July 23, 2024

Ewoosoft Co., Ltd.
c/o Priscilla Chung
Regulatory Affairs Consultant
18881 Von Karman Ave. STE 160
IRVINE, CA 92612

Re: K241114
Trade/Device Name: EzDent-i / E2 / Prora View / Smart M Viewer (v3.5)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 6, 2023
Received: June 24, 2024

Dear Priscilla 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Radiologic 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241114

Device Name
EzDent-i/E2/Prora View/Smart M Viewer (v3.5)

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.

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
PRAStaff@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

(K241114)

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

1. **Date**: 7/22/2024

2. **Applicant / Submitter**

Ewoosoft Co., Ltd.
801-ho, Vatechnetworks Bldg., 13, Samsung 1-ro 2-gil,
Hwaseong-si, Gyeonggido , Republic of Korea
Tel: +82 31 8015 6172 Fax: +82 31 8015 6196
Contact person: Sunny Lee
Email: sunny.lee@ewoosoft.com

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

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, CA 92612
Tel: 714.202.5789 Fax: 714.409.3357
Email: juhee.c@LKconsultingGroup.com

4. **Subject Device:**

- Trade/Device Name: EzDent-i/E2/Prora View/Smart M Viewer (v3.5)
- 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 (v3.4)
- 510k Number: K223820
- 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 v3.5 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, K231757) 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 /Intra-Oral Scanner images by interfacing with X-ray capture software.

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:

	Unmodified Device	Modified Device	Comparison
Device name	EzDent-i v3.4	EzDent-i v3.5	Version Change
510K number	K223820	K241114	-
Manufacturer	Ewoosoft	Ewoosoft	Same
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.	Same
Regulatory Number & Common Name	21 CFR 892.2050 Medical image management and processing system	21 CFR 892.2050 Medical image management and processing system	Same
Device Class	Class II	Class II	Same
Software Documentation Level	Moderate	Basic	Same
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	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	Same

	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.	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	Same
Minimum Server PC System	- CPU: Dual-Core Processor @ 3.4GHz - RAM: 4GB - Display 1280×1024	- CPU: Dual-Core Processor @ 3.4GHz - RAM: 8GB - Display 1280×1024	Equivalent Updated PC system requirements are intended to better fit the current PC part market situation for availability. The key requirements such as CPU are not changed thus the modifications do not affect substantial equivalence to the predicate device.
Minimum Client PC System	- CPU: Dual-Core Processor @ 2.7GHz - RAM: 4GB - Display 1024×768	- CPU: Dual-Core Processor @ 2.7GHz - RAM: 4GB - GPU: Internal or External GPU Supporting OpenGL2.1 - Display 1024×768	
Network	Wired or Wireless Network - Wired: 100M ethernet LAN	Wired or Wireless Network - Wired: 100M ethernet LAN	Same

	(CAT 5 cable) - Wireless: 802.11n	(CAT 5 cable) - Wireless: 802.11n	
Operating System	Microsoft Windows 10,11	Microsoft Windows 10,11	Same
User Interface	Mouse, Keyboard	Mouse, Keyboard	Same
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	Same
32 bit / 64 bit	32 / 64 bit	32 / 64 bit	Same
Image format	DICOM	DICOM	Same
Patient Database Compatibility	SQL	SQL	Same
Includes Image Measurement tools	Linear distance, angle	Linear distance, angle	Same
Image viewing	Full, side by side, gallery, thumbnail	Full, side by side, gallery, thumbnail	Same
Image manipulation	Brightness, contrast, sharpness, inverse, film view, rotate, zooming, whitening, nerve canal tracing, memo	Brightness, contrast, sharpness, inverse, film view, rotate, zooming, whitening, nerve canal tracing, memo	Same
Implant module	Generic implant libraries	Generic implant libraries	Same
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.	Same

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, multi-line, rectangle, polygon, ruler, protractor, smile library, smudge, brush, redeye reduction, select region, copy / paste	Equivalent 1) [Multi-line] tool, an upgrade to existing [Line] tool is added. 2) A tool to directly open Annotation Properties dialog added. The role of the dialog is identical to the annotation settings on the Settings dialog of the unmodified device. Thus, the modifications do not affect substantial equivalence to the predicate device.
Distribution of Installation File for Upgrade	USB	USB, EzUpdater	Equivalent Online distribution of installation files supported through EzUpdater. However, the installation process is identical.
Customer Support	Manufacturer website, phone number, and e-mail information provided.	Manufacturer website, phone number, and e-mail information provided.	Same (with a tool to access to CS website)
Dose Information Display	File information	File information, Dose indicator(if applicable)	Equivalent Dose indicator is added in order to support EzSensor XHD(K232255). However, the role of EzDent-i is not to calculate the

			information but to visualize the received information into dose indicator. Thus, the key feature, displaying the received value, is identical to the predicate device and the modification does not affect substantial equivalence to the predicate device.
Report Management	Create, open, view, edit, delete	Create, open, view, edit, delete	Same (with [Delete] feature added to thumbnail list)
Pre-integrated PMS	Clever	Clever Dent(Previous name: Clever), Weclever	Equivalent The list of pre-integrated PMS is expanded. The modification is only an upgrade of existing feature and the modification does not affect substantial equivalence to the predicate device
Send E-mail	Send e-mail, attachment, signature, convert report to, convert image to, patient information anonymization	Send e-mail, attachment, compress to zip file, signature, convert report to, convert image to, patient information anonymization	Equivalent [Compress to .zip file] feature is added as an upgrade to the attachment. The modification is not a newly added feature but identical to the [Compress to .zip file] feature on the Export function of

			the predicate device. The key features of Send E-mail function is not changed thus, the modification does not affect substantial equivalence to the predicate device.

EzDent-i v3.5 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 PC system requirement information change, EzUpdater added for online downloads, Customer Support Icon added for user convenience, and some upgrades in Viewer Tab, Patient Management, and E-mail 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.

9. Technological Characteristics:

EzDent-i v3.5 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.
Also we have addressed the recommendations in the most recent cybersecurity guidance, "Cybersecurity in Medical Devices Quality System Considerations and Content of Premarket Submissions".

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.