September 11, 2023

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

Re: K231757
Trade/Device Name: Ez3D-i /E3
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH

Dear Priscilla Chung:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 14th, 2023. Specifically, FDA is updating this SE Letter's incorrect product code as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Lu Jiang, OHT8: Office of Radiological Health, 240-402-5779, lu.jiang@fda.hhs.gov.

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

July 14, 2023

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

Re: K231757
Trade/Device Name: Ez3D-i /E3
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: June 12, 2023
Received: June 16, 2023

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 (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
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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)*
K231757

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.

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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

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

1. **Date:** 6/12/2023

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: Young Seok Kim
Email: eddie.kim@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: Ez3D-i /E3
- Version #: v5.5
- 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: Ez3D-i /E3
- Version #: v5.4
- 510(k) number: K222069
- Regulation number 21 CFR 892.2050
- Regulation name: Picture Archiving and Communications System
- Regulatory Class: Class II

- Classification Product Code: LLZ

6. Device Description:

Ez3D-i v5.5 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.

7. 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.

8. Substantial Equivalence:

8.1. Comparison chart of features and specifications

	Subject Device	Predicate Device
Device Name	Ez3D-i v5.5(E3)	Ez3D-i v5.4(E3)
510K number	-	K222069
Manufacturer	Ewoosoft	Ewoosoft
Indications 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	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
Platform	IBM-compatible PC or PC network	IBM-compatible PC or PC network
Operating System	Microsoft Window 10 or higher	Microsoft Window 10 or higher
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	64 bit	64 bit
Image format	DICOM	DICOM
Image Measurement Tools	Length, Multi Length, Angle, Multi Angle, Circle, ROI/Area, Volume, Profile	Length, Multi Length, Angle, ROI/Area, Volume, Profile
Image viewing	Full, side by side, gallery, thumbnail	Full, side by side, gallery, thumbnail
Image manipulation	Grayscale, invert, emboss, brightness, contrast, gamma, sharpen, median, despeckle, hue, saturation, equalize, flip, mirror, masking, rotate, magnify, annotation, cephalometric tracing, ceph growth projections, implant simulations	Grayscale, invert, emboss, brightness, contrast, gamma, sharpen, median, despeckle, hue, saturation, equalize, flip, mirror, masking, rotate, magnify, annotation, cephalometric tracing, ceph growth projections, implant simulations
3D imaging capability	Ez3D-i can view, transfer and process 3D radiographs. Furthermore, it supports Smart Click, Smart Clipping, Implant Simulation and Canal Draw.	Ez3D-i can view, transfer and process 3D radiographs. Furthermore, it supports Smart Click, Smart Clipping, Implant Simulation and Canal Draw.
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

8.2. Substantial Equivalence Discussion

Ez3D-i v5.5 described in this 510(k) has the same intended use and the same technical characteristics as the unmodified device (K211791, Ez3D-i /E3).

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 modifications are changes in PC system requirement information, upgrades on Main Menu (size adjustment for 3D photo and reorientation function), Settings Dialog (server control panel button, DICOM tag customization, and acquisition information display option), Open function (search function, additional side panel, and Patient tab in the environment settings), MPR tab (Switch to Focus CT function), TMJ tab (Draw Curve function), and CONSULT tab and Report (inserting server images).

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.

9. Technological Characteristics:

Ez3D-i v5.5 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.

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.