510(k) Summary

(K190791)

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

1. **Date:** 04/18/2019

2. **Applicant / Submitter**

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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 measure 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 to predict orthodontic treatment/ surgery results 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 (K173863) 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 (K173863, 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 Privacy Policy and Help Document on the program and also the SEGMENT and REPORT Tabs have been upgraded. The Privacy Policy has been added to the Settings tab of the subject device which the predicate device doesn't have. The Help Document which is the same as the User Manual is now can be viewed on the program of the subject device. The predicate device doesn't have this feature either. For the SEGMENT tab, Quick Segmentation function has been separated into Teeth Segmentation and Bone Segmentation so that the user can segment teeth data only. The Manual segmentation function with various features has been added to this tab as well. This manual segmentation tab provides a range of drawing tools that allow users to adjust the image to show the patient the results of any dental work. It is only intended as a visual aid for the patient. Lastly, the Report tab format has been upgrade for user convenience.

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.