EBM Technologies, Inc.
℅ Mr. John Su
Regulatory Affairs Manager
5F., No. 516, Sec. 1, Neihu Rd.
Taipei, Taiwan 11493
REPUBLIC OF CHINA

October 5, 2020

Re: K202292
Trade/Device Name: UDE
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 27, 2020
Received: August 12, 2020

Dear Mr. Su:

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,

For

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)*

K202292

Device Name
UDE

Indications for Use *(Describe)*

UDE software is intended to display images from CT, MR, CR, US, XA and SC for the trained physician 's diagnosis or referring purpose. UDE provides wireless and portable access to medical images. It is not intended to be used as, or to replace, a full diagnostic workstation or system and should be used only when there is no access to a workstation. This device is not to be used for mammography diagnosis.

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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K202292

5.1 Device Submitter

EBM Technologies Incorporated
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Contact Person: John Su
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5.2 Device Name

Device Trade Name: UDE
Device Class : Class 2
Product Code : LLZ
Regulation name and number: Picture Archiving and Communications System , 21 CFR 892.2050

5.3 Substantially Equivalent (predicate) device(s)

Device Trade Name: EBM iDO Viewer
510(k) Number: K140399
Device Class : Class 2
Product Code : LLZ
Regulation name and number: Picture Archiving and Communications System , 21 CFR 892.2050
Manufacturer: EBM Technologies Incorporated

5.4 Device Description:

UDE is a software device that can be installed on Apple iPad Pro. Through wireless network, user can login, query and display the images which are stored in heir existing UDE server. The device can be installed in iOS 9, 11, 12 and 13 version platform such as iPad /iPhone, but can't be installed in platforms other than iOS 9, 11, 12 and 13 version . The image display quality on iPad /iPhone will be almost the same as on iPad Pro when it is used for diagnosis purpose of CT, MR, US, XA and SC. However, if it is used for CR diagnosis purpose, we will strongly suggest that users should adopt iPad Pro. because the screen size of iPad Pro is larger than those of Apple® iPad/iPhone.

Main features of UDE are listed below

- Receive, Store, Retrieve, Display, and Process Digital Images(CT, MR, US, CR, Full- Field Mammography, XA,SC etc.)
- The displayed CT, MR, CR,, US,XA and SC images can be diagnosed by the trained physicians.
- The displayed CT, MR, CR, Full- Field Mammography, US, XA and SC images can be referred by the trained physicians. Mammography images are not for diagnostic use
- Communication log file
- Auto delete old images (FIFO)
- Overlay labels
- User Authentication
- Display of Clinical Patient Data
- Distance Calculation
- layout adjustment (1×1, 2×1, 1×2, 2×2)
- Pan
- Zoom
- Window Level
- Cine Loop
- Mammography hanging protocol

5.5 Indication for Use:

UDE software is intended to display images from CT, MR, CR, US, XA and SC for the trained physician 's diagnosis or referring purpose. UDE provides wireless and portable access to medical images. It is not intended to be used as, or to replace, a full diagnostic workstation or system and should be used only when there is no access to a workstation. This device is not to be used for mammography diagnosis.

5.6 Technical characteristics

UDE is a software device that can be installed on Apple iPad Pro. Through wireless network, user can login, query and display the images which are stored in heir existing UDE server.
It has functions related to the medical image presentation and processing. These functions can help the trained physician to perform the medical images review and diagnosis if environment lighting condition has been evaluated and in opportune setting.

Device Comparison between subject and predicate

Device	**Subject device**	**Predicate device**	**Comparison and Explanation of Differences**
Topic	UDE	EBM iDO Viewer	
510k number	N/A	K140399	
Intended Use / Indications for Use	UDE software is intended to display images from CT, MR , CR, US, XA and SC for the trained physician ‘s diagnosis or referring purpose. UDE provides wireless and portable access to medical images. It is not intended to be used as, or to replace, a full diagnostic workstation or system and should be used only when there is no access to a workstation. This device is not to be used for mammography diagnosis.	EBM iDO Viewer software is intended to display images from CT/MR for the trained physician ‘s diagnosis or referring purpose. EBM iDO Viewer provides wireless and portable access to medical images. It is not intended to be used as, or to replace, a full diagnostic workstation or system and should be used only when there is no access to a workstation. This device is not to be used for mammography.	The images displayed by subject device have extended to CR and Full-Field Mammography , US, XA and SC. It leads to the change of intended use. It raises no new issues of safety or effectiveness
Receive, Store, Retrieve, Display, and Process Digital Medical Images	Yes	Yes	No difference
Display of Clinical Patient Data When No Access to a Workstation	Yes	Yes	No difference
Distance Calculation	Yes	Yes	No difference
layout adjustment (1×1, 2×1, 1×2, 2×2)	Yes	Yes	No difference

Window / Level	Yes	Yes	No difference
Zoom, Pan	Yes	Yes	No difference
User Authentication	Yes	Yes	No difference
Modality images for diagnosis	CT, MRI, CR, ,US, XA,SC	CT, MRI	The images displayed by subject device has extended to CR, US, XA, and SC. It raises no new issues of safety or effectiveness
Modality images for reference. Mammography images are not for diagnostic use.	CT, MRI, CR, Full-Field Digital Mammography ,US, XA,SC	CT, MRI ,US, CR,XA,SC	The modalities connected with subject device has extended to Full-Field Mammography. It raises no new issues of safety or effectiveness
Mammography hanging protocol	Yes	No	Subject device has added a new image process function which raise no new issues of safety or effectiveness
Communication log file	Yes	No	Subject device has added a new image process function which raise no new issues of safety or effectiveness
Auto delete old images (FIFO)	Yes	No	Subject device has added a new image process function which raise no new issues of safety or effectiveness
Overlay labels	Yes	No	Subject device has added a new image process function which raise no new issues of safety or effectiveness
Remote Handheld Viewing	Yes	Yes	No difference
Operating Platform	Apple® iOS	Apple® iOS	No difference
Hardware Requirements	Apple® iPad Pro	Apple® iPad/iPhone	The hardware to be installed is different. It raises no new issues of safety or effectiveness
Screen technology	12.9”/11’’TFT Color LCD Panel	9.7”TFT Color LCD Panel (Apple® iPad) 3.5”TFT Color LCD Panel (Apple® iPhone)	The screen size of iPad Pro is larger than those of Apple® iPad/iPhone. It raises no new issues of safety or effectiveness
Screen resolution in pixels/square inch	264 ppi	264 ppi (Apple® iPad) 326 ppi (Apple® iPhone)	The screen of iPad Pro has the same resolution as that of Apple® iPad, but is different that of iPhone. It raises no new issues of safety or effectiveness

5.7 Performance data from non-clinical Testing

The software verification testing and validation testing based on IEC 62304 workflows have been performed by designed engineer or professional personnel. These testing include unit, integration and system tests. The test results of software verification and validation had all met and passed the acceptance criteria referred to medical image software quality request.

The non-clinical performance of display had been conducted according to the description and requirements described in the AAPM Assessment of Display Performance for Medical Imaging Devices (2005) document by a third party to ensure high quality laboratory results. All tests had passed successfully.

5.8 Performance data from clinical Testing

Given the differences from the predicate device iDO Viewer (K140399), no clinical testing of the UDE software is necessary for this submission. The subject software is based on the cleared predicate. Moreover, bench testing results are showing adequate performance of the iPad Pro display used in combination with the UDE software.

5.9 Conclusion

Based on all above evidence, UDE described in this 510(K) is, in our opinion, substantially equivalent to the predicate devices.