Implanter LLC
% Dr. Jorge Millan
Regulatory Affairs Manager
7600 NW 69th Avenue
MEDLEY, FL 33166

December 3, 2018

Re: K173083
Trade/Device Name: IMPLANTER DENTAL PLANNING SOFTWARE
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 26, 2018
Received: October 30, 2018

Dear Dr. Millan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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) K173083*

Device Name

IMPLANTER DENTAL PLANNING SOFTWARE

Indications for Use *(Describe)*

The IMPLANTER DENTAL PLANNING SOFTWARE is a device that employs previously scanned DICOM CT images in a software tool which serves as an aid to visualizing and preplanning of dental implant surgery.

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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510K SUMMARY

IMPLANTER DENTAL PLANNING SOFTWARE

K173083

SUBMITTER

IMPLANTER LLC
7600 NW 69TH AVENUE
MEDLEY, FL 33166

US AGENT

JORGE MILLAN, PHD
REGULATORY AFFAIRS MANAGER
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DATE OF SUMMARY: Dec 3, 2018

DEVICE NAME AND CLASSIFICATION

TRADE NAME: IMPLANTER DENTAL PLANNING SOFTWARE

CLASSIFICATION NAME: *892.2050 Picture Archiving and Communication System*
Product Code: LLZ

REGULATORY CLASS: *Class II*
PANEL IDENTIFICATION *Radiology*

DEVICE DESCRIPTION

The Implanter Dental Implant Planning Software is a software aimed to help simplifying dental implant surgery and enhancing its mechanical and esthetic implications in the prosthetic stage. Implanter Dental Implant Planning Software allows dental implant professionals to plan their implant surgeries and/or to design surgical appliances that will be used during surgery. The program will present the clinician with various reformatted CT/CBCT images of their patient's jaw(s), allow the placement and manipulation of virtual implants, and provide measurement and other tools to assist the clinician. Since the primary purpose of Implanter Dental Implant Planning Software is to aid the planning of implant surgeries, Implanter Dental Implant Planning Software will allow the surgeon to place simulated implants on the image and to gauge their size and position relative to the surrounding anatomy.

Implanter is a digital image processing software for Windows that loads images in DICOM format (CT and CBCT images) and rebuilds them in order to get different views that allows the dentist to assess the patient´s anatomy, plan a dental implant surgery, and design a printable surgical guide based on the former.

The software allows the dentist to:

- use a dental virtual implant gallery to plan a surgery choosing the proper implant size. The IMPLANTER software contains a virtual dental implants library based on the Groovy Implants from Noble Biocare® (FDA cleared under K050258).
- Implanter Dental Planning Software generates 3D models and exports these models in a format suitable for 3D printing to be used as physical models for visualization or educational purposes only. This clearance does not cover medical devices manufactured from those output files.
- save the surgical planning session of a patient for later analysis.

Indications for Use: The IMPLANTER DENTAL PLANNING SOFTWARE is a device that employs previously scanned DICOM CT images in a software tool which serves as an aid to visualizing and preplanning of dental implant surgery.

Comparison with the Predicate Devices [21 CFR 807.92(a) (6)]

The IMPLANTER DENTAL PLANNING SOFTWARE is equivalent to the VIRTUAL IMPLANT PLACEMENT (VIP) DENTAL IMPLANT SURGERY PLANNING SOFTWARE by Implant Logic Systems Ltd cleared under K060267 and the IPS software by Symbio Dental LLC cleared under K113404.

Technical Characteristics Comparison:

The basic and main technical features of the subject device IMPLANTER DENTAL PLANNING SOFTWARE are the same as the predicated device

Feature Comparison:

Subject device has similar features and functionality as the predicate device:

Table of comparison similarities and differences

Feature	IMPLANTER K#173083	VIRTUAL IMPLANT PLACEMENT K060267	IPS K113404
Image Source	CT Scanner	CT Scanner	CT Scanner, Cone beam CT machines, CT scanners
IFU	This device employs previously scanned DICOM CT images in a software tool which serves as an aid to visualizing and pre-planning of dental implant surgery	This device employs previously scanned DICOM CT images in a software tool which serves as an aid to visualizing and pre-planning of dental implant surgery	IPS is a prescription use software used by dentist and dental lab technicians for the visualization and image segmentation of DICOM data from medical scanners such as CT. The software aids the users in the creation of 3D models of oral maxillofacial region and in planning dental surgical treatments and placement of dental implants
Prescription use	Yes	Yes	Yes
Tools	Visualization, Implant Placement, distance measurement	Visualization, Implant Placement, Distance measurement,	Visualization, implant and nerve placement, measurement o distance, angle measurement, density determination, segmentation tool
Image Format Standard	DICOM PS 3.1	DICOM PS 3.1	DICOM

Reads DICOM directly	Yes	Yes	Yes
Displays axial, cross sectional and panoramic images	Yes	Yes	Yes
Implants modeled as conical sections	Yes	Yes	-
Implants modeled as 3D objects	No	No	Yes
3D view	Yes	Yes	Yes
Distance and ROI tools	Yes	Yes	Yes
Sinus lift tool	No	No	-
3D segmentation	No	No	Yes
Input implant models*	Yes	Yes	Yes
Report generation	Yes	Yes	Yes
Host Platform	PC	PC	PC
Output compatibility	CAD, rapid prototyping machines	---	CAD, rapid prototyping machines
Operating System	Windows 7.0 and later	Windows 98, 2000 and XP	Windows XP, Vista, 7
Host RAM	4 GB RAM	256 MB RAM	Not specified
Host Magnetic Storage	500 MB	10 GB hard drive	Not specified
CD ROM	Yes (for installation)	Yes (for installation)	Yes
Host Processor	Quad Core	Pentium III, 500 MHz	Not specified

*Implant models based on Groovy Implants from Noble Biocare® (FDA cleared under K050258).

Discussion of similarities: The IMPLANTER system features and functionalities are equivalent as those of predicate devices. All devices are software-based PC systems, using DICOM libraries and image controls for viewing and image manipulation. All systems use standard menu based graphical user interface.

Discussion of differences: The IPS system (K113404) has additional features and functionalities than the IMPLANTER system has. IMPLANTER system requires more RAM memory and less hard disk space than the VIRTUAL IMPLANT PLACEMENT device

(K060267), making it faster for image viewing. These differences and features do not raise safety or effectiveness concerns.

EFFECTIVENESS AND SAFETY CONSIDERATIONS

Clinical Test:

Clinical testing is not required.

Non-clinical Test:

The IMPLANTER DENTAL PLANNING SOFTWARE has documented, validated and verified its software system. Performance tests have been conducted to verify equivalent performance to predicate devices. Performance tests include measurement accuracy of 3D and 2D measuring tools, neve tracing and implant positioning, and implant drilling accuracy. Report generation has also been validated to verify accuracy of the information reported.

Substantially Equivalent Determination

The subject device has similar technology characteristics and has the same intended use, as legally marketed devices. There are no differences between the devices that affect the usage, safety and effectiveness, thus no new question is raised regarding the safety and effectiveness. In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, IMPLANTER IMPLANT PLANNING SOFTWARE is substantially equivalent to the predicate device with regards to safety and effectiveness.