



Food and Drug Administration
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EWOO SOFT Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
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800 Roosevelt, Suite 417
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January 12, 2017

Re: K163533
Trade/Device Name: EzDent-i; E2; ProraView
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 blue ink that reads "Michael D. O'Hara". The signature is written over a large, semi-transparent watermark of the FDA logo.

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

Indications for Use

510(k) Number (if known)

K163533

Device Name

EzDent-i; E2; ProraView

Indications for Use (Describe)

EzDent-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.

EzDent-i is intended for use as software to acquire, view, save 2D image files, and load DICOM project files from panorama, cephalometric, and intra-oral imaging equipment.

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

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

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3. U.S. Designated Agent

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4. Trade/Proprietary Name:

EzDent-i; E2; ProraView

5. Common Name:

Dental Imaging Software

6. Classification:

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

7. Device Description:

EzDent-i is a device that provides various features to acquire, transfer, edit, display, store, and perform digital processing of medical images. EzDent-i is a patient & image management software specifically for digital dental radiography. It also provides server/client model so that the users upload and download clinical diagnostic images and patient information from any workstations in the network environment.

EzDent-i supports general image formats such as JPG and BMP for 2D image viewing as well as DICOM format. For 3D image management, it provides uploading and downloading support for dental CT Images in DICOM format. It interfaces with a 3D imaging software made by our company, the Ez3D-i (K131616, K150761, K161246) but the EzDent-i itself does not view, transfer or process 3D radiographs.

EzDent-i supports the acquisition of dental images by interfacing with OpenCV library to import the intra-oral camera images. It also supports the acquisition of CT/Panoramic/Cephalo/Intra-Oral Sensor images by interfacing with X-ray capture software.

EzDent-i makes it easier to diagnose and analyze 2D dental images with simple and convenient user interface. EzDent-i's main functions are;

- Easy and convenient data search function for patient information and clinical images
- Various image viewing format for 2D dental images
- Various image processing functions including adjustment of brightness and contrast for images
- Measurement function of length and angle for 2D images
- Dental implant simulation for treatment planning and effective patient consultation
- Crown simulation for more effective patient consultation
- Print function supporting various viewing output format

8. Indication for use:

EzDent-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.

EzDent-i is intended for use as software to acquire, view, save 2D image files, and load DICOM project files from panorama, cephalometric, and intra-oral imaging equipment.

9. Predicate Device:

EzDent-i; E2; ProraView (K161117) by EWOO SOFT Co., Ltd.

10. Substantial Equivalence:

EzDent-i v2.1 described in this 510(k) has the same intended use and the same technical characteristics as the unmodified device.

The subject device and the unmodified device 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, image edit, measurements and manipulation. The differences are that the subject device has additional features such Quick Settings, Displaying Patient's test report, Layout Manager, and Insight Navi functions.

These differences are not significant since they are additional features for user convenience and do not raise the 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 device.

11. Technological Characteristics:

EzDent-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.