Deeptek Medical Imaging Private Limited
% Manoj Zacharias
US Agent
Liberty Management Group Ltd.
75 Executive Drive, Suite 114
Aurora, IL 60504

April 11, 2023

Re: K222781
Trade/Device Name: Augmento
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 10, 2023
Received: March 14, 2023

Dear Manoj Zacharias:

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 and Part 809); 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,

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.

510(k) Number *(if known)*
K222781

Device Name
Augmento

Indications for Use *(Describe)*
Augmento is a web-based PACS and radiology workflow management solution. It receives digital images and data from various DICOM compliant sources (i.e. CT scanners, MR scanners, ultrasound systems, RF Units, PET Units, computed & digital radiographic devices, secondary capture devices, imaging gateways and other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and/or across computer networks at distributed locations.

Only preprocessed DICOM "for presentation" images can be interpreted for primary image diagnosis in mammography. Lossy compressed images and digitized film screens of mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets technical specifications identified by the FDA.

This system is meant to be used by trained and qualified medical professionals, e.g physicians, radiologists, nurses, and medical technicians.

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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510(k) Summary (K222781)

[AS REQUIRED BY 21CFR807.92]

I. APPLICANT INFORMATION

Submitter's Name	DEEPTEK MEDICAL IMAGING PRIVATE LIMITED
Submitter's Address	3rd floor, Ideas to impact, Pallod Farms 3, Baner, 411045, Pune, Maharashtra, INDIA
Name of Contact Person	Kallol Sen
Designation	Head of Quality and Regulatory compliance
Contact Number	+91 9804019133
Contact E-mail	regulatory@deeptek.ai
Date of Summary Prepared	03/04/2023

II. DEVICE DETAILS

Device Trade Name	Augmento
Device Common Name	Medical image management and processing system
Regulation Name	Medical image management and processing system
Regulation Number	21 CFR 892.2050
Device Class	Class 2
Product Code	LLZ

III. PREDICATE DEVICE DETAILS

Device Trade Name	NubeX
Device Manufacturer Name	TechHeim Co., Ltd
510(k) Number	K211480
Regulation Number	21 CFR 892.2050
Device Class	Class 2
Product Code	LLZ

IV. DEVICE DESCRIPTION

Augmento is a web based PACS and radiology workflow management solution. It is used to receive DICOM images from multiple systems, organize and store them into a centrally managed worklist and distribute the information across a web-based network. It is used by hospitals, imaging centers, radiologists, radiology professional services providers, and any user who requires and is granted access to the patient image, information, and reports. It is intended to be used as a platform for the diagnosis and analysis of radiology images by trained and qualified medical personnel such as radiologists, physicians, nurses, and medical technicians.

It receives digital images and data from various DICOM-compliant sources (i.e., CT scanners, MR scanners, ultrasound systems, RF Units, PET Units, computed & digital radiographic devices, secondary capture devices, imaging gateways, and other imaging sources). It provides MPR/MIP post-processing components that allow enhanced visualization to radiologists and assist them in diagnostic analysis and quantification of Computed Tomography (CT) and Magnetic Resonance (MR) images. When images are reviewed and used for diagnosis, it is the responsibility of the medical professional to determine if the quality of the images is suitable for clinical application.

It provides optional integration with FDA-cleared 3rd party AI models. The solution only provides support for the visualization of outputs of 3rd party AI models "as-is". The safety and effectiveness of the 3rd party model is covered under the original 3rd party manufacturer's regulatory clearance. Augmento receives the output merely displays the simple output and the original image is always accessible. It is the responsibility of qualified medical practitioners to review the AI output, confirm the finding, and perform the diagnosis.

Augmento incorporates the following:

1. The system consists of the Gateway that is installed on the client side within the network of the modality/PACS. It can be deployed over conventional TCP/IP networking infrastructure available in most healthcare organizations. The Gateway is installed on a computer with a stable internet connection for web-based transmission or connected to a Local Area Network (LAN) for image transmission within a given network. The gateway receives the DICOM images from various DICOM-compliant sources and pushes them to the Augmento platform. The gateway also receives secondary capture images from the Augmento platform and sends these out to the connected hospital PACS.
2. It has a Study List, which includes all the studies that are uploaded to the system.
3. It has a radiology workflow management system. Supervisors can assign the studies to Radiologists. Radiologists can then view the study images, diagnose them and prepare reports.
4. It is used by radiologists to view the DICOM images for diagnosis and reporting. The viewer supports DICOM images from Digital X-Ray (DX), Computerized Radiography (CR), Ultrasound (US), Computed Tomography (CT), Magnetic Resonance (MR), Nuclear Medicine (NM), Digital Mammography (MG), Positron Emission Tomography (PET), Radiographic imaging (RG), Radio Fluoroscopy (RF) and X-Ray Angiography (XA).
5. It supports optional integration with FDA-cleared 3rd party AI models. It sends the input study to the 3rd party AI model, receives the AI output and displays outputs of the 3rd party AI model "as-is" in the Viewer

for visualization by the Radiologist to assist in diagnosing the study. Outputs are displayed in accordance with the 3rd party provider's regulatory clearance. The original image is always accessible.

6. It can provide alerts for the studies in the Worklist based on the outputs provided by the 3rd party AI models.
7. It displays the output of the 3rd party AI model in the Viewer for visualization by the Radiologist to assist in diagnosing the study.
8. It provides MPR/MIP 2D multi-planar reconstruction post-processing components that allow enhanced visualization to radiologists and assist them in diagnostic analysis.
9. The Analytics component provides analytical reports based on the studies uploaded and reported on the system.
10. Smart Notifications are sent to all users on all important events in the application. None of these notifications are related to potentially suspected findings identified by the FDA-cleared 3rd party AI models optionally integrated with Augmento.
11. It provides a communication feature to all the users associated with a given study.
12. For data storage, an RDBMS is used. For saving and retrieving DICOM images, thumbnails, clinical documents, and radiologist signatures an object storage server is used.
13. The network type used is TLS-based transmission with HTTPS and AES encryption.

V. INDICATIONS FOR USE

Augmento is a web-based PACS and radiology workflow management solution. It receives digital images and data from various DICOM compliant sources (i.e. CT scanners, MR scanners, ultrasound systems, RF Units, PET Units, computed & digital radiographic devices, secondary capture devices, imaging gateways, and other imaging sources). Images and data can be stored, communicated, processed, and displayed within the system and/or across computer networks at distributed locations.

Only preprocessed DICOM "for presentation" images can be interpreted for primary image diagnosis in mammography. Lossy compressed images and digitized film screens of mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets the technical specifications identified by the FDA.

This system is meant to be used by trained and qualified medical professionals, e.g physicians, radiologists, nurses, and medical technicians.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: General Comparison

Sl. No	Features compared	Proposed Device	Predicate Device	Result
General Information				
1.	510(k) Number	K222781	K211480	-
2.	Manufacturer	DEEPTEK MEDICAL IMAGING PRIVATE LIMITED	TECHHEIM CO., LTD	-
3.	Common Name	Medical image management and processing system	Medical image management and processing system	Same
4.	Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
5.	Classification	Class II	Class II	Same
6.	Regulation number	21 CFR 892.2050	21 CFR 892.2050	Same
7.	Product Code	LLZ	LLZ	Same
8.	Indications For Use	Augmento is a web-based PACS and radiology workflow management solution. It receives digital images and data from various DICOM-compliant sources (i.e. CT scanners, MR scanners, ultrasound systems, RF Units, PET Units, computed & digital radiographic devices, secondary capture devices, imaging gateways, and other imaging sources). Images and data can be stored, communicated, processed, and displayed within the system and/or across computer	NubeX PACS is a software device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations. Only preprocessed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed mammographic images and	Same

Sl. No	Features compared	Proposed Device	Predicate Device	Result
		networks at distributed locations. Only preprocessed DICOM "for presentation" images can be interpreted for primary image diagnosis in mammography. Lossy compressed images and digitized film screens of mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets the technical specifications identified by the FDA. This system is meant to be used by trained and qualified medical professionals, e.g., physicians, radiologists, nurses, and medical technicians.	digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets technical specifications identified by FDA. Typical users of this system are trained professionals, e.g. Physicians, radiologists, nurses, and medical technicians.	
9.	Prescription or OTC	Prescription	Prescription	Same
Specifications				
10.	Modalities	Various Image sources	Various image sources	Same
11.	Web browser software	Google Chrome, Mozilla, and Edge	Google Chrome	Similar[1]
12.	Resolution	32bit Color Display & 1920x1080	32bit Color Display & 1920x1080	Same
13.	Image Storage	Yes	Yes	Same
14.	Software environment	OS: Windows 10	OS: Windows 10	Same

Sl. No	Features compared	Proposed Device	Predicate Device	Result
		Functions		
15.	Main Functions	• Log In • Worklist – Search Filter • Worklist – Open image • Work list- study List • Worklist – Report • Worklist – Series • Viewer – View exam • Viewer – Control View window • Viewer – view mode (real resolution) • Viewer – View mode (Highlight) • Viewer – Stacking • Viewer – Changing the layout • Viewer – Comparative study • Viewer – Preset filter • Viewer - Zoom • Viewer – Panning • Viewer - Invert Image • Viewer – Viewing mode (Normal/ Image/ Stack/ Custom/ Annotation) • Viewer – Comparative study • Viewer – Rotation • MIP/MPR Reconstruction • Viewer – Reference line • Viewer – Sharpening • Viewer – Measure • Viewer – Inverting image color • Viewer – Cine • Viewer- Overlaying.	• Log In • Worklist – Search Filter • Worklist – Open image • Worklist – exam list • Worklist – Report • Worklist – Series • Viewer – View exam • Viewer – Control View window • Viewer – view mode (large) • Viewer – view mode (real resolution) • Viewer – View mode (Highlight) • Viewer – Stacking • Viewer – Changing the layout • Viewer – Preset filter • Viewer - Zoom • Viewer – Panning • Viewer - Invert Image • Viewer – Viewing mode (Normal/ Image/ Stack/ Custom/ Annotation) • Viewer – Comparative study • Viewer – Advanced image operation • Viewer – Scout line • Viewer – Rotation • Viewer – Sharpening • Viewer – Cine	Similar[2]
16.	3D Cursor	Yes	Yes	Same

Sl. No	Features compared	Proposed Device	Predicate Device	Result
17.	Optional Integration of FDA-cleared 3rd party AI models	Yes	No	Different
18.	Operation feature	• Web environment-based PACS. • Viewing and handling DICOM medical images. • Review and report study located on a server	• Web environment-based PACS. • Viewing and handling DICOM medical images. • Review, modify and approve the study located in a server.	Same

The technological principle for both the subject and predicate devices are the same in terms of Prescription Use, support of various modalities, resolution, image storage, use of DICOM Standard, 3D Cursor, and Operation features. Most of the features, specifications and functions of both the subject and predicate devices like indications for use, software web browser, software intended environment, study viewer, and study worklist are similar.

Augmento provides the feature of optional integration with external FDA-cleared 3rd party AI models whereas NubeX does not claim to have this feature. The integration with the FDA-cleared 3rd party AI models is optional, based on the user's discretion, and always in accordance with the 3rd party manufacturer's regulatory clearance. Further, Augmento receives the AI output and merely displays the output of the integrated FDA-cleared 3rd party AI models, "as-is". Similarly, the Arterys MICA (K203744) device included such an addition with the ability to integrate with 3rd party AI models and display the model's outputs within their viewer. Hence, the difference does not affect the product effectiveness and safety.

VII. NON-CLINICAL PERFORMANCE DATA

The Non-Clinical performance activities include:

- Risk management & Cybersecurity
  - Device Hazard analysis
  - Cybersecurity Risk Assessment
- Usability Testing
- Software Verification & Validation
  - User Acceptance Testing
  - Software Unit Test
  - Software Integration Test and System Test
- Angle Measurement Study
- Augmento - 3rd Party AI Model Integration Interface Testing

Non-clinical testing consisted of:

- Device Hazard Analysis and mitigations, and design considerations pertaining to intentional and unintentional risks associated with Augmento to reduce the risks as per ISO 14971:2019, evidence of Risk-handling activities that may be invoked throughout the life of the device, are detailed.
- Vulnerability Assessment & Penetration testing to check whether the security controls are adequately implemented in Augmento to mitigate the cybersecurity risks.
- Usability testing for verifying and validating the usability of the Augmento user interface in reference to IEC 62366-1:2015 are done.
- User Acceptance Testing is to test all the features which comply with the intended use of Augmento. The intended use of the software is verified against SRS / SDS documents.
- Unit Testing is to verify end-to-end workflow-based units encompassing all the major units of the product, ensuring that the unit code is complying with the correctness, completeness, and intended use of the product.
- In Integration testing, end-to-end integration of the different software components covering APIs, external SOUP applications and tools, independent Libraries, etc across all the different features, and functionalities of Augmento are tested. System testing covers all the functional testing for end-to-end working. The functionalities cover, but are not restricted to Configuration and Settings, User management, DICOM viewer and DICOM Acceptor's working, Search operations, Assigning Radiologists, Smart tags operations, Conversation operations, Report Management, Audit Log Management, Error Handling, and Hospital Management
- Unit testing, Integration & System testing, and User Acceptance Testing (UAT) for which test cases were created and executed. The test cases were addressed and successfully passed the acceptance criteria.
- Angle Measurement study was conducted to establish the substantial equivalence of the limit and accuracy of the angle tool of Augmento in comparison with an FDA-cleared DICOM viewer. In the study, an FDA-cleared DICOM viewer was used to measure the common angles from different X-ray scans. Replicability was demonstrated by measurements made by two readers in twelve independent X-ray scans from four different categories: frontal chest, AP knee, lateral ankle, and AP pelvis. These measurements were compared to the angles measured using Augmento. Two statistical analysis tests: the equivalence test and T-test were used. The limit of the angle measurement tool of Augmento is observed to be equivalent to the angle measurement tool of FDA-cleared DICOM viewer (Sotneta MedDream Viewer(K162011)) is in the range of 0° and 180°. The results conclude that the two viewers are substantially equivalent.
- The integration interface between Augmento and 3rd party AI model was tested to confirm that the integrity of the source DICOM file and output from AI models is unaltered and hence, does not get impacted when the source file is sent to the AI model for findings and the AI model sends the output to Augmento through the interface.

The non-clinical testing demonstrates that the subject device performs in accordance with its intended use, complies with the requirements specified in the FDA-recognized consensus standards, software level of concern is "moderate" and meets the acceptance criteria indicating that the subject device does not raise any new safety and/or effectiveness concerns and is substantially equivalent to the predicate.

The standards applicable as per Recognized Consensus Standards are as below:

- IEC 62304 Edition 1.1 2015-06 Consolidated Version Medical device software - Software life cycle processes.
- IEC 62366-1:2015: Medical devices-Part 1: Application of usability engineering to medical devices.
- ISO 14971 Third Edition 2019-12 Medical Devices - Application of risk management to medical devices.
- NEMA PS 3.1 - 3.20 2021 Digital Imaging and Communications in Medicine (DICOM) Set.
- IEC ISO 10918-1 First edition 1994-02-15 Information technology - Digital compression and coding of continuous-tone still images: Requirements and guidelines [Including Technical Corrigendum 1 (2005)].

VIII. CONCLUSION

The subject device and the predicate device NubeX (K211480) have similar indications for use, technological characteristics, and principles of operation. Based on the technological characteristics and non-clinical performance testing we conclude that Augmento is as safe and effective as its predicate device and does not raise any new issues related to safety and effectiveness compared to the predicate. Therefore, the subject device Augmento is substantially equivalent to the predicate device.