Ewoosoft Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt STE 200
IRVINE CA 92620

February 25, 2020

Re: K200178
Trade/Device Name: Ez3D-i /E3
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 23, 2020
Received: January 24, 2020

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K200178

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.

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510(k) Summary

(K200178)

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

1. **Date:** 2/21/2020

2. **Applicant / Submitter**

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

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4. **Trade/Proprietary Name:**

Ez3D-i / E3

5. **Common Name:**

Dental Imaging Software

6. **Classification:**

- Regulation number: 21 CFR 892.2050
- Regulation name: Picture archiving and communications system
- Regulatory class: II
- Product code: LLZ

7. **Device Description:**

Ez3D-i is 3D viewing software for prompt and accurate diagnosis 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.
Ez3D-i is a useful tool for an easier diagnosis and analysis by processing a 3D image with simple and convenient user interface. Ez3D-i's main functions are;

- Image adaptation through various rendering methods such as Teeth/Bone/Soft tissue/MIP
- Versatile 3D image viewing via MPR Rotating, Curve mode
- "Sculpt" for deleting unnecessary parts to view only the region of interest.
- Implant Simulation for efficient treatment planning and effective patient consultation
- Canal Draw to trace alveolar canal and its geometrical orientation relative to teeth.
- "Bone Density" test to estimate bone density around the site of an implant(s)
- Various utilities such as Measurement, Annotation, Gallery, and Report
- 3D Volume function to transform the image into 3D Panorama and the Tab has been optimized for Implant Simulation.
- Provides the Axial View of TMJ, the Condyle/Fossa images in 3D and the Section images, and supports functions to separate the Condyle/Fossa and display the bone density
- STO/VTO Simulation for orthodontic treatment/surgery visualization with 3D Photo image.
- Segmentation function to get tooth segmentation data from CT, label each segmented tooth data as an object and utilize them in simulation such as tooth extraction, implant simulation, etc.

8. 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.

9. Predicate Device:

- Ez3D-i /E3 (K190791) by Ewoosoft Co., Ltd.
  - Regulation number: 21 CFR 892.2050
  - Regulation name: Picture archiving and communications system
  - Regulatory class: II
  - Product code: LLZ

10. Substantial Equivalence:

Ez3D-i described in this 510(k) has the same intended use and the same technical characteristics as the unmodified device (K K190791, 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 differences are that the subject device has additional features such as adding ENDO tab, Measurement tools upgrade(Multi Angle/Circle) and adding a save feature to the previously cleared Ceph tab.

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.

11. Technological Characteristics:

Ez3D-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.
We have referenced the following standard and FDA guidance when developing and validating the subject device.

- ISO 14971:2012, Application of risk management to medical devices.
- ISO 13485 : 2016, Quality Management Systems-Medical Devices-System Requirements for Regulatory Purposes
- IEEE Std 1012-1986, Standard for Software Verification and Validation Plans
- IEEE Std 829-1983, Standard for Software Test Documentation
- IEC 62304 : Medical device software - Software life-cycle processes
- FDA Guidance for General Principles of Software Validation
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

- FDA Guidance for Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software
- FDA Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

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