements Specification, architecture diagram, risk analysis (IEC 62304 Level C), and algorithm version control records consistent with locked AI/ML device requirements.

Section 12 — Performance Testing

Provide performance testing data including sensitivity, specificity, false positive rate per scan, nodule measurement accuracy, and segmentation performance evaluated on a representative clinical dataset with radiologist ground truth annotation, consistent with OEB predicate performance characterization.

REGULATORY PATHWAY DECISION

Traditional 510(k)

Estimated timeline: 52 weeks

Traditional 510(k) is appropriate because multiple cleared OEB-code predicates (K251203, K242919, K221592) demonstrate that AI-based pulmonary nodule CAD software is a well-established device type with a clear predicate lineage, and the device does not qualify for Special 510(k) (no prior cleared version of the submitter's own device) or Abbreviated 510(k) (no single recognized consensus standard fully characterizes performance for AI lung nodule CAD). The substantial equivalence argument is straightforward given identical intended use and technological characteristics to K251203, and no novel risks requiring De Novo or PMA classification have been identified.

Alternative Pathways Considered:

- Abbreviated 510(k): Could be considered if FDA recognizes a consensus standard fully covering AI/ML lung nodule CAD performance, but no such standard currently exists that would satisfy all performance characterization requirements.
- De Novo: Not appropriate given the existence of multiple cleared OEB predicates; De Novo would only apply if no legally marketed predicate could be identified.

De Novo Eligibility: Not Applicable

Multiple cleared OEB-code predicates exist for AI-based pulmonary nodule CAD, precluding De Novo eligibility under 21 CFR 513(f)(2).

Breakthrough Device: Not Applicable

AI-based pulmonary nodule CAD is a well-established device category with multiple cleared devices, and the device does not address an unmet need for a life-threatening or irreversibly debilitating condition beyond existing cleared alternatives.

Pre-Submission Meeting: Recommended

A Pre-Submission meeting is recommended to confirm FDA's acceptance of the proposed predicate strategy (K251203 primary, K242919 split), align on AI/ML performance testing dataset requirements, and clarify PCCP applicability expectations under the January 2025 guidance before investing in full clinical validation studies.

PCCP: Not Required

A Predetermined Change Control Plan (PCCP) is not required for a locked algorithm device but is strongly recommended if the submitter anticipates future algorithm updates, as the January 2025 AI-Enabled Device Software Functions guidance encourages PCCPs to streamline post-market modifications; if submitted, the PCCP should define the modification protocol, performance monitoring plan, and impact assessment methodology for any future algorithm retraining or threshold adjustments.

Next Steps & Resources

Curated FDA resources for the recommended pathway.

- **510(k) Submission Methods Overview**
  Entry point — overview of the 510(k) pathway and when it applies.
- **Content of a 510(k) Submission (21 CFR 807.87)**
  Regulatory requirements for 510(k) submission content.
- **eSTAR Template (Mandatory)**
  Electronic submission template — required for most 510(k) submissions.
- **The 510(k) Program (Substantial Equivalence Framework)**
  Foundational FDA guidance on demonstrating SE.
- **Acceptance Review Checklist**
  RTA checklist — ensures your submission will be accepted for substantive review.

TESTING IMPLICATIONS

Likely Bench Testing:

- Nodule detection sensitivity and false positive rate per scan on a representative multi-site CT dataset
- Nodule segmentation accuracy (Dice coefficient, Hausdorff distance) versus expert radiologist ground truth
- Nodule diameter and volume measurement accuracy and reproducibility across CT scanner manufacturers and acquisition parameters
- Algorithm performance across clinically relevant subgroups (nodule size, morphology, density: solid, subsolid, ground-glass)
- Standalone reader study or reader performance study demonstrating clinical utility as decision support
- Cybersecurity testing per FDA Cybersecurity guidance including penetration testing and SBOM documentation
- DICOM conformance and interoperability testing across representative PACS platforms
- Usability/human factors validation per FDA Human Factors guidance for radiologist-facing AI decision support interface

Software Level	Major — The device is AI/ML-based SaMD whose failure to detect or incorrectly measure a pulmonary nodule could result in delayed lung cancer diagnosis, constituting a serious injury risk that requires Major software level documentation per FDA Software as a Medical Device guidance and IEC 62304 Level C compliance.
Clinical Data	Likely Needed — Clinical performance data (reader study or retrospective multi-site validation) is required to characterize AI algorithm sensitivity, specificity, and measurement accuracy on a representative U.S. patient population consistent with OEB predicate performance characterization expectations.
Biocompatibility	Likely Not Needed
Electrical Safety	Likely Not Needed

SAFETY SUMMARY

MAUDE adverse events and recall data from openFDA. Design-related recalls are flagged per FDA guidance.

K-NUMBER	DEVICE	MAUDE EVENTS	RECALLS
K242919	V5med Lung AI	0	0
K221592	AVIEW Lung Nodule CAD	0	0
K251769	RevealAI-Lung	0	0
K251203	AVIEW Lung Nodule CAD	0	0
K243239	Lung AI (LAI001)	0	0

Note: MAUDE reports include voluntary and mandatory reports of adverse events. High counts may reflect market adoption. Design-related recalls indicate fundamental design flaws per FDA guidance. Always verify at accessdata.fda.gov.

MARKET CONTEXT

Clearances in last 5 years: 8

Average clearance time: 210 days

Key manufacturers: Coreline Soft Co., Ltd., V5med, Inc., Siemens Healthineers, iCAD, Inc.

The OEB product code has seen accelerating AI/ML-based lung nodule CAD clearances from 2023 through 2025, with FDA demonstrating consistent acceptance of deep learning-based detection and measurement tools using reader study performance data and locked algorithm architectures.

AI/ML DEVICE ASSESSMENT

Based on FDA January 2025 "AI-Enabled Device Software Functions" guidance and IMDRF SaMD framework.

IMDRF SaMD Risk Category

Category III — Under the IMDRF SaMD Risk Framework, this device is Category III (high impact on patient management, serious condition) because it informs lung cancer screening decisions — a situation where incorrect output could directly influence treatment decisions for a life-threatening condition, even though a radiologist reviews the output.

Algorithm Classification

locked

PCCP Scope

A PCCP is not required for this locked algorithm device but is recommended if the submitter anticipates future algorithm retraining, threshold modifications, or expansion to new CT scanner types; if submitted, the PCCP should define the scope of permissible modifications, the performance evaluation protocol for each modification, and the impact assessment methodology per the January 2025 AI-Enabled Device Software Functions guidance.

Algorithm Change Protocol

For a locked algorithm, any post-market change to the AI model weights, architecture, training data, or decision thresholds that could affect safety or effectiveness must be submitted as a new 510(k) or evaluated under a cleared PCCP; the submitter should establish internal change control procedures (IEC 62304 compliant) to classify and document all algorithm changes and determine regulatory pathway applicability before implementation.

Data Documentation

The January 2025 AI-Enabled Device Software Functions guidance requires documentation of training dataset characteristics (size, demographics, imaging equipment diversity, annotation methodology, train/validation/test split), algorithm performance on a locked test set representative of the U.S. intended use population, transparency disclosures regarding AI model inputs and outputs, and a performance monitoring plan describing how real-world performance will be tracked post-clearance; additionally, the submission should include a Model Card or equivalent transparency document describing algorithm design choices, known limitations, and subgroup performance to support FDA's review of AI/ML-specific risks.

PREDICATE SELECTION NARRATIVE

Ready-to-use text for inclusion in the 510(k) Summary per FDA guidance Section VI.

The predicate selection for this 510(k) submission was conducted in accordance with FDA's September 2023 guidance 'Best Practices for Selecting a Predicate Device,' which directs applicants to identify predicates with the most similar intended use and technological characteristics, a clean postmarket safety record, and clearance using well-established methods. Following a systematic review of legally marketed devices within product code OEB (Radiology, Computer Aided Detection/Diagnosis Software), K251203 (AVIEW Lung Nodule CAD, Coreline Soft Co., Ltd., cleared December 3, 2025) was selected as the primary predicate based on its identical intended use as AI-based software to assist radiologists in detecting, segmenting, and measuring pulmonary nodules on chest CT images to support lung cancer screening workflows, its identical technological characteristics as a locked deep learning algorithm operating on DICOM CT input with PACS-integrated output, its clearance under the same 21 CFR 892.2050 classification, and its clean postmarket safety record with zero MAUDE events and no recalls.

K242919 (V5med Lung AI, V5med, Inc., cleared March 27, 2025) was selected as a split predicate to further support the technological characteristics comparison, consistent with FDA guidance permitting the use of multiple predicates when no single predicate shares both identical intended use and identical technological characteristics with the subject device. K242919 provides an independent manufacturer data point demonstrating FDA's broad acceptance of AI/ML-based lung nodule detection and measurement tools within OEB, and its predicate lineage through K221592 and K161201 reinforces the well-established nature of the underlying technological approach. Both predicates were cleared using well-established AI/ML CAD methods, have zero MAUDE adverse events, and have not been subject to any recalls, satisfying all four Best Practices criteria.

The predicate lineage for K251203 traces through K221592 (AVIEW Lung Nodule CAD, February 2023), K203258 (syngo.CT Lung CAD), K192880 (InferRead Lung CT.AI), and ultimately to K043617 (IMAGECHECKER CT CAD SOFTWARE SYSTEM), establishing a continuous chain of cleared AI-based lung nodule CAD devices within OEB dating to 2004 and demonstrating that the subject device's technological approach is well-established within the meaning of FDA guidance. Cross-code candidates (K243239, MYN; K251769, POK) were evaluated but not selected as predicates due to their different product code classifications, which would weaken the substantial equivalence argument and introduce unnecessary regulatory complexity when same-code predicates with superior alignment are available.

REGULATORY PATHWAY NOTES

The device falls squarely within the well-established OEB product code for AI-based pulmonary nodule CAD, and the predicate landscape as of early 2026 is highly favorable with three same-code cleared predicates from 2023-2025 providing a robust substantial equivalence foundation. The January 2025 AI-Enabled Device Software Functions guidance does not mandate a PCCP for locked algorithms but submitters should proactively address algorithm transparency, training data documentation, and performance monitoring commitments in the 510(k) to anticipate FDA reviewer expectations. Given the AI/ML nature of the device, FDA reviewers will scrutinize dataset representativeness, subgroup performance, and reader study design — early Pre-Submission alignment on these elements is the single highest-value regulatory investment before submission.

RECOMMENDED NEXT STEPS

- 1. File Pre-Submission meeting request with FDA CDRH identifying K251203 as primary predicate and K242919 as split predicate, and requesting alignment on AI/ML performance dataset requirements and PCCP applicability.
- 2. Design and execute multi-site clinical validation study (retrospective or prospective) measuring nodule detection sensitivity, false positive rate, segmentation accuracy, and measurement reproducibility on a representative U.S. patient population across diverse CT scanner platforms.
- 3. Prepare complete software documentation package per IEC 62304 Level C including Software Description Document, Software Requirements Specification, architecture diagram, SOUP list, risk management file (ISO 14971), and algorithm version control records.
- 4. Conduct human factors validation study with representative radiologist users to demonstrate safe and effective use of the AI decision-support interface per FDA Human Factors guidance.
- 5. Prepare cybersecurity documentation including threat model, SBOM, penetration testing results, and vulnerability management plan per FDA Cybersecurity guidance for SaMD, and draft optional PCCP defining future algorithm modification protocol if post-market updates are anticipated.

REGULATORY REFERENCES

FDA guidance documents this analysis references. Click any title to open the FDA.gov source page.

Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission

September 2023

PRIMARY METHODOLOGY REFERENCE. Defines the four best-practice criteria for predicate selection — (1) well-established methods, (2) postmarket safety performance, (3) no unmitigated safety issues, (4) no design-related recall — that drive the FDA Best Practices Scorecard in every report this tool generates.

The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

July 2014

Foundational SE-determination framework that the 2023 Best Practices guidance sits inside. Defines how indications, technological characteristics, and performance data combine to demonstrate substantial equivalence — the structure the SE Comparison table in this report follows.

De Novo Classification Process (Evaluation of Automatic Class III Designation)

October 2021

Pathway for novel, low-to-moderate risk devices without an adequate predicate.

Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations

January 2025

Lifecycle-management expectations and submission content for AI-enabled devices.

Marketing Submission Recommendations for a Predetermined Change Control Plan for AI/ML-Enabled Device Software Functions

December 2024

PCCP framework — how to pre-authorize planned algorithm changes without re-submitting.

Breakthrough Devices Program

September 2023

Expedited development and review for devices addressing life-threatening or irreversibly debilitating conditions.

Clinical Decision Support Software

September 2022

Criteria for when CDS software is / is not a regulated device under 21st Century Cures.

Software as a Medical Device (SaMD): Clinical Evaluation

December 2017

Framework for generating clinical evidence to support SaMD.

Software as a Medical Device (SaMD): Possible Framework for Risk Categorization and Corresponding Considerations

September 2014 (IMDRF)

IMDRF risk categorization (I–IV) referenced in the AI/ML assessment section.

eSTAR Program

Ongoing

Electronic submission template mandatory for most 510(k) submissions. The eSTAR Mapping section aligns each analysis area to the corresponding eSTAR section.

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This report is for informational and research purposes only. It does not constitute regulatory, legal, or professional advice. The analysis contained in this report is AI-generated and has not been reviewed by FDA or any regulatory authority.

The identification of predicate devices, substantial equivalence comparisons, safety data summaries, and regulatory pathway suggestions are automated assessments based on publicly available data from openFDA and should be independently verified.

This report should be reviewed by a qualified regulatory professional before being used in connection with any FDA submission, including but not limited to 510(k) premarket notifications.

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