August 3, 2023

Imidex Inc.
% Kris Zeschin
Chief Operating Officer
3513 Brighton Blvd., Suites 456 7 454
DENVER, CO 80216

Re: K223133
Trade/Device Name: VisiRad XR
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: July 3, 2023
Received: July 3, 2023

Dear Kris Zeschin:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223133

Device Name
VisiRad XR

Indications for Use *(Describe)*
VisiRad XR is a computer-aided detection (CADe) device intended to identify and mark regions of interest that may be suspicious for lung nodules and masses on chest radiographs. It identifies features associated with pulmonary nodules and masses from 6-60mm in size. Detection of suspicious findings by VisiRad XR is intended as an aid only after the physician has performed an initial interpretation; it is not intended to replace the review by a qualified radiologist and is not intended to be used for triage or to make or confirm a diagnosis. The intended patient population for VisiRad XR consists of patients >21 years of age on whom chest radiographs have been acquired in an outpatient or emergency department setting.

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.

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Section 5: 510(k) Summary

1 Applicant Name and Address

Name: IMIDEX, Inc.

Address: 3513 Brighton Blvd #456
Denver, CO 80216

Official Contact: Kris Zeschin, Chief Operating Officer

2 Summary Preparation Date: September 29, 2022

3 Device Name and Classification

Trade Name: VisiRad XR
Common Name: Medical image analyzer
Classification Name: Medical image analyzer
Device Classification: Class II, 21 CFR 892.2070
Product Code: MYN

4 Predicate Device

Name: Samsung Auto Lung Nodule Detection, K201560
Device Classification: Class II, 21 CFR 892.2070
Product Code: MYN

5 Device Description

5.1 VisiRad XR is a computer aided detection (CADe) software as a medical device (SaMD) product intended to detect lung nodules and masses from 6-60mm in chest radiographs. VisiRad XR takes DICOM images as input, utilizes machine learning algorithms to detect suspicious regions and outputs a secondary DICOM with annotated regions of interest (ROIs).

5.2 VisiRad XR's output secondary DICOM includes text that indicates that it was analyzed by VisiRad XR and a link to the user manual. If no ROIs are detected by VisiRad XR, the returned secondary DICOM states "No Nodules/Masses Found".

5.3 VisiRad XR is intended to be used as a second-read only after the clinician has performed their initial interpretation. The secondary DICOM does not overwrite or replace the primary radiograph, it is returned such that it hangs, using standard DICOM hanging protocol, behind the primary image.

6 Intended Use

6.1 VisiRad XR is intended to identify and mark regions of interest suspicious for lung nodules and masses on chest radiographs.

7 Indications for Use

7.1 VisiRad XR is a computer-aided detection (CADe) device intended to identify and mark regions of interest that may be suspicious for lung nodules and masses on chest radiographs. It identifies features associated with pulmonary nodules and masses from 6-60mm in size. Detection of suspicious findings by VisiRad XR is intended as an aid only after the physician has performed an initial interpretation; it is not intended to replace the review by a qualified radiologist and is not intended to be used for triage or to make or confirm a diagnosis. The intended patient population for VisiRad XR consists of patients >21 years of age on whom chest radiographs have been acquired in an outpatient or emergency department setting.

8 Substantial Equivalence

8.1 VisiRad XR has the same intended use as the predicate device. Differences in indications for use do not constitute a new intended use and differences in technological characteristics do not raise new questions of safety and effectiveness.

	Proposed Device	Predicate Device
Device Name	VisiRad XR	AutoLung Nodule Detection (ALND)
Manufacturer	IMIDEX, Inc.	Samsung Electronics
510(k) Number	--	K201560
Classification Regulation	21 CFR 892.2070	21 CFR 892.2070
Product Code	MYN	MYN
Intended Use	VisiRad XR is intended to to identify and mark regions of interest suspicious for lung nodules and masses on chest radiographs.	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.
Indications for Use	VisiRad XR is a computer-aided detection (CADe) device intended to identify and mark regions of interest that may be suspicious for lung nodules and masses on chest radiographs. It identifies features associated with pulmonary nodules and masses from 6-60mm in size. Detection of suspicious findings by VisiRad XR is intended as an aid only after the physician has performed an initial interpretation; it is not intended to replace the review by a qualified radiologist and is not intended to be used for triage or to make or confirm a diagnosis. The intended patient population for VisiRad XR consists of patients >21 years of age on whom chest radiographs have been acquired in an outpatient or emergency department setting.	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.
Image Modality	X-ray	X-ray

Study Type	Chest	Chest
Clinical Finding	Lung lesion detection using marked regions of interest (ROIs)	Lung lesion detection using marked regions of interest (ROIs)
Intended Users	Physician	Physician
Intended User Workflow	Device intended as a second-reader for physicians interpreting chest radiographs	Device intended as a second-reader for physicians interpreting chest radiographs
Patient Population	Adults with Chest Radiographs	Adults with Chest Radiographs
Technology	Machine learning	Machine learning
Input Type	Digital X-rays in DICOM format	Digital X-rays in DICOM format
Imaging protocols	Chest AP/PA	Chest PA
Output	ROI marked on duplicated input image	Information for ROI to be marked on the duplicated input image
Platform	Secure cloud-based processing and delivery of outputs	Secure on-premise processing and delivery of outputs

8.2 **Comparison of Indications**

8.2.1 VisiRad XR and Samsung ALND both analyze chest radiographs for the presence of lung nodules, return regions of interest (ROIs) on a secondary DICOM and act as a second-read for clinicians. VisiRad XR detects masses in addition to nodules (lesions are considered a "mass" if they are greater than 30mm in diameter, while a "nodule" is less than 30mm in diameter) and is a cloud-based software that operates on both AP and PA image views, as well as multiple chest radiograph hardware systems. Samsung ALND is limited to PA view images and its own S-Station hardware and software system. Both devices are only intended as an aid to the physician and not intended to replace the diagnosis by the physician. The differences in Indications for Use do not constitute a new intended use, as both devices are intended to assist physicians in identifying suspicious regions on chest radiographs and marking them with ROIs.

8.3 **Comparison of technological characteristics**

8.3.1 Performance and clinical testing were performed to support the safety and effectiveness of the technological differences between VisiRad XR and the predicate device. The results of these tests demonstrate that VisiRad XR has been designed and tested to conform to its intended use and comparably to the predicate device. Technological differences do not present any new safety or effectiveness concerns. As such, it can be considered substantially equivalent to the predicate devices.

9 Software Verification and Validation

9.1 **Non-clinical Performance Testing**

9.1.1 Software verification and validation testing were conducted to provide evidence that VisiRad XR meets user needs and its intended use. Testing results demonstrate that the software specifications meet acceptance criteria and support claims of substantial equivalence. Documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

9.1.2 A standalone performance test was executed on VisiRad XR to demonstrate generalizability and performance endpoints on a broad, representative dataset. The dataset consisted of data from three sources: National Lung Screening Trials (NLST) and two independent data sites. NLST is a high-quality, outpatient dataset that enrolled current or former heavy smokers. NLST consists of a set of patients that did not have lung cancer at study initiation, with geographic and demographic representation across the country. The two independent sites were a Level II trauma center at a rural group practice in Montana and a Level I trauma center in a metropolitan area of Colorado. Data was acquired from each site's emergency department between 2016 and 2021.

9.1.3 The primary endpoint for the standalone performance test was device sensitivity calculated at an image level. The study was executed at a fixed operating threshold. Study results demonstrated an overall sensitivity of 0.83 (95% CI: 0.81-0.84) with average false positives per image of 1.5.

9.1.4 Device performance was stratified across multiple subgroups (age, gender, race, hardware used). Device performance remains consistent between gender, age groups and hardware type used.

9.1.5 Area Under the Curve (AUC) of the Receiver Operating Characteristic (ROC) curve was assessed as a secondary endpoint in the standalone performance test. Overall AUC, calculated non-parametrically, was 0.73 (95% CI: 0.71-0.74).

9.1.6 The software level of concern for VisiRad XR is Moderate, since a malfunction of, or a latent design flaw in, the software device may lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

9.2 **Clinical Performance Testing**

9.2.1 IMIDEX conducted a fully-crossed multiple reader, multiple case (MRMC) retrospective reader study at two sites to validate the impact of VisiRad XR on reader performance in detecting pulmonary nodules and masses on chest radiographs. The study consisted of 24 clinical readers (12 per site) and 600 total patient images (300 per site).

9.2.2 The study was performed on retrospective chest radiographs taken on patients in emergency department and outpatient settings. The subject population was composed of patients from across the United States (data collection sites included Colorado, Ohio, New Jersey, South Carolina, Iowa and Wisconsin) who represent the range of age, racial and ethnic groups and geographic diversity that are representative of the intended use population. Women made up 56% of the study; of the population that disclosed racial data, 47% of the patient population identified as a racial group other than white or Caucasian.

9.2.3 The results of subgroup analyses showed that there were no clinically meaningful differences among the different demographic populations in study outcomes; reader performance improved across all evaluated demographic subgroups with the use of VisiRad XR.

9.2.4 The readers participating in the study were radiologists from multiple regions within the US with varied years of experience and specialties. They were de-identified for the purposes of the study.

9.2.5 The study was conducted sequentially to simulate use of the product in clinical practice. Readers interpreted the same radiograph twice in a row, first unaided then aided by VisiRad XR. They were asked to interpret the radiographs as they would in standard clinical practice and note nodules or masses with a bounding box and associated level of confidence in their interpretation.

9.2.6 The study compared unaided and aided radiologist performance at detecting pulmonary nodules and masses as compared to the reference standard. The primary objective of the study was to determine whether the accuracy of readers aided by VisiRad XR was superior to the accuracy of readers unaided by VisiRad XR as determined by the image-level Area Under the Curve (AUC) of the Receiver Operating Characteristic (ROC) curve. For both sites, the use of VisiRad XR improved readers' AUC with statistical significance. Mean AUCs for the two conditions calculated across all readers were compared using a two-sided test at the alpha=0.05 level of significance with a p value < 0.025, yielding an average reader improvement in overall average AUC for both sites of 0.027. Site I demonstrated an average AUC improvement of 0.035 (95% CI: 0.021, 0.048) and Site II demonstrated an average AUC improvement of 0.018 (95% CI: 0.005, 0.031).

9.2.7 Secondary endpoints for the study included sensitivity and specificity. Average sensitivity across all readers increased by 0.076. Site I demonstrated an average sensitivity improvement of 0.097 and Site II demonstrated an average sensitivity improvement of 0.053. Average specificity across all readers decreased by 0.086, with a decrease of 0.114 for Site I and 0.06 for Site II.

9.2.8 Although Samsung ALND did not publish clinical performance data in its 510(k) summary, the predicate device for Samsung ALND (Riverain ClearRead Detect) achieved the same clinical performance endpoints as VisiRad XR, demonstrating a statistically significant change in AUC between aided and unaided clinical reads. This demonstrates that VisiRad XR is substantially equivalent to its predicate device in clinical performance.

10 Conclusions

10.1 The conclusions drawn from the standalone and clinical studies demonstrate that VisiRad XR is safe, effective, and performs as well as its proposed predicate device. The special controls for the Medical Image Analyzer (CADe) 21 CFR 892.2070 regulation are satisfied by demonstrating effectiveness of the device in both the standalone testing and the clinical testing, showing superiority of aided versus unaided reads in clinical testing, and communicating testing results in the labeling. The technological differences between VisiRad XR and the predicate device do not raise concerns of safety and effectiveness. As such, VisiRad XR is substantially equivalent to the cleared Samsung Auto Lung Nodule Detection device.