February 17, 2023

Ewoosoft Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
IRVINE CA 92612

Re: K223820
Trade/Device Name: EzDent-i / E2 / Prora View/ Smart M Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 15, 2022
Received: December 21, 2022

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. 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223820

Device Name
EzDent-i /E2 /Prora View/ Smart M Viewer

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.

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.

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510(k) Summary
(K223820)

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

1. **Date**: 1/10/2023

2. **Applicant / Submitter**

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3. **U.S. Designated Agent**

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4. **Subject Device:**

- Trade/Device Name: EzDent-i / E2 / Prora View / Smart M Viewer
- Version #: v3.4
- Regulation Number: 21 CFR 892.2050
- Regulation Name: Medical Image Management and Processing System
- Regulatory Class: Class II
- Product Code: LLZ

5. **Predicate Device:**

- Manufacturer: Ewoosoft Co., Ltd.
- Trade/Device Name: EzDent-i / E2 / Prora View / Smart M Viewer
- Version #: v.3.3
- 510k Number: K222145
- Regulation Number: 21 CFR 892.2050
- Regulation Name: Medical Image Management and Processing System

- Regulatory Class: Class II
- Product Code: LLZ

6. Device Description:

EzDent-i v3.4 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, K163539, K173863, K190791, K200178, K211791, K222069) but the EzDent-i itself does not view, transfer or process 3D radiographs. None of the changes to the predicate software are related to the 3D functions.

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 /Intra-Oral Scanner images by interfacing with X-ray capture software.

The software level of concern is Moderate.

7. 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.

8. Substantial Equivalence:

	Modified Device	Unmodified Device
Device name	EzDent-i v3.4	EzDent-i v3.3
510K number	K223820	K222145
Manufacturer	Ewoosoft	Ewoosoft
Indications 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 and save 2D image files, load DICOM project files from panorama, cephalometric, and intra-oral imaging equipment.	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 and save 2D image files, load DICOM project files from panorama, cephalometric, and intra-oral imaging equipment.
Technology/Principle of Operation	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. 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 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. 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.
Platform	IBM-compatible PC or PC network	IBM-compatible PC or PC network
Operating System	Windows 10, 11	Windows 10, 11
User Interface	Mouse, Keyboard	Mouse, Keyboard
Image Input Sources	Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device
32 bit / 64 bit	32 / 64 bit	32 / 64 bit
Image format	DICOM	DICOM
Patient Database Compatibility	SQL	SQL
Includes Image Measurement tools	Linear distance, angle	Linear distance, angle
Image viewing	Full, side by side, gallery, thumbnail	Full, side by side, gallery, thumbnail
Image manipulation	Brightness, contrast, sharpness, inverse, film view, rotate, zooming, whitening,	Brightness, contrast, sharpness, inverse, film view, rotate, zooming, whitening,

	nerve canal tracing, memo	nerve canal tracing, memo
Implant module	Generic implant libraries	Generic implant libraries
3D imaging capability	Includes interface to 3D imaging software, Ez3D-i. EzDent-i imaging software does not view, transfer or process 3D radiographs.	Includes interface to 3D imaging software, Ez3D-i. EzDent-i imaging software does not view, transfer or process 3D radiographs.
Image annotation	Text, paint, ellipse, pointer, select, draw, magnify, line, rectangle, polygon, ruler, protractor, smile library, smudge, brush, redeye reduction, select region, copy / paste	Text, paint, ellipse, pointer, select, draw, magnify, line, rectangle, polygon, ruler, protractor, smile library, smudge, brush, redeye reduction, select region, copy / paste

EzDent-i v3.4 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 modifications are adding [Image Share] and [IO sensor image Preview] functions, upgrading the setting tab and the header & footer setting, also supporting image acquisition from PSP scanner. A brief description of the changes from the predicate are as below.

- Setting tab upgrade
  - Dose unit setting can be set separately for extraoral and intraoral x-ray system.
  - Premium skin theme has been added.
  - [Server Control Panel] button has been added.
  - Crown color feature has been added.
  - DICOM tag add/edit/delete feature has been added.

- Acquisition tab upgrade
  Acquisition tab supports PSP scanner images.

- Patient tab upgrade
  [Image Share] function has been added to patient tab.

- Report tab upgrade
  Additional Header/footer setting features

- Viewer tab upgrade
  IO Sensor filtering preview function on the Viewer tab has been revised.

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

9. Technological Characteristics:

EzDent-i v3.4 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.

10. Performance Data:

SW verification/validation and the measurement accuracy test 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.

11. Conclusion:

The subject device is substantially equivalent in the areas of technical characteristics, general function, application, and indications for use. The new device does not introduce a fundamentally new scientific technology, and the device has been validated through system level test. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.