3D Industrial Imaging Co., Ltd.
℅ Sanglok Lee
Manager, Wise Company Inc.
#303, 142, Gasan digital 1-ro
Geumcheon-Gu 08507
REPUBLIC OF KOREA

April 10, 2020

Re: K200078
Trade/Device Name: VARO Plan
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: January 8, 2020
Received: January 14, 2020

Dear Sanglok Lee:

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
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 on last page.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"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."

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510(k) Summary – Traditional 510(K)

The assigned 510(k) Number: Not yet assigned

01. Date of Submission: 2020.01.08

02. Applicant / Submitter

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Tel. +82-70-8766-9192

03. Submission Correspondent

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04. Proposed Device Identification

Device Identification and Regulatory information
Proprietary Name: VARO Plan
Common Name: Radiological Imaging Software
Device Class: Class II
Regulation Number: 21 CFR 892.2050
Product Code: PNN (Orthodontic Software); LLZ

Indication for use: VARO Plan 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.

05. Predicate Device Identification

- Predicate device 1
510(k) Number: K180629
Device Name: Dentiq Guide
Manufacturer: 3D Industrial Imaging Co. Ltd

- Predicate device 2
510(k) Number: K152078
Device Name: Implant Studio™
Manufacturer: 3Shape Medical A/S

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06. Device Description

VARO Plan is a pure software device.
VARO Plan is a dental implant surgical guide design software that is used to design surgical procedure guidelines for implanting one or more dental implants based on CT and the Tray data. Implant library, which includes certified implants, and sleeve libraries are provided. The guide model designed in accordance with the established dental implant operation plan can be exported as STL files.

The followings are the major functions of VARO Plan.

- Patient Management and Surgical Plan Management
- Data Management and Matching
- Crown Model Management and Mesh Edit
- Panoramic Screen Generation and Nerve Setting
- Implant Simulation
- Surgical Guide Design
- Results output.
- Report
- Project Information Management

07. Technological Characteristics:

VARO Plan requires Windows 7 64bit OS or above. To ensure proper operation, we recommend installing the subject device on a system with the following specifications or higher.

Item	Specifications
Processor	Intel i3 Dual Core or Higher
System Memory	16 GB or Higher
HDD	2 GB free hard disk space or Higher
Graphics Card	Graphics cards compatible with DirectX 11 or Higher
Display	1600 x 900 or Higher

Table 1. Minimum PC Specification Requirements for VARO Plan

The device does not contact the patient, nor does it control any life sustaining devices.
VARO Plan 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.

08. Substantially Equivalent

VARO Plan has the same intended uses, principle of operation and similar technical characteristics and functionality as predicate devices.

	Subject Device	Predicate Device 1	Predicate Device 2	Substantial Equivalence
Device Name	VARO Plan	Dentiq Guide	Implant Studio™	-
510K number	-	K180629	K152078	-
Classification	Regulation number: 21 CFR 892.2050 Product code: LLZ	Regulation number: 21 CFR 892.20503 Product code: LLZ	Regulation number: 21 CFR 892.2050 Product code: LLZ	Equivalent
Manufacturer	3D Industrial Imaging Co. Ltd	3D Industrial Imaging Co. Ltd	3Shape Medical A/S	-
	VARO Plan Software is a stand-alone Windows-based software			Equivalent

Indications for Use	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.			
	Dentiq Guide 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.			
	Implant Studio™ is indicated for use as medical front-end software that can be used by medically trained professionals for the purpose of visualizing gray value images. 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.			
Platform	IBM-compatible PC or PC network	IBM-compatible PC or PC network	IBM-compatible PC or PC network	Equivalent
Computer	OS: Microsoft	OS: Microsoft	OS: Windows 7 or	Equivalent

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System Requirement	Window 7, 8 or 10 64-bit CPU: Inter i-3 core or higher RAM: 2 GB Monitor Resolution:1600 x 900 or Higher Video Card: compatible with DirectX 10.1 or Higher HDD: 2 GB free hard disk space Network: Network Internet connection Mouse: With the wheel button	Window 7, 8 or 10 64-bit CPU: Inter i-3 core or higher RAM: 2 GB Monitor Resolution:1600 x 900 or Higher Video Card: compatible with DirectX 10.1 or Higher HDD: 2 GB free hard disk space Network: Network Internet connection Mouse: With the wheel button	8 64-bit CPU: IntelCore i7 or higher RAM: 16GB or better Monitor Resolution: 1920x1200 or higher Video Card Memory: 2GB GeForce or better Available HDD Space: 500GB Network: Network Internet connection Mouse: With the wheel button	
User Interface	Monitor, Mouse, Keyboard	Monitor, Mouse, Keyboard	Monitor, Mouse, Keyboard	Equivalent
Image Input Sources	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device.	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device.	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device.	Equivalent
Data Format	DICOM, STL	DICOM, STL	DICOM, STL, DCM	Different The Implant Studio™ supports its own format as well which is DCM format.
Software Function	MPR (multi-planar reconstruction), panoramic, and, 3D image reconstruction for analyzing anatomical condition	MPR (multi-planar reconstruction), panoramic, and, 3D image reconstruction for analyzing anatomical condition	Axial, cross-sectional, tangential, panoramic, 3D views for displaying the 3D volumetric data for analyzing anatomical condition	Equivalent

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	Graphic visualization interface for placing the implant in mandible or maxilla images,	Graphic visualization interface for placing the implant in mandible or maxilla images,	Various image views, such as axial, cross-sectional, tangential, and panoramic, provided for placing the implant	
	Nerve module for assisting users in distinguishing inferior alveolar nerve (passing through mandibular canal)	Nerve module for assisting users in distinguishing inferior alveolar nerve (passing through mandibular canal)	Nerve module to assist in distinguishing the nerve mandibular channel	
	Simulation of different sized implants	Simulation of different sized implants	Different implants selected from implant database. Change the diameter and length of the implant selected.	
	Adjustment of implant location, including position and direction	Adjustment of implant location, including position and direction	Aligning implant by moving and rotating the implant with the mouse	
	Alignment function for multiple implants,	Alignment function for multiple implants,	Alignment function for multiple implants,	
	Simulation of crown	Simulation of crown	Abutment and virtual teeth tools provided	
	Measurement tools for measuring length and angle	Measurement tools for measuring length and angle	Active measurement tools, length and angle, for individual measuring of implant position	
	Bone quality (indicated by CT number) displayed in the point around the implant	Bone quality (indicated by CT number) displayed in the point around the implant	Bone densitometry with a density statistic for density measuring in the point around the positioned implant	

	The treatment plan of the patient can be saved in the computer storage media. The plan can be retrieved later on for revision.	The treatment plan of the patient can be saved in the computer storage media. The plan can be retrieved later on for revision.	All working steps are saved automatically to the patient file, called the plan.	
	Compatible with dental 3D printers, milling machines and CAM equipment that support the STL file format.	Compatible with dental 3D printers, milling machines and CAM equipment that support the STL file format.	Compatible with dental 3D printers, milling machines and CAM equipment that support the STL file format.	
	-	-	Gingiva supported surgical guide design possible	Different VARO Plan Software does not provide edentulous treatment and subsequent design of gingiva supported guides.
Anatomic Area	Maxilla, Mandible	Maxilla, Mandible	Maxilla, Mandible	Equivalent

Comparing to as Implant Studio™ (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 devices.

09. Non clinical Testing

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 and Surgical

guide model) in the subject device. The P/F criteria was less than 2% average and maximum absolute difference. Accuracy test of Surgical guide model 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).
- 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.

10. Clinical Testing

Clinical testing is not a requirement and has not been performed.

11. 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 VARO Plan described in this submission is substantially equivalent to the predicate device.