



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

EWOO SOFT Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
800 Roosevelt STE 417
IRVINE CA 92620

December 23, 2016

Re: K163539
Trade/Device Name: Ez3D-i / E3
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 9, 2016
Received: December 16, 2016

Dear Ms. Chung:

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style. Behind the signature is a large, light blue watermark of the letters "FDA".

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K163539

Device Name

Ez3D-i /E3

Indications for Use (Describe)

Ez3D-i is dental imaging software that is intended to provide diagnostic tools for maxillofacial radiographic imaging. These tools are available to view and interpret a series of DICOM compliant dental radiology images and are meant to be used by trained medical professionals such as radiologist and dentist.

Ez3D-i is intended for use as software to load, view and save DICOM images from CT, panorama, cephalometric and intraoral imaging equipment and to provide 3D visualization, 2D analysis, in various MPR (Multi-Planar Reconstruction) functions.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. Date: 12/09/2016

2. 510k Applicant / Submitter

EWOOOFT Co., Ltd.

801-ho, Vatechnetworks Bldg., 13,
Samsung 1-ro 2-gil, Hwaseong-si,
Gyeonggi-do , 18449 , Republic of Korea
Tel : +82-31-8015-6172 Fax : +82-31-8015-6196

Contact Person: Young Seok Kim
Email: ys.kim@ewoosoft.com

3. U.S. Designated Agent

Priscilla Chung
LK Consulting Group USA, Inc.
800 Roosevelt STE 417
Irvine CA 92620
Tel: 714.202.5789 Fax: 714.409.3357
Email: juhee.c@LKconsultingGroup.com

4. Trade/Proprietary Name:

Ez3D-i / E3

5. Common Name:

Dental Imaging Software

6. Classification:

System, image processing, radiological (21CFR 892.2050, Product code LLZ, Class 2, Radiology)

7. Device Description:

Ez3D-i is 3D viewing software for dental CT images in DICOM format with a host of useful functions including MPR, 2-dimensional analysis and 3-dimensional image reformation. It provides advanced simulation functions such as Implant Simulation, Drawing Canal, and Implant Environ Bone Density, etc..for the benefit of effective doctor and patient communication and precise treatment planning.

Ez3D-i is a useful tool for diagnosis and analysis by processing a 3D image with simple and convenient user interface. Ez3D-i's main functions are;

- Image adaptation through various rendering methods such as Teeth/Bone/Soft tissue/MIP
- Versatile 3D image viewing via MPR Rotating, Curve mode
- "Sculpt" for deleting unnecessary parts to view only the region of interest.
- Implant Simulation for efficient treatment planning and effective patient consultation
- Canal Draw to trace alveolar canal and its geometrical orientation relative to teeth.
- "Bone Density" test to measure bone density around the site of an implant(s)
- Various utilities such as Measurement, Annotation, Gallery, and Report
- 3D Volume function to transform the image into 3D Panorama and the Tab has been optimized for Implant Simulation.
- Provides the Axial View of TMJ, the Condyle / Fossa images in 3D and the Section images, and supports functions to separate the Condyle / Fossa and display the bone density.

8. Indication for use:

Ez3D-i is dental imaging software that is intended to provide diagnostic tools for maxillofacial radiographic imaging. These tools are available to view and interpret a series of DICOM compliant dental radiology images and are meant to be used by trained medical professionals such as radiologist and dentist.

Ez3D-i is intended for use as software to load, view and save DICOM images from CT, panorama, cephalometric and intraoral imaging equipment and to provide 3D visualization, 2D analysis, in various MPR (Multi-Planar Reconstruction) functions.

9. Predicate Device:

Ez3D-i /E3 (K161246) by EWO SOFT Co., Ltd.

10. Substantial Equivalence:

Ez3D-i described in this 510(k) has the same intended use and the same technical characteristics as the unmodified device (K161246).

The subject device and the predicate devices are substantially equivalent, having the same indications for use and functionalities like operation software, computer platform, picture

archiving and communication format, image format, image processing features, windowing, 3D image construction, image edit, measurements and manipulation.

The differences are that the subject device has additional features such as USB Model, Quick Settings, Skin Theme, Implant Guide, Dual monitor and 3D Object Manager functions.

These differences are not significant since they do not raise any new or potential safety risks to the user or patient and questions of safety or effectiveness. Based on the test results submitted in this 510K, we conclude that the subject device is substantially equivalent to the predicate devices.

11. Technological Characteristics:

Ez3D-i is a software device that does not contact the patient, nor does it control any life sustaining devices. Results produced by the software's diagnostic, treatment planning and simulation tools are dependent on the interpretation of trained and licensed radiologists, clinicians and referring physicians as an adjunctive to standard radiology practices for diagnosis.

12. Performance Data:

Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the modified devices. The device passed all of the tests based on pre-determined Pass/Fail criteria.

13. Conclusion:

The new device and the predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not introduce a fundamentally new scientific technology, and the non-clinical tests demonstrated that the device is substantially equivalent to the predicate device.