DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

3D Industrial Imaging Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
800 Roosevelt Ste 417
IRVINE CA 92620

October 5, 2016

Re: K160666
Trade/Device Name: Dentiq3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 15, 2016
Received: September 20, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K160666

Device Name

Dentiq3D

Indications for Use *(Describe)*

Dentiq3D 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.

Dentiq3D 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.

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510(k) Summary

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

1. **Date:** 09/15/2016

2. **Applicant / Submitter**

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Contact person: Jin Sa Kim/ Manager, Regulatory Affairs Team

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

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4. **Trade/Proprietary Name:**

Dentiq3D

5. **Common Name:**

Radiological Imaging Software

6. **Classification:**

System, image processing, radiological (21CFR 892.2050, Product code LLZ, Class 2, Radiology)

7. **Device Description:**

Dentiq3D is a dental image software platform for the 3D visualization and analysis of volume data. Dentiq3D is optimized for analyzing volume data from CT scan and enables users to examine volume data through 3D visualization, 2D analysis, and various MPR

functions to manipulate CT images. The functions include canal tracing, implant simulation, volume segmentation and airway measurement.

The following are the major functions of Dentiq3D.

- Visualizes CT volume data
- Supports various types of data
- Measures 3D object
- Analyzes and filters volume data
- Publishes various forms of report
- 3D visualization by using GPU
- Loads and saves project files
- Restores (Undo) or repeats (Redo) tasks based on operation history
- Supports a user-friendly interface

8. Indication for use:

Dentiq3D 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.

Dentiq3D 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:

- Primary Predicate Device: Ez3D Plus by EWOOSOFT Co., Ltd. (K152746)
- Reference Predicate Device: InVivo Dental by Anatomage Inc. (K123519)

10. Substantial Equivalence:

Dentiq3D described in this 510(k) has the same intended use and similar technical characteristics as Ez3D Plus (K152746) by EWOOSOFT Co., Ltd and InVivo Dental (K123519) by Anatomage, Inc.

The subject device and predicate device are substantially equivalent, having the same indications for use, the same principle of operation, and similar 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.
Comparing to InVivo Dental (K123519), the differences are such that Dentiq3D lacks the capability to fabricate implant surgical guides and has no functions to create orthodontic tracing analysis using 3D volume data.

Any differences between the predicate device and the proposed device 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 results of software validation and performance tests, we conclude that the proposed device is substantially equivalent in performance to existing legally marketed devices.

11. Technological Characteristics:

Dentiq3D 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 subject device. The device passed all of the tests based on pre-determined Pass/Fail criteria.

13. Conclusion:

The subject 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. Therefore, it is our opinion that the Dentiq3D described in this submission is substantially equivalent to the predicate device.