



May 27, 2026

Fujifilm Corporation
% Chaitrali Kulkarni
Sr. Regulatory Affairs Specialist
Fujifilm Healthcare Americas Corporation
81 Hartwell Ave.
Suite 100
LEXINGTON, MA 02421

Re: K254075

Trade/Device Name: Synapse Lung Nodule AI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: OEB
Dated: April 24, 2026
Received: April 24, 2026

Dear Chaitrali Kulkarni:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Lu Jiang". The signature is written over a large, light blue, semi-transparent watermark of the letters "FDA".

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K254075

Device Name

Synapse Lung Nodule AI

Indications for Use (Describe)

The Synapse Lung Nodule AI is a computer-assisted detection software device intended to be used as concurrent reader to aid the radiologist in the detection of pulmonary nodules during the review of CT examinations of the chest on the lung cancer screening population according to the lung cancer screening protocols. The Synapse Lung Nodule AI requires that both lungs be in the field of view. The Synapse Lung Nodule AI provides adjunctive information such as bounding boxes, segmented contours, and measurement values, and is not intended to be used without the original CT series. The Synapse Lung Nodule AI is also not intended to be used for the differentiation of the detected regions between benign and malignant.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared:	November 21st, 2025
Submitter's Information:	FUJIFILM Corporation 26-30 NISHIAZABU, 2-CHOME MINATO-KU, TOKYO 106-8620
Contact Person:	Kotei Aoki Senior Regulatory Affairs Specialist Telephone: (765) 246-2931 Email: kotei.aoki@fujifilm.com
Device Trade Name:	Synapse Lung Nodule AI
Device Common Names:	Medical image management and processing system
Device Classification Name:	Medical image management and processing system
Product Code:	OEB
Regulation Number:	21 CFR 892.2050
Device Class:	Class II
Panel:	Radiology
Predicate Devices:	ClearRead CT (K161201) Riverain Technologies, Inc

1. Description of the Device

The Synapse Lung Nodule AI is a dedicated post-processing application that detects lung nodules of 4 mm and above in the non-contrast chest CT images within the Lung Cancer Screening population. This device is intended to be used as a concurrent reading tool and as an add-on software product running with other FUJIFILM hosting applications. The lung nodule detection model was trained using a Convolutional Neural Network (CNN) based algorithm with chest CT images.

The Synapse Lung Nodule AI retrieves images from PACS system, detects and quantifies nodules in the images, and provides detected nodule information back into PACS system. The stored nodule information includes bounding boxes, segmented contours, and measurement values (volume/long axis length/short axis length/average axis length/average HU value) for each nodule. The nodule information is displayed in PACS viewer, specifically Synapse PACS (K190232), for confirming it during the interpretation.

The output is displayed as a rectangular bounding box representing nodule location and includes additional optional nodule measurements. Additionally, a polygon circumscribing each segmented contour is also displayed when the user's mouse cursor is over the bounding box.

2. Indications for Use

The Synapse Lung Nodule AI is a computer-assisted detection software device intended to be used as concurrent reader to aid the radiologist in the detection of pulmonary nodules during the review of CT examinations of the chest on the lung cancer screening population according to the lung cancer screening protocols. The Synapse Lung Nodule AI requires that both lungs be in the field of view. The Synapse Lung Nodule AI provides adjunctive information such as bounding boxes, segmented contours, and measurement values, and is not intended to be used without the original CT series. The Synapse Lung Nodule AI is also not intended to be used for the differentiation of the detected regions between benign and malignant.

3. Substantial Equivalence Comparison

This section describes the comparison matrix for Synapse Lung Nodule AI. The primary predicate device and reference device are listed in Table 1.

Table 1 List of predicate and reference device	
Primary predicate device	ClearRead CT (K161201)
Reference device	InferRead Lung CT.AI (K192880)

The Synapse Lung Nodule AI is substantially equivalent to the ClearRead CT ([K161201](#)) that is legally marketed. A detailed comparison of Synapse Lung Nodule AI to the predicate device is described in Table 2. InferRead Lung CT.AI ([K192880](#)) is used as a reference device primarily due to the similarity in nodule markings and access to the original CT scans.

Table 2 Device features and technical characteristics comparison matrix			
Device Name	Synapse Lung Nodule AI (Subject Device)	ClearRead CT (K161201) (Predicate Device)	Comparison
Indications for Use	The Synapse Lung Nodule AI is a computer-assisted detection software device intended to be used as concurrent reader to aid the radiologist in the detection of pulmonary nodules during the review of CT examinations of the chest on the lung cancer screening population according to the lung cancer screening protocols. The Synapse Lung Nodule AI requires that both lungs be in the field of view. The Synapse Lung Nodule AI provides adjunctive information such as bounding boxes, segmented contours, and measurement values, and is not intended to be used without the original CT series. The Synapse Lung	ClearRead CT™ is comprised of computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during review of CT examinations of the chest on an asymptomatic population. The ClearRead CT requires both lungs be in the field of view. ClearRead CT provides adjunctive information and is not intended to be used without the original CT series.	The indications for use of Synapse Lung Nodule AI are the substantially equivalent to the indications for use of the previously cleared ClearRead CT.

	Nodule AI is also not intended to be used for the differentiation of the detected regions between benign and malignant.		
Intended Use	Computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during review of CT examinations of the chest.	Computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during review of CT examinations of the chest.	Same
Reading Paradigm	Concurrent	Concurrent	Same
Slice Thickness	Less than 3mm	Less than 3mm	Same
Modality Vender	Canon, GE, Philips, Siemens	Canon, GE, Philips, Siemens	Same
Accessories/Tools Required by the User (Platform)	Must be used in conjunction with a PACS system or an Image Viewer that reads DICOM images.	Must be used in conjunction with a PACS system or an Image Viewer that reads DICOM images.	Same
User Access Point	Post Processing Application	Post Processing Application	Same
Image Input	DICOM	DICOM	Same
Type of Scans	CT	CT	Same
Automatically Locate and Identify Lung Nodules	Yes	Yes	Same

Modifies the Original CT Scan	No	Yes	Synapse Lung Nodule AI does not modify the original scan, only shows the locations of pulmonary nodules. This difference does not raise different questions of safety and effectiveness.
Requires a Disjoint Comparison with the Original CT Scan	No	Yes	Synapse Lung Nodule AI displays the original CT scans with overlaid device outputs in a single view. Therefore, disjoint comparison with the original CT is not required. In contrast, the Predicate device (ClearRead CT) creates a separate vessel-suppressed CT series, requiring side-by-side review and thus disjoint comparison. This feature is similar to the Reference device (InferRead Lung CT.AI) in which the results are overlaid on the original CT without separate images. This difference does not

			raise different questions of safety and effectiveness.
Nodule Marking	A bounding box is provided around nodules	CADe marks and associated region descriptors are provided	Although the nodule marking methods are different from the predicate device (ClearRead CT), this feature does not raise different questions of safety and effectiveness. The same method can be confirmed in the reference device (InferRead Lung CT.AI).
Outline of nodule	Yes The segmented contour is provided on all slices to indicate a region of interest when mouse cursor moves over the identified nodule.	Yes The segmented contour is provided on the center slice with ellipses on +/- one slice to indicate a region of interest.	Synapse Lung Nodule AI is providing segmented contour on all slices to the identified nodule with mouse cursor moves over. The predicate device does not provide segmented contours for all slices but only on the center slice. Please note Synapse Lung Nodule AI is providing segmented contours after the intended user identified the nodule. So this difference does not raise

			different questions of safety and effectiveness.
Provides Nodule Measurements	Yes The volume, maximum axial plane diameter, minimum axial plane diameter, mean diameter and average density in Hounsfield units are provided. The maximum and minimum axial plane diameter line on a slice to indicate a region of interest when mouse cursor moves over the identified nodule.	Yes The volume, maximum axial plane diameter, minimum axial plane diameter, and average density in Hounsfield units are provided.	The nodule characteristics for Synapse Lung Nodule AI is substantially similar to the nodule characteristics of the predicate device (ClearRead CT). The difference is that Synapse Lung Nodule AI provides the maximum and minimum axial plane diameter line on a slice to indicate a region of interest after the intended user identified the nodule. This difference does not raise different questions of safety and effectiveness.
Detection Target(s)	Solid, Sub Solid (part solid and ground glass) nodules	Solid, Sub Solid (part solid and ground glass) nodules	Same
Size of Detection Targets	4mm and above, supports visualization of nodules smaller than 4mm	5mm and above, supports visualization of nodules smaller than 5mm	Although the size of detection targets of Synapse Lung Nodule AI is different from the predicate device (ClearRead CT), this feature does not raise different questions of safety and

			effectiveness. The same method can be confirmed in the reference device (InferRead Lung CT.AI).
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4. Testing and Performance Information

Nonclinical testing result:

The purpose of Software Development Process for Synapse Lung Nodule AI is to carry out the activities relating to the establishment of the software development plan (or plans) for definitely conducting software hazard analysis, risk management, requirement analysis, architectural design, the design specification, unit implementation and verification, software integration and integration testing, software system test, software release, software maintenance. The main activities in software development process are described as follows.

- Software development plan
- Software hazard analysis and risk management
- Software requirements analysis/specification
- Software architectural design
- Software detailed design specification
- Software unit module implementation and verification
- Software integration and system testing

Clinical performance tests:

A retrospective multi-reader multi-case (MRMC) study and standalone performance evaluation were conducted to assess the performance of Synapse Lung Nodule AI for low-dose chest CT scans acquired in a lung cancer screening population.

The dataset included 300 chest CT exams collected from three geographically distinct US regions, comprising 100 cases with at least one lung nodule and 200 normal controls. All CT scans were performed following lung cancer screening protocols recommended by the American Association of Physicists in Medicine. Demographic characteristics of the study population are summarized in Table 3; the mean patient age was 65.8 years (SD 6.8), with 53.0% males and 47.0% females. The cohort was racially diverse and included images from multiple CT scanner manufacturers.

Ground truth was established by consensus majority decision of three US board-certified thoracic radiologists.

Fifteen board-certified thoracic radiologists participated in the MRMC study under a randomized crossover design with a minimum four-week washout period. Readers interpreted all cases unaided and aided by Synapse Lung Nodule AI in randomized order.

The MRMC primary endpoint demonstrated statistically significant improvement in diagnostic accuracy with AI assistance. The average AUROC increased from 0.768 (95% CI: 0.727–0.809) unaided to 0.835 (95% CI: 0.799–0.872) aided (difference: 0.067; $p < 0.001$). Localization accuracy measured by LROC improved from 0.723 (95% CI: 0.679–0.767) unaided to 0.800 (95% CI: 0.758–0.841) aided (difference: 0.076; $p < 0.001$). Reading time per case was significantly

reduced by an average of 0.76 minutes (95% CI: -1.07 to -0.49; $p < 0.001$).

Standalone algorithm performance met all pre-specified performance criteria. Sensitivity for nodule detection was 78.3% (95% CI: 71.0–84.8%). The false positive rate per case was 0.76 (95% CI: 0.64–0.90). The Dice similarity coefficient for 3D nodule segmentation was 0.81 (95% CI: 0.79–0.83).

Table 3 Demographic information for all cases			
Summary	No Nodules (N=200)	One or More Nodules (N=100)	Total (N=300)
Age (years)			
Mean (SD)	66.0 (6.40)	65.6 (7.64)	65.8 (6.83)
Median	66.5	66.0	66.0
Min, Max	50, 81	50, 79	50, 81
Sex			
Male	108 (54.0%)	51 (51.0%)	159 (53.0%)
Female	92 (46.0%)	49 (49.0%)	141 (47.0%)
Race			
White	87 (43.5%)	54 (54.0%)	141 (47.0%)
Black or African American	4 (2.0%)	1 (1.0%)	5 (1.7%)
Not reported	109 (54.5%)	45 (45.0%)	154 (51.3%)
Collection US Region			
CENTRAL	61 (30.5%)	30 (30.0%)	91 (30.3%)
EAST	85 (42.5%)	47 (47.0%)	132 (44.0%)
WEST	54 (27.0%)	23 (23.0%)	77 (25.7%)
CT Manufacturer			
Canon	33 (16.5%)	13 (13.0%)	46 (15.3%)
GE MEDICAL SYSTEMS	59 (29.5%)	27 (27.0%)	86 (28.7%)
Philips	31 (15.5%)	15 (15.0%)	46 (15.3%)
Siemens Healthineers	77 (38.5%)	45 (45.0%)	122 (40.7%)
Slice Thickness (mm)			
Mean (SD)	1.5 (0.58)	1.5 (0.57)	1.5 (0.58)
Median	1.3	1.3	1.3
Min, Max	1, 3	1, 3	1, 3

Overall, these results demonstrate that Synapse Lung Nodule AI significantly improves radiologist sensitivity and localization accuracy for lung nodule detection on lung cancer screening chest CT, while reducing reading times and maintaining a low false positive rate. These data support the safety and effectiveness of the device for its intended use.

Verification and Validation:

Testing for verification and validation involved system level functionality test, component testing, verification testing, integration testing, usability testing, installation testing, labeling testing, as well as the testing for risk mitigations associated with the risk management process. In addition, benchmark performance testing was conducted using actual clinical images to help demonstrate that the lung nodule detection functions implemented in Synapse Lung Nodule AI achieved the expected accuracy performance. Pass/Fail criteria were based on the requirements and intended use of the product. Test results showed that all tests passed successfully according to the design specifications.

Cybersecurity:

The confidentiality, integrity and availability are maintained by Synapse Lung Nodule AI in accordance with *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (April 8, 2022)*.

Synapse Lung Nodule AI is connected through DICOM standard to medical devices and to a PACS system storing data generated by these medical devices, and it retrieves image data via network communication based on the DICOM standard. Therefore, Synapse Lung Nodule AI assures an adequate degree of protection for cybersecurity.

Performance standards:

- *Digital Imaging and Communications in Medicine (DICOM) Set (PS 3.1 – 3.20) (2024e).*
- *IEC 62304 Edition 1.1 2015-06, Medical Device Software - Software Life Cycle Processes.*
- *ISO 14971:2019 2019-12-10, Medical Devices - Application of Risk Management to Medical Devices.*
- *ISO 20417 First edition 2021-04 Corrected version 2021-12, Medical devices - Information to be supplied by the manufacturer.*
- *IEC 81001-5-1 Edition 1.0 2021-12, Health software and health IT systems safety effectiveness and security - Part 5-1: Security - Activities in the product life cycle.*
- *AAMI CR34971:2022, Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning.*
- *IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Medical devices - Part 1: Application of usability engineering to medical devices.*
- *IEC 82304-1 Edition 1.0 2016-10, Health software - Part 1: General requirements for product safety.*

5. Conclusion

Performance tests were conducted to test the functionality of the subject device, Synapse Lung Nodule AI. Results of all conducted testing were acceptable in supporting the claim of substantial equivalence.