October 5, 2023

DeepTek Medical Imaging Pvt Ltd
℅ Carrillo Rory
Quality & Regulatory Consultant
3rd Floor, Ideas to Impact, Pallod Farms 3
Behind Vijay Sales, Baner
Pune, Maharashtra 411405
INDIA

Re: K231001
Trade/Device Name: DeepTek CXR Analyzer v1.0
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: September 8, 2023
Received: September 8, 2023

Dear Carrillo Rory:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices
and Electronic Products
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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)*

K231001

Device Name

DeepTek CXR Analyzer v1.0

Indications for Use *(Describe)*

DeepTek CXR Analyzer v1.0 is a computer-assisted detection (CADe) software device that analyzes chest radiograph studies using machine learning techniques to identify, categorize, and highlight suspicious ROIs in one of the following categories: Lungs, Pleura, Cardiac, and Hardware. The device is intended for use as a concurrent reading aid for radiologists. DeepTek CXR Analyzer v1.0 is indicated for adults and transitional adolescents (18 to <22 years old but treated like adults) only.

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.

K231001

510(k) Summary

1. General Information

510(k) Sponsor	DeepTek Medical Imaging Pvt Ltd
Address	3rd Floor, Ideas to Impact, Pallod Farms 3 Behind Vijay Sales, Baner Pune, India, Maharashtra 411405
Correspondence Person	Rory A. Carrillo Regulatory Consultant Cosm
Contact Information	Email: rory@cosmhq.com Phone: 415-580-0916
Date Prepared	April 07, 2023

2. Proposed Device

Proprietary Name	DeepTek CXR Analyzer v1.0
Common Name	CXR Analyzer
Classification Name	Medical image analyzer
Regulation Number	892.2070
Regulation Name	Medical image analyzer
Product Code	MYN
Regulatory Class	II

3. Predicate Device

Proprietary Name	Chest-CAD
Premarket Notification	K210666
Classification Name	Medical image analyzer
Regulation Number	892.2070
Regulation Name	Medical image analyzer
Product Code	MYN
Regulatory Class	II

4. Device Description

DeepTek CXR Analyzer is a computer-assisted detection (CADe) software device developed to assist radiologists in identifying suspicious regions of interest (ROIs) in the following categories: Lungs, Pleura, Cardiac, and Hardware. DeepTek CXR Analyzer detects suspicious ROIs by analyzing adult frontal chest radiographs using deep learning algorithms and provides relevant annotations to assist radiologists with their interpretations.

The device has an authentication graphical user interface, which allows the user to authenticate themselves. The user can connect the PACS with the DeepTek CXR Analyzer using the configuration interface. The user can enter the PACS AE Title, IP address, Listener and Sender Port number to configure the device. Once the device is configured correctly, DeepTek CXR Analyzer receives chest radiographs from the configured PACS in DICOM format as input. DeepTek CXR Analyzer identifies suspicious ROIs in the following categories: Lungs, Pleura, Cardiac, and Hardware, and sends the secondary capture DICOM with AI output to the same PACS over the DICOM protocol. The output DICOM File Processing component creates a DICOM image containing the original radiograph with a message stating that the image was analyzed by DeepTek CXR Analyzer (with information containing manufacturer name, product name, product version, and a link to user manual) and color-coded bounding boxes containing suspected ROIs. If no suspicious ROIs are detected in the image, the output will not contain any bounding boxes and will have a message stating "No Suspicious ROI(s) Detected". In the event of any type of failure in the workflow, a human-readable error message representing the type of failure will be logged in the Logs interface.

DeepTek CXR Analyzer does not make treatment recommendations or provide a diagnosis. Radiologists should review images annotated by DeepTek CXR Analyzer concurrently with original, unannotated images before making the final decision on a case. DeepTek CXR Analyzer is an adjunct tool and does not replace the role of the radiologists. The CAD-generated output should not be used as the primary interpretation by radiologists.

DeepTek CXR Analyzer has been trained using a large and diverse dataset of more than 100,000 chest X-ray images sourced from 30 distinct sites from India, including medical imaging centers, data partners, and medical hospitals, and over 15 different modality manufacturers. The inclusion of such a diverse range of data ensures that the performance of the DeepTek CXR Analyzer generalizes to a wide variety of confounders.

DeepTek CXR Analyzer is not designed to detect conditions other than those classified under the following categories: Lung, Cardiac, Pleura, and Hardware. Radiologists should review original images for all suspected ROIs.

5. Indications For Use

The DeepTek CXR Analyzer V1.0 is a computer-assisted detection (CADe) software device that analyzes chest radiograph studies using machine learning techniques to identify, categorize, and highlight suspicious ROIs in one of the following categories: Lungs, Pleura, Cardiac, and Hardware. The device is intended for use as a concurrent reading aid for radiologists. DeepTek CXR Analyzer V1.0 is indicated for adults and transitional adolescents (18 to <22 years old but treated like adults) only.

6. Substantial Equivalence

Feature/ Function	**Proposed Device** DeepTek CXR Analyzer	**Predicate Device** Chest-CAD (K210666)
Indications for Use	The DeepTek CXR Analyzer V1.0 is a computer-assisted detection (CADe) software device that analyzes chest radiograph studies using machine learning techniques to identify, categorize, and highlight suspicious ROIs in one of the following categories: Lungs, Pleura, Cardiac, and Hardware. The device is intended for use as a concurrent reading aid for radiologists. DeepTek CXR Analyzer V1.0 is indicated for adults and transitional adolescents (18 to <22 years old but treated like adults) only.	Chest-CAD is a computer-assisted detection (CADe) software device that analyzes chest radiography studies using machine learning techniques to identify, categorize, and highlight suspicious regions of interest (ROI). Any suspicious ROI identified by Chest-CAD is assigned to one of the following categories: Cardiac, Mediastinum/Hila, Lungs, Pleura, Bones, Soft Tissues, Hardware, or Other. The device is intended for use as a concurrent reading aid for physicians. Chest-CAD is indicated for adults only.
Image Modality	X-ray	X-ray
Study Type	Chest	Chest
Image Type	DICOM	DICOM
Clinical Output	Identify and mark regions of interest (ROIs) on chest radiographs	Identify and mark regions of interest (ROIs) on chest radiographs

Feature/ Function	**Proposed Device** DeepTek CXR Analyzer	**Predicate Device** Chest-CAD (K210666)
Clinical Finding	Identified ROIs are assigned to one of the following categories: Lungs, Pleura, Cardiac, or Hardware	Identified ROIs are assigned to one of the following categories: Cardiac, Mediastinum/Hila, Lungs, Pleura, Bones, Soft Tissues, Hardware, or Other
Intended Users	Radiologists	Physicians
Intended User Workflow	Device intended for use as a reading aid for radiologists interpreting chest radiographs	Device intended for use as a reading aid for physicians interpreting chest radiographs
Patient Population	Adults with Chest Radiographs	Adults with Chest Radiographs
Algorithm Methodology	Artificial Neural Networks	Artificial Neural Networks
Platform	Secure on-premise processing and delivery of chest radiographs	Secure cloud-based processing and delivery of chest radiographs
Image Source	Digital X-ray	Digital X-ray
Image Viewing	Image displayed on PACS system	Image displayed on PACS system

7. Performance Data

Safety and performance of the DeepTek CXR Analyzer has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification, validation, standalone and clinical performance testing. Additionally, the software validation activities were performed in accordance with *IEC 62304 Edition 1.1 2015-06 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 *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"*

Performance data from standalone and clinical performance assessments are summarized below.

Standalone Performance Assessment

DeepTek conducted a standalone performance assessment to evaluate the performance of DeepTek CXR Analyzer software device in detection (by measuring sensitivity, specificity, and AUROC) and localization (by measuring wAFROC-FOM) of suspicious ROIs from chest X-rays and classifying each ROI into one of the following four categories: Lungs, Pleura, Cardiac, or Hardware.

The primary objective of this study was to measure and report the performance of DeepTek CXR Analyzer independently in the absence of any interaction with human readers.

The test dataset included 2,000 scans from the NIH Chest X-ray Database and 1,000 scans from the Segmed Insight Platform. The dataset from NIH Chest X-ray Database included chest radiographs from 55.6% male and 44.4% female patients. 30.1% of radiographs included in the study were acquired in AP view and 69.9% of radiographs were acquired in PA view. The dataset from the Segmed Insight Platform included data from 13 different sites across various regions of the United States. The dataset from Segmed Insight Platform included chest radiographs from 45.7% male and 54.3% female patients. 21.6% of the chest radiographs were from the age group 18-35, 38.4% of the chest radiographs were from the age group 36-60, and 40% of the chest radiographs were from patients aged 61 years and above. 40.5% of radiographs included in the study were acquired in AP view and 59.5% of radiographs were acquired in PA view. Out of 1,000 scans, racial information was available for 699 scans with individuals of White (46%), Black (15.7%), Asian (5.8%), and other racial (2.3%) backgrounds. Ethnicity information was available for 286 (28.6%) scans with individuals of Hispanic or Latino (20.2%) and non-Hispanic or non-Latino (8.4%) ethnicity. The data was acquired from the following X-ray imaging devices: Samsung Electronics (25.6%), Fujifilm Corporation (20.8%), Konica Minolta (13.7%), Carestream Health (20.3%), Canon Inc. (7.8%), GE Healthcare (7.7%), PACSGear (3.3%), Siemens (0.6%), and Philips Medical Systems (0.2%). This dataset was not used for the DeepTek CXR Analyzer model training and development. Individuals involved in the model development exercise were not involved in the study design or analysis.

The ground truth for each case and category was established by a panel of 3 U.S. board-certified radiologists with 9, 11, and 25 years of experience, respectively. The ground truth (GT) label for the presence or absence of ROI for each category was defined as the majority opinion of 2 out of the 3 the radiologists. If the majority opinion stated suspicious ROI was present for a particular category, the union of the area encompassed by the bounding boxes made by all annotators identifying suspicious ROI for that particular category was taken as ground truth ROI. If the majority opinion stated suspicious ROI was absent, ROI was not demarcated on the image.

The detection performance and localization performance results were as follows:

Detection Performance

The device performance in detecting suspicious ROIs was measured by the area under the receiver operating characteristic (AUROC) curve and the sensitivity and specificity obtained by the device at the recommended operating threshold. AUROCs were highest for Cardiac (0.978 [0.968-0.985]) and Hardware (0.980 [0.976-0.983]) and lowest for Pleura (0.964 [0.954-0.970]). Sensitivity was highest for Hardware (0.947 [0.936-0.955]) and lowest for Lungs 0.903 [0.887-0.914]. Specificity was highest for Hardware (0.947 [0.936-0.955]) and lowest for Pleura (0.897 [0.879-0.911]).

The DeepTek CXR Analyzer demonstrated the following results for detection of ROIs.

Image-Level Detection Performance			
	Sensitivity [95% CI]	**Specificity [95% CI]**	**AUROC [95% CI]**
Lungs	0.903 [0.887-0.914]	0.937 [0.927-0.948]	0.971 [0.968-0.976]
Pleura	0.924 [0.902-0.932]	0.897 [0.879-0.911]	0.964 [0.954-0.970]
Cardiac	0.924 [0.890-0.952]	0.930 [0.925-0.941]	0.978 [0.968-0.985]
Hardware	0.947 [0.936-0.955]	0.947 [0.939-0.954]	0.980 [0.976-0.983]
Aggregate	**0.926 [0.917-0.933]**	**0.933 [0.925-0.938]**	**0.974 [0.970-0.977]**

Table 1. Sensitivity, specificity, and AUROC for detection of ROIs in Lungs, Pleura, Cardiac, and Hardware by DeepTek CXR Analyzer.

Localization Performance

The device performance in localizing the suspicious ROIs was measured by the area under the weighted alternative free-response receiver operating characteristic curve as the figure of merit (wAFROC-FOM). DeepTek CXR Analyzer was excellent across all four categories with the highest wAFROC-FOM for Cardiac (0.952 [0.941-0.966]) and Hardware (0.954 [0.948-0.963]), and the lowest for Pleura (0.884 [0.866-0.902]). The device achieved an aggregated wAFROC-FOM of (0.920 [0.908-0.926]) across all chest findings together.

The DeepTek CXR Analyzer demonstrated the following results for localization of ROIs.

ROI-Level Localization Performance	
	wAFROC-FOM [95% CI]
Lungs	0.913 [0.904-0.924]
Pleura	0.884 [0.866-0.902]
Cardiac	0.952 [0.941-0.966]
Hardware	0.954 [0.948-0.963]
Aggregate	**0.920 [0.908-0.926]**

Table 2: wAFROC-FOM for localization of ROIs in Lungs, Pleura, Cardiac, and Hardware by DeepTek CXR Analyzer

Clinical Performance Assessment

DeepTek conducted a fully-crossed multiple reader, multiple case (MRMC) retrospective study to determine the impact of the DeepTek CXR Analyzer on reader performance in detecting and localizing suspicious ROIs in chest radiographs. This study protocol was designed in accordance with FDA's guidance document for industry and FDA staff titled "*Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data in Premarket Notification (510(k)) Submissions*".

The primary objective of the clinical reader study was to determine whether the performance of readers aided by DeepTek CXR Analyzer is superior to their performance when unaided by DeepTek CXR Analyzer, as determined by the wAFROC-FOM score.

Null hypothesis H_0: $\text{wAFROC-FOM}_{aided} - \text{wAFROC-FOM}_{unaided} \leq 0$

Alternate hypothesis H_1: $\text{wAFROC-FOM}_{aided} - \text{wAFROC-FOM}_{unaided} > 0$

where $\text{wAFROC-FOM}_{aided}$ is the population-mean wAFROC-FOM for aided reads, and $\text{wAFROC FOM}_{unaided}$ is the population-mean for unaided reads.

The test dataset consisted of 300 frontal chest radiographs obtained from 13 U.S. hospitals. 24 U.S. board-certified radiologists with varying levels of experience were enrolled in this study. The clinical performance assessment consisted of two independent reading sessions separated by a washout period of 30 days in order to mitigate memory bias. During the first reading session, the readers evaluated each scan in the test dataset while not being aided by the device (unaided reading). During the second reading session, the readers evaluated each scan again, but this time they were aided by the device (aided reading). The evaluation workflow for the unaided and aided readings was identical except that, during the aided reading, a secondary image containing device output markers was shown to the readers in addition to the original image.

The area under the weighted alternative free-response receiver operating characteristic curve as the figure of merit (wAFROC-FOM) was used for comparing the performance of the readers during the unaided reading sessions with their performance during the aided reading sessions.The wAFROC-FOM for aided readings was 0.893 [0.871-0.914], which was significantly higher ($p<0.0001$) than the wAFROC-FOM of 0.821 [0.791-0.852] for unaided readings

The DeepTek CXR Analyzer demonstrated the following results in clinical performance assessment.

Category	**wAFROC-FOM**	
	Unaided [95% CI]	**Aided [95% CI]**
Lungs	0.853 [0.820-0.887]	0.919 [0.896-0.943]
Pleura	0.806 [0.763-0.850]	0.853 [0.815-0.892]
Cardiac	0.825 [0.781-0.869]	0.886 [0.842-0.930]
Hardware	0.919 [0.887-0.950]	0.952 [0.931-0.973]
Aggregate	**0.821 [0.791-0.852]**	**0.893 [0.871-0.914]**

Table 3: wAFROC-FOM scores for unaided and aided readers when localizing ROIs in Lungs, Pleura, Cardiac, and Hardware

The localization-level clinical performance assessment demonstrated that 24/24 (100%) readers showed an improvement in wAFROC-FOM for localizing suspicious ROIs across all categories when they were aided by DeepTek CXR Analyzer.

Summary for Improvement in wAFROC-FOM of readers
23/24 (96%) readers showed an improvement in wAFROC-FOM for localizing suspicious lungs ROIs
21/24 (88%) readers showed an improvement in wAFROC-FOM for localizing suspicious pleura ROIs
24/24 (100%) readers showed an improvement in wAFROC-FOM for localizing suspicious cardiac ROIs
20/24 (83%) readers showed an improvement in wAFROC-FOM for localizing suspicious hardware ROIs
24/24 (100%) readers showed an improvement in wAFROC-FOM for localizing suspicious ROIs across all categories

Table 4: Improvement in wAFROC-FOM for aided readings

Sensitivity and specificity across all readers and categories during unaided and aided readings are presented in Table 5.

Reader	Category	Sensitivity		Specificity	
		Unaided [95% CI]	Aided [95% CI]	Unaided [95% CI]	Aided [95% CI]
All readers	Aggregate	0.810 [0.699-0.902]	0.886 [0.813-0.945]	0.911 [0.804-0.972]	0.949 [0.884-0.990]

Table 5: Sensitivity and specificity across all readers and categories during the unaided and aided reading sessions

8. Conclusion

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