July 19, 2018

3D Industrial Imaging Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
Lk Consulting Group USA, Inc.
690 Roosevelt
IRVINE CA 92620

Re: K180629
Trade/Device Name: DentiqGuide
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 22, 2018
Received: July 6, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

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)*

K180629

Device Name

DentiqGuide

Indications for Use *(Describe)*

DentiqGuide Software is a stand-alone Windows-based software application to support the treatment planning for dental implantation. It is designed for qualified dental practitioners, including dentists and lab technicians. The software imports the medical image dataset of the patient in DICOM format from medical CT or dental CBCT scanners for pre-operative planning and simulation of dental placement.
It is intended for use as pre-operative planning software for the placement of dental implant(s) based on imported CT image data, optionally aligned to an optical 3D surface scan. Virtual Crowns can be used for optimized implant positioning under the prosthetic aspect. The digital three dimensional model of a surgical guide for a guided surgery can be designed based on the approved implant position. This 3D data can be exported to manufacture a separate physical product.
Indications of the dental implants do not change with guided surgery compared to conventional surgery.
Use of the software requires that the user has the necessary medical training in implantology and surgical dentistry.

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

(K180629)

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

1. **Date:** 07/13/2018

2. **Applicant / Submitter**

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Seoul National University, Daehak-dong,
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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:**

DentiqGuide

5. **Common Name:**

Radiological Imaging Software

6. **Classification:**

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

7. **Device Description:**

DentiqGuide is a software device used to pre-operatively plan the placement of a dental implant and to visualize a patient's CT image optionally aligned to an optical 3D surface

data. Virtual crowns can be used to guide the planning under the final prosthetic aspect. The surgical guide data can be designed then exported to an external system for manufacturing.

The device has no patient contact.

The followings are the major functions of DentiqGuide.

- Patient management and operation plan management
- Data loading and matching
- Crown model management and mesh editing
- Panoramic screen creation and neural tube setting
- Implant planning
- Surgical guide design
- Report
- Project information management
- Interworking with cloud

8. Indication for use:

DentiqGuide Software is a stand-alone Windows-based software application to support the treatment planning for dental implantation. It is designed for qualified dental practitioners, including dentists and lab technicians. The software imports the medical image dataset of the patient in DICOM format from medical CT or dental CBCT scanners for pre-operative planning and simulation of dental placement.
It is intended for use as pre-operative planning software for the placement of dental implant(s) based on imported CT image data, optionally aligned to an optical 3D surface scan. Virtual Crowns can be used for optimized implant positioning under the prosthetic aspect. The digital three dimensional model of a surgical guide for a guided surgery can be designed based on the approved implant position. This 3D data can be exported to manufacture a separate physical product.
Indications of the dental implants do not change with guided surgery compared to conventional surgery.
Use of the software requires that the user has the necessary medical training in implantology and surgical dentistry.

9. Predicate Device:

Implant Studio™ by 3Shape Medical A/S (K152078) (LLZ, 21 CFR 892.2050)

10. Substantial Equivalence:

The DentiqGuide described in this 510(k) has the same intended use and similar technical characteristics as Implant Studio™ (K152078) by 3Shape Medical A/S.

The subject device and the predicate device are substantially equivalent, having the same indications for use, the same principle of operation, and similar functionalities like operation software, computer platform, image format, image processing features, windowing, 3D image construction, image edit, measurements and manipulation.

Comparing to as Implant Studio™ 2015-1 (K152078), the differences are such that the predicate device supports its own format additionally and the subject device does not have the feature for edentulous treatment and subsequent design of gingiva supported guides. However, these differences do not raise questions of safety or effectiveness since the two features of the predicate devices are additional options.

Based on the results of software validation and performance tests and the information provided herein, we conclude that the proposed device is substantially equivalent to the predicate device.

11. Technological Characteristics:

DentiqGuide 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:

SW verification and validation testing activities such as code review, module review, integration review, and dynamic tests were conducted to establish the performance, functionality and reliability characteristics of the subject device.
Also the following performance tests were conducted to verify the performance of the subject device and find out any limitations.
- Accuracy test for measurement made in the subject device from loaded CT datasets using phantom by comparing the true values of the phantom and the measured values (Length, Angle, HU) in the subject device. The P/F criteria was less than 2% average and maximum absolute difference.
- Accuracy test to demonstrate that the generated output surgical guide by the subject device matches the user input requirements (Guide thickness, Offset from teeth to guide, Offset from sleeve to guide). The P/F criteria was less than 2% average and maximum absolute difference.
- Accuracy test to verify the size of the implants (Diameter and Length) which the implant library of the subject device provides by comparing them to the real size values of the implant. The P/F criteria was less than 2% average and maximum absolute difference.

The testing results support that the subject device is substantially equivalence to the predicate device.

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 DentiqGuide described in this submission is substantially equivalent to the predicate device.