Milvue
℅ Rory Carrillo
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45 Bartlett St.
San Francisco, California 94110

May 10, 2024

Re: K232410
Trade/Device Name: SmartChest
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: August 10, 2023
Received: April 8, 2024

Dear Rory Carrillo:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological 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.

Submission Number *(if known)*

K232410

Device Name

SmartChest

Indications for Use *(Describe)*

SmartChest is a radiological computer assisted triage and notification software that analyzes frontal chest X-ray images (Postero-Anterior (PA) or Antero-Posterior (AP)) of transitional adolescents (18 - 21 yo but treated like adults) and adults (≥22 yo) for the presence of suspected pleural effusion and/or pneumothorax. SmartChest uses an artificial intelligence algorithm to analyze the images for features suggestive of critical findings and provides case-level output available to a PACS (or other DICOM storage platforms) for worklist prioritization.

As a passive notification for prioritization-only software tool within the standard of care workflow, SmartChest does not send a proactive alert directly to a trained medical specialist.

SmartChest is not intended to direct attention to a specific portion of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

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.

510(k) #: K232410

510(k) Summary

Prepared on: 2024-04-06

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SmartChest
Common Name	Radiological computer aided triage and notification software
Classification Name	Radiological Computer-Assisted Prioritization Software For Lesions
Regulation Number	21 CFR 892.2080
Product Code	QFM

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate#	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211733	Lunit INSIGHT CXR Triage	QFM

Device Description Summary

21 CFR 807.92(a)(4)

SmartChest is a radiological computer assisted triage and notification software that analyzes frontal chest X-ray images (Postero-Anterior (PA) and/or Antero-Posterior (AP)) of transitional adolescents (18 ≤ age ≤ 21 yo but treated like adults) and adults (22 yo ≤ age) for the presence of suspected pleural effusion and/or pneumothorax. The software utilizes AI-based image analysis algorithms to detect the findings.

SmartChest provides case-level output available in the workstation for worklist prioritization by appropriately trained medical specialists qualified to interpret chest radiographs.Chest radiographs are automatically received from the user's image acquisition or storage systems (e.g., PACS, other DICOM storage platforms) and processed by SmartChest for analysis. After receiving Chest X-Ray images, the device automatically analyzes the images and identifies pre-specified suspected findings (pleural effusion and/or pneumothorax). Then the analysis results are passively sent by SmartChest via a notification to the worklist software being used (PACS, or other platforms).

The results are made available via a newly generated DICOM series (containing a secondary capture image), where DICOM tags contains the following information:

1. "SUSPECTED FINDING" or "CASE PROCESSED" if the algorithm ran successfully, "NOT PROCESSED" if the algorithm receives a study containing chest images that are not part of the intended use (lateral views or excluded age for example).

2. "SUSPECTED PLEURAL EFFUSION" OR "SUSPECTED PNEUMOTHORAX" if one pre-specified finding category identified OR,

3. "SUSPECTED PLEURAL EFFUSION, PNEUMOTHORAX" if the two pre-specified finding categories identified

4. The secondary capture image returned in the storage system indicates at the study-level:
   - The number of images received by SmartChest,
   - The number of images processed by SmartChest,
   - The status of the study: "NOT PROCESSED", "SUSPECTED FINDING" or "CASE PROCESSED".

The DICOM storage component may be a Picture Archiving and Communications (PACS) system or other local storage platforms. This would allow the appropriately trained medical specialists to group suspicious exams together that may potentially benefit their prioritization. Chest radiographs without an identified anomaly are placed in the worklist for routine review, which is the current standard of care.

The device is not intended to be a rule-out device and for cases that have been processed by the device without notification for pre-specified suspected findings it should not be viewed as indicating that the pre-specified findings are excluded. SmartChest device does not alter the order nor remove imaging exams from the interpretation queue. Unflagged cases should still be interpreted by medical specialists.

The notification is contextual and does not provide any diagnostic information. The results are not intended to be used on a stand-alone basis for clinical decision-making. The summary image will display the following statement: "The product is not for Diagnostic Use-For Prioritization Only".

Model Training
The training of the algorithm is made by using X-Ray radiographies collected from an unfiltered stream of exams in four French institutions between October 2018 & December 2021.

The distribution of data, aggregated from unfiltered streams of exams of targeted institutions is necessarily representative of the real-life distribution. The Training Set is composed of 9560 images, the distribution of exams per pathology for the Training Set is as follows:

i. No findings - 7,412 images
ii. Pleural Effusion - 1,435 images
iii. Pneumothorax - 713 images

These images are then processed to fit the model's requirements, which can involve resizing and normalizing the images. A structure of the CNN is then defined, which consists of different types of layers. The collected data are used to train the model, adjusting its weights based on the errors it makes in predictions. To fine-tune the model and prevent it from overly specializing in the training data, a separate validation set is used. Finally, the model's performance is assessed with a testing set to see how well it can handle unseen data. Depending on the results, it is possible to go back and adjust the data, model's structure, or fine-tuning parameters, then repeat the training process until the model performs satisfactorily

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

SmartChest is a radiological computer assisted triage and notification software that analyzes frontal chest X-ray images (Postero-Anterior (PA) or Antero-Posterior (AP)) of transitional adolescents (18 - 21 yo but treated like adults) and adults (≥22 yo) for the presence of suspected pleural effusion and/or pneumothorax. SmartChest uses an artificial intelligence algorithm to analyze the images for features suggestive of critical findings and provides case-level output available to a PACS (or other DICOM storage platforms) for worklist prioritization.

As a passive notification for prioritization-only software tool within the standard of care workflow, SmartChest does not send a proactive alert directly to a trained medical specialist.

SmartChest is not intended to direct attention to a specific portion of an image. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The predicate device Indications for Use is: Lunit INSIGHT CXR Triage is a radiological computer-assisted triage and notification software that analyzes adult chest X-ray images for the presence of pre-specified suspected critical findings (pleural effusion and/or pneumothorax). Lunit INSIGHT CXR Triage uses an artificial intelligence algorithm to analyze images for features suggestive of critical findings and provides case-level output available in the PACS/workstation for worklist prioritization or triage. As a passive notification for prioritization-only software tool within standard of care workflow, Lunit INSIGHT CXR Triage does not send a proactive alert directly to the appropriately trained medical specialists. Lunit INSIGHT CXR Triage is not intended to direct attention to specific portions of an image or to anomalies other than pleural effusion and/or pneumothorax. Its results are not intended to be used on a stand-alone basis for clinical decision-making.

The Indications for Use are similar and the Intended Use is the same.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device (SmartChest) and the predicate device (Lunit INSIGHT CXR) are both radiological computer assisted prioritization notification software. The technologies use artificial intelligence algorithms to analyze radiological images.

The subject and predicate devices share similar technological characteristics as follows:
- target population, intended user and use environment, anatomical site and modality, means of notification, standalone performance level, and triage effectiveness.

All outputs are the same between the subject device and the primary device.

The only difference is related to the predicate device being able to connect to radiological imaging equipment and in parallel also connecting to PACS. The subject device only connects to the PACS (or other DICOM storage platforms) and flags cases there.

These differences do not change or modify the risks associated with the device type nor does it raise new questions of safety or effectiveness.

Both the subject device and predicate device are only intended to passively notify the end user that a study is suspicious of the indicated findings and enable them to prioritize those studies, but the end user is still required to review all images and make the find clinical diagnosis.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Safety and performance of the SmartChest product has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with IEC 62304:2006/ A1:2016 - Medical device software - Software life cycle processes, in addition to the FDA Guidance documents, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submission for Management of Cybersecurity in Medical Devices."

Standalone Performance Testing

Two individual standalone performance assessment studies were conducted to evaluate the effectiveness of SmartChest. The studies were conducted on a dataset representative of the US population. This performance test data set was obtained from sites that were different from the training data sites and therefore this ensured the independence of the test data from training data. Each study was conducted on a dataset of 300 Chest X-Ray cases of transitional adolescent (18-21 years old) and adult (22 years and older) US subjects obtained from multiple institutions across the US..The ground-truth for the presence or absence of pneumothorax and pleural effusion was established by three ABR-certified radiologists with a minimum of 5 years of experience in cardiothoracic radiology: two radiologists independently interpreted each case and the third radiologist independently reviewed the cases where there was disagreement between the first two. The final reference standard was determined by majority consensus.

The evaluated performance metrics were similar to the predicate device: ROC AUC, Sensitivity, Specificity, and mean execution time (time from submission of the CXR case to the device to the provision of an output as a notification). For pneumothorax, the results are as follows: ROC AUC 0.989 [0.978; 0.997], Sensitivity 92.7% [95% CI: 87.4-96.2], and Specificity 97.3% [95% CI:93.4-99.1], Mean execution time of 2.322 ± 0.267 seconds on a local server and 28.542 ± 8.254 seconds on a cloud server. The dataset consisted of male (167 cases) and female (133 cases) and included an age range from 18 years to above 65 years. Images were obtained from rural (49) and urban (251) sites from across New York, North Carolina, Texas, and elsewhere. The dataset was obtained from various imaging system manufacturers and included AP (115 cases) and PA views (160 cases).

For pleural effusion, the results were as follows: ROC AUC 0.975 [0.960; 0.987], Sensitivity 93.3% [95% CI: 88.1-96.4], Specificity 90.0% [95% CI: 84.1-94.1], Mean execution time of 2.288 ± 0.165 seconds on a local server and 28.257 ± 7.226 seconds on a cloud server. The dataset consisted of male (158 cases) and female (142 cases) and included an age range from 18 years to above 65 years. Images were obtained from rural (53) and urban (247) sites from across New York, North Carolina, Texas, Washington, and elsewhere. The dataset was obtained from various imaging system manufacturers and included AP (105 cases) and PA views (180 cases).

In Summary, the SmartChest device performed successfully in the clinical pivotal studies. Standalone detection performance and execution time for pleural effusion and pneumothorax were adequate as compared to the predicate device. SmartChest device can therefore be considered as safe and effective as the predicate device.

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, the SmartChest product raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.