



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.
2651 E. Chapman Avenue, Suite 110
FULLERTON CA 92831

January 3, 2016

Re: K152746
Trade/Device Name: Ez3D Plus
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 15, 2015
Received: December 22, 2015

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 and is positioned above the typed name and title.

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)

K152746

Device Name

Ez3D Plus

Indications for Use (Describe)

Ez3D Plus 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 Plus 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) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. Date: 12/15/2015

2. Applicant / Submitter

EWOOSOFT Co., Ltd.
401-1-ho, 13, Samsung 1-ro 2-gil
Hwaseong-Si, Gyeonggi-do, 18449
Republic of Korea
Tel: +82 31 8015 6171 Fax: +82 31 696 7420
Contact person: Young Seok Kim
Email: ys.kim@ewoosoft.com

3. U.S. Designated Agent

Priscilla Chung
LK Consulting Group USA, Inc.
2651 E. Chapman Ave. Ste 110,
Fullerton, CA 92831
Tel: 714.202.5789 Fax: 714.409.3357
Email: juhee.c@LKconsultingGroup.com

4. Trade/Proprietary Name:

Ez3D Plus

5. Common Name:

Radiological Imaging Software

6. Classification:

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

7. Device Description:

Ez3D plus is a dental imaging software for PCs that provides fast diagnosis through 3D visualization, 2D analysis, and various MPR functions to manipulate CT images in DICOM format.

The features include canal tracing, implant simulation, and bone density profiling of the area surrounding the implant.

Ez3D plus makes 3D image analysis easier through a simple and convenient user interface. The following are the major functions of Ez3D plus.

- Convenient 2D and 3D image observation with the ability to access all the functions of Ez3D plus with a single click of the mouse.
- Quicker image analysis using Cross-Sectional View, which processes vertical images of the dental arch.
- Implant simulation tools provide treatment planning and make for effective patient consultations.
- Convenient confirmation of bone density profiles for the areas around an implant site. Combined with canal tracing, a user can also easily locate the implant site in relation to its distance with the mandibular canal.
- Easy access to various rendering methods, including VR (Volume Rendering), MIP, miniIP, and X-ray.
- 3-D image diagnosis through the use of rendering functions like MPR Rotating Axes, Curve, and 3D zoom.
- Segmentation allows users to easily remove unnecessary parts of an image or extract areas that meet a specific data value.
- A range of utilities including Reports, Counsel, and Free Draw.
- Ability to easily control user settings such as for default windowing and sectional gap/thickness.
- Convenient management and addition of objects, color maps, and fine tuning presets.

8. Indication for use:

Ez3D Plus 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 Plus 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:

- OnDemand3D^{G2} by CyberMed, Inc. (K113543)
- coDiagnostiX Implant Planning Software by Straumann US (K1302724)

10. Substantial Equivalence:

Ez3D Plus described in this 510(k) has the same intended use and similar technical characteristics as OnDemand3D by CyberMed, Inc (K113543) and coDiagnostiX Implant

Planning Software by Straumann US (K1302724). We have identified coDiagnostiX Implant Planning Software as a reference predicate device which has an auto canal draw (detect) function as the subject device.

The subject device and predicate devices are substantially equivalent, having the same indications for use and similar 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 such that Ez3D Plus lacks the capability to fabricate implant surgical guides and has no functions to create orthodontic tracing analysis using 3D volume data.

Any differences between the predicate device and the proposed devices 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 results of software validation and performance tests, we conclude that the proposed device is substantially equivalent to existing legally marketed devices.

11. Technological Characteristics:

Ez3D Plus 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 subject device. The device passed all of the tests based on pre-determined Pass/Fail criteria.

13. Conclusion:

The subject device and the predicate devices 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 nonclinical tests demonstrate that the device is safe and effective. Therefore, it is our opinion that the Ez3D Plus described in this submission is substantially equivalent to the predicate devices.