August 31, 2021

Samsung Electronics Co., Ltd.
℅ Jaesang Noh
Senior Professional, Regulatory Affairs
129, Samsung-ro, Yeongtong-gu
Suwon-si, Gyeonggi-do 16677
REPUBLIC OF KOREA

Re: K201560
Trade/Device Name: Auto Lung Nodule Detection
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical image analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: July 15, 2021
Received: July 20, 2021

Dear Jaesang Noh:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201560

Device Name
Auto Lung Nodule Detection

Indications for Use *(Describe)*
The Auto Lung Nodule Detection is computer-aided detection software to identify and mark regions in relation to suspected pulmonary nodules from 10 to 30 mm in size. It is designed to aid the physician to review the PA chest radiographs of adults as a second reader and be used as part of S-Station, which is operation software installed on Samsung Digital X-ray Imaging systems. Auto Lung Nodule Detection cannot be used on the patients who have lung lesions other than abnormal nodules.

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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SAMSUNG ELECTRONICS Co., Ltd.

510(k) Premarket Notification - Traditional

Section 5: 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted accordance with requirements of 21 CFR 807.92

1. **Date:** August 26, 2021

2. **Submitter**
   A. Company Name: SAMSUNG ELECTRONICS Co., Ltd.
   B. Address: Address: 129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16677, Republic of Korea

3. **Primary Contact Person**
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4. **Secondary Contact Person**
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   E. E-Mail: ngujar@samsungneurologica.com

5. **Proposed Device**
   A. Trade Name: Auto Lung Nodule Detection
   B. Device Name: Auto Lung Nodule Detection
   C. Common Name: Medical image analyzer
   D. Classification Name: Medical image analyzer
   E. Product Code: MYN
   F. Regulation: 21 CFR 892.2070

6. **Predicate Device**
   A. Manufacturer: Riverain Medical Group, LLC
   B. Trade Name: ClearRead Detect

C. Classification: Medical image analyzer

D. Product Code: MYN

E. 510(k) Number or PMA Number: P000041

F. Decision Date: July 12, 2001

	Predicate Device
Trade Name	ClearRead Detect
Classification Name	Medical image analyzer
Product Code	MYN
Regulation	21 CFR 892.2070
PMA#	P000041
Decision Date	July 12, 2001

*The product code MYN has been reclassified from Class III to Class II since February 21, 2020.

7. Device Description

Auto Lung Nodule Detection is a Computer-Aided Detection (CADe) device that is designed to perform CAD processing in Chest X-ray images for indication of locations for high nodule probability, which has an effective detection sizes from 10 mm to 30 mm.

Auto Lung Nodule Detection receives images acquired with SAMSUNG Digital X-ray Imaging Systems as an input and identifies suspected nodules, and then sends information of suspected nodules to the visualization part of S-Station, which is installed on all kinds of SAMSUNG Digital X-ray Imaging Systems, to generate output images with circular marks. The CAD performed images, are displayed on the screen by S-Station without defeat of original images and used as a second reader only after the initial read is completed.

8. Intended Use

The Auto Lung Nodule Detection is computer-aided detection software to identify and mark regions in relation to suspected pulmonary nodules from 10 to 30 mm in size. It is designed to aid the physician to review the PA chest radiographs of adults as a second reader and be used as part of S-Station, which is operation software installed on Samsung Digital X-ray Imaging systems. Auto Lung Nodule Detection cannot be used on the patients who have lung lesions other than abnormal nodules.

9. Summary of Technological characteristic of the proposed device compared with the predicate device

Samsung believes that the proposed device is substantially equivalent to the predicate device because some differences in the design and features is considered low risk and do not raise new questions on safety and effectiveness of the proposed device for its intended use based on the non-clinical and clinical testing.

A. Comparing with Predicate Device

		Predicate Device	Proposed Device
Device Name		ClearRead Detect	Auto Lung Nodule Detection
Manufacture		Riverain Medical Group, LLC	Samsung Electronics
PMA Number		PMA P000041	-
Indication for use		CLEARREAD DETECT is a computer-aided detection (CAD) system intended to identify and mark regions of interest (ROIs) on digitized frontal chest radiographs. It identifies features associated with solitary pulmonary nodules from 9 to 30 mm in size, which could represent early-stage lung cancer. The device is intended for use as an aid only after the physician has performed an initial interpretation of the radiograph.	The Auto Lung Nodule Detection is computer-aided detection software to identify and mark regions in relation to suspected pulmonary nodules from 10 to 30 mm in size. It is designed to aid the physician to review the PA chest radiographs of adults as a second reader and be used as part of S-Station, which is operation software installed on Samsung Digital X-ray Imaging systems. Auto Lung Nodule Detection cannot be used on the patients who have lung lesions other than abnormal nodules.
Intended users		Physician	Physician
Intended body part		Chest	Chest
Imaging modality		X-ray	X-ray
Key feature		Identification of lung nodules	Identification of lung nodules
Technology		heuristic decision rules, artificial neural network, and fuzzy logic	Machine learning
Operating systems		Standard PC/Windows	Standard PC/Windows
Input	Image type	DICOM	DICOM
	Applicable Protocols	Chest PA/AP	Chest PA
Output	Output type	ROI marked on the duplicated input image	Information for ROI to be marked on the duplicated input image
	Marker type/size	Circular/Adjustable	Circular/Fixed
	Report	The number of findings	The number of nodule markers
Reader workflow		Second reader workflow	Second reader workflow

10. Safety and Effectiveness Information

Software design description, hazard analysis, and labeling information are provided in support of

this premarket notification for the proposed device. The device labeling contains instructions for use with cautions to provide for safe and effective use of the device. The results of the hazard analysis with appropriate risk controls indicate the proposed device is of moderate level of concern, as per the FDA Guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Device” issued on May 11, 2005.

11. Software Verification and Validation

A. Non-clinical Testing

Non-clinical tests were conducted for Auto Lung Nodule Detection during the device development in accordance with Samsung verification and validation process complied with the FDA Quality System Regulations, ISO 13485 requirements, and the following standards.

- ISO14971:2007, Medical devices - Application of risk management to medical devices (2nd Ed.)
- IEC62304:2006, Medical devices - Software life cycle processes
- IEC62366-1:2015, Medical device – Part1: Application of usability engineering to medical devices

Verification and validation activities for Auto Lung Nodule Detection were conducted to provide evidences that the design meets user needs and intended use and application specification. The testing results support that all the software specifications have met the acceptance criteria and the claims of substantial equivalence.

B. Clinical Performance Testing

Clinical evaluation was performed to validate the clinical efficacy of Samsung Auto Lung Nodule Detection (ALND) in helping radiologists find pulmonary nodules on digital chest radiographs. In this clinical study, nodule detection performances of human readers were measured using a test dataset containing both normal and diseased images. Readers were asked to mark their region of nodule suspicion on the images while also providing confidence scores on each decision they have made. After independent reading, readers were allowed to adjust their confidence scores after reviewing the ALND's detection results. Nodule detection performances before and after ALND were measured via sensitivity, false positives per image (FPPI), and jackknife alternative free response receiver operating characteristic (JAFROC) figure of merit (FOM). The results have demonstrated that all readers' nodule detection performances using the proposed device have increased with statistical significance. Therefore, the proposed device could provide potential assistance for radiologists in the interpretation and detection of pulmonary nodules when used as an assistant tool.

12. Conclusions

Results of all conducted testing were found acceptable in supporting the claim of substantial equivalent to the predicate device.