DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 27, 2017

EBM Technologies, Incorporated
% Mr. John Su
Quality Manager
5f., No. 516, Sec. 1, Neihu Rd.
Taipei, 114 Taiwan
REPUBLIC OF CHINA

Re: K162285
Trade/Device Name: EBM iDO Viewer 1.2.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 28, 2016
Received: January 5, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162285

Device Name
EBM iDO Viewer 1.2.1

Indications for Use *(Describe)*
EBM iDO Viewer 1.2.1 software is intended to display images from CT, MR , CR, US, XA and SC for the trained physician 's diagnosis or referring purpose. EBM iDO Viewer 1.2.1 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

5.1 Device Submitter

EBM Technologies Incorporated
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Phone: 886 2 8751 4567
Fax: 886 2 8751 3300
Contact Person: John Su
Quality Manager
Tel: 808. 397.6809
john@ebmtech.com

Date of Submission: Aug 15, 2016

5.2 Device Name

Device Trade Name: EBM iDO Viewer 1.2.1
Common/Classification Name: Picture Archiving and Communications System (21 CFR 892.2050, Product Code LLZ)

5.3 Substantially Equivalent (predicate) device(s)

Device Trade Name: EBM iDO Viewer
510(k) Number: K140399
Manufacturer: EBM Technologies Incorporated

5.4 Device Description:

EBM iDO Viewer 1.2.1 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 EBM PACS server. The device can be installed in iOS 5.0 or later version platform such as iPad, but can't be installed in platforms other than iOS 5.0 or later version . It will be almost the same image quality of CT, MR , US, XA and SC as displayed on iPad Pro when it is used for diagnosis purpose. However, if it is used for CR diagnosis purpose, we will strongly suggest that users should adopt iPad

Pro.

5.5 Indication for Use:

EBM iDO Viewer 1.2.1 software is intended to display images from CT, MR , CR, US, XA and SC for the trained physician ‘s diagnosis or referring purpose. EBM iDO Viewer 1.2.1 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

EBM iDO Viewer 1.2.1 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 EBM PACS 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.

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

Clinical testing were conducted by a panel of three board-certified radiologists reading the same images under different environmental lightning conditions. Under the usage condition requested by the indications for use, they were comfortable with the diagnostic mode of EBM iDO Viewer 1.2.1 as a device.

All three radiologists agree that the software and devices provide acceptable quality for diagnostic or remote reviewing use if the device is operated within the intended use.

5.9 Conclusion

Based on all above evidence, EBM iDO Viewer 1.2.1 described in this 510(K) is, in our opinion, substantially equivalent to the predicate devices.