



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

Saturn Imaging, Inc.
% Mr. Beender Yang
President
79, Sec. 1, Xintai 5th Road, 14F-11
New Taipei City 22101
TAIWAN

January 12, 2016

Re: K151152
Trade/Device Name: ImplantMax Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 22, 2015
Received: January 7, 2016

Dear Mr. Yang:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a large, semi-transparent watermark of the FDA logo.

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

Indications for Use

510(k) Number (if known)
K151152

Device Name
ImplantMax Software

Indications for Use (Describe)

ImplantMax Software is a stand-alone Windows-based software application to support the diagnosis and 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 and transfers the dataset into 3D dataset for pre-operative planning and simulation of dental placement.

The planned implant position can be exported and displayed as the position data of each joint of the articulated arm of ImplantMax Workstation. The user can manually set the position of ImplantMax Workstation arm to match the setting values displayed by ImplantMax Software. ImplantMax Workstation is set to the position to fabricate the surgical template. Please note that ImplantMax Workstation is not part of this 510(k) premarket notification.

The patient population is the general public.

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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Appendix A - 510(k) Summary

5.1 Applicant's Name and Address

Saturn Imaging Inc.
79, Sec.1, Xintai 5th Rd., 14F-11
New Taipei City 221, Taiwan
Telephone number:+886-2-8698-3330
Fax Number: +886-2-8698-3327
Contact Person: Beender Yang, President

5.2 Data of Submission: 04 / 16 / 2015

5.3 Device Information

Trade Name: ImplantMax Software
Common Name: Dental 3D diagnosis and implant planning software
Classification Name: Image Processing System
510(k) Number: K151152
Regulation Number: 21 CFR 892.2050
Product Code: LLZ

5.4 Predicate Device

Manufacturer: Straumann US
Trade Name: coDiagnostiX Implant Planning Software
510(k) Number: K130724
Regulation Number: 21 CFR 892.2050
Product Code: LLZ

5.5 Device Description

ImplantMax is a software interface for the transfer and visualization of 3D medical imaging information from medical CT (computed tomography) or dental CBCT (cone-beam computed tomography) scanner. It is designed to support the diagnosis and treatment planning for dental implantation with the 3D graphic representation. To facilitate the planning, the major software functions are provided as follows.

(1) MPR (multiplanar reconstruction), panoramic, and, 3D image reconstruction

- for analyzing anatomical condition,
- (2) Graphic visualization interface for placing the implant in mandible or maxilla images,
 - (3) Nerve module for assisting users in distinguishing inferior alveolar nerve (passing through mandibular canal),
 - (4) Simulation of different sized implants,
 - (5) Adjustment of implant location, including position and direction,
 - (6) Alignment function for multiple implants,
 - (7) Simulation of abutment and crown,
 - (8) Measurement tools for measuring length and angle,
 - (9) Bone quality (indicated by CT number) displayed in the area around the implant.

The implant position can be exported and displayed as the joint position of the articulated arm of ImplantMax Workstation that is a separated manually-operated device for fabricating the surgical template.

5.6 Intended Use

ImplantMax Software is a stand-alone Windows-based software application to support the diagnosis and 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 and transfers the dataset into 3D dataset for pre-operative planning and simulation of dental placement.

The planned implant position can be exported and displayed as the position data of each joint of the articulated arm of ImplantMax Workstation. The user can manually set the position of ImplantMax Workstation arm to match the setting values displayed by ImplantMax Software. ImplantMax Workstation is set to the position to fabricate the surgical template. Please note that ImplantMax Workstation is not part of this 510(k) premarket notification.

The patient population is the general public.

5.7 Substantial Equivalence to Predicate Device

The comparison of intended use and technological characteristics of subject and predicate devices is as follows.

Characteristic	Subject Device	Predicate Device	Difference Interpretation
K Number	K151152	K130724	-
Trade Name	ImplantMax Software	coDiagnostiX	-
Common Name	Dental 3D diagnosis and implant planning software	Dental 3D diagnosis and implant planning software	-
Classification	Regulation number: 21 CFR 892.2050 Product code: LLZ	Regulation number: 21 CFR 892.2050 Product code: LLZ	-
Intended Use	<p>ImplantMax Software is a stand-alone Windows-based software application to support the diagnosis and treatment planning for dental implantation. It is designed for qualified dental practitioners, including dentists and lab technicians.</p> <p>The software imports the medical image dataset of the patient in DICOM format from medical CT or dental CBCT scanners and transfers the dataset into 3D dataset for pre-operative planning and simulation of dental placement.</p>	<p>Straumann coDiagnostiX is an implant planning and surgery planning software tool intended for use by dental practitioners with appropriate training in dental implantology.</p> <p>This software reads imaging information output from medical scanners such as CT or DVT scanners. It allows pre-operative simulation and evaluation of patient anatomy, dental implant placement and surgical treatment options.</p>	

Characteristic	Subject Device	Predicate Device	Difference Interpretation
	<p>The planned implant position can be exported and displayed as the position data of each joint of the articulated arm of ImplantMax Workstation. The user can manually set the position of ImplantMax Workstation arm to match the setting values displayed by ImplantMax Software. ImplantMax Workstation is set to the position to fabricate the surgical template. Please note that ImplantMax Workstation is not part of this 510(k) premarket notification.</p>	<p>For automated manufacturing of drill guides in the dental laboratory environment, the coDiagnostiX software allows for export of data to 3D manufacturing systems, or coDiagnostiX can provide printouts of template plans for the creation of surgical templates using a manually operation gonyX table.</p>	<p>ImplantMax Software does not provide automated manufacturing of surgical templates.</p> <p>ImplantMax Software is intended to export the planned implant position for the creation of surgical templates using a manually operated ImplantMax Workstation. The intended use is substantially equivalent to coDiagnostiX provides printouts of template plans for the creation of surgical templates using a manually operation gonyX table.</p> <p>The difference does not raise new issue of safety and effectiveness.</p>

Characteristic	Subject Device	Predicate Device	Difference Interpretation
Target Population	General public	General public	-
Software Function	MPR (multiplanar reconstruction), panoramic, and, 3D image reconstruction for analyzing anatomical condition	Axial, cross-sectional, tangential, panoramic, 3D views for displaying the 3D volumetric data for diagnosis purpose	-
	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 to assist in distinguishing the nerve mandibular channel	-
	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	Aligning implant by moving and rotating the implant with the mouse	-
	Alignment function for multiple implants,	Parallelizing function for adjustment for adjacent images.	-
	Simulation of abutment and crown,	Abutment and virtual teeth tools provided	-
	Measurement tools for measuring length and	Active measurement tools, length and angle, for	-

Characteristic	Subject Device	Predicate Device	Difference Interpretation
	angle	individual measuring of implant position	
	Bone quality (indicated by CT number) displayed in the area around the implant	Bone densitometry with a density statistic for density measuring in the area around the positioned implant; a density allocation along and transverse to, the implant cover area is displayed	-
	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.	-
	The implant position recorded in the plan can be exported from ImplantMax Software and used as input data for the positioning device to fabricate surgical templates in the laboratory environment. The positioning device is a manual serial-linked articulated arm with four rotary joints. For each target implant direction, four angulation counts of the joints are displayed on the screen to guide the user to set the arm to the target position.	The template plan can be printed for the manual gonyX rotary table for surgical template fabrication in the lab environment. The printout contains 4 vernier scales (angulation) for each implant that guide the user to set the table to that implant direction.	-
Computer System	OS: Windows XP/Win7 CPU: Intel Pentium M-715, 1.5GHz or higher	OS: Microsoft Windows 7, XP, Vista. CPU: Intel Core or AMD Athlon 64 X2	The predicate device can be run on Apple operating system

Characteristic	Subject Device	Predicate Device	Difference Interpretation
Requirement	Memory: 2G or higher Video Card: Independent graphics card (from ATI or nVidia) with 512M memory or higher	Main memory: 2GB Hard disk: 1GB free, plus 50 MB per plan Screen resolution: 1024 x 768 pixels The software can also be run on the Apple operating system with minimum system requirements of: Macintosh computer with Intel process Mac OSX 10.6 or newer “Parallels Desktop” for Macintosh including valid Windows license	but ImplantMax Software cannot. The difference does not raise new issue of safety and effectiveness.
Image Import	DICOM data format from CT/DVT scanner saved on CDROM, PC or network.	DICOM data from CT/DVT scanner saved on CDROM, PC or network.	-
Anatomic Area	Maxilla, Mandible	Maxilla, Mandible	-
Safety Information	The device does not contact patient, nor does it control any life sustaining devices.	coDiagnostiX is not intended to be used in direct contact with the patient nor is it intended to be used with life sustaining devices.	-

Conclusion

Based on the side-by-side comparison, the differences between the subject and predicate devices do not raise new issues of safety and effectiveness. We conclude that ImplantMax Software is substantially equivalent to the predicate device in technological characteristics of intended use, software functions, target population, material, computer system requirement, image data format,

anatomic area, and safety information. The comparison demonstrates that ImplantMax Software is as safe, as effective, and performs as well as the predicate device.

5.8 Performance Testing

Software verification and validation testings were performed to ensure that the device subject to this 510(k) Premarket Notification functions as intended and that design input matches design output. In particular, the following verification and validation activities were performed:

Verification:

The functional testing was performed to verify the complete integrated system against the design inputs listed in the SDS document. The testing was performed under the engineering (development) environment by qualified personnel of Saturn. The testing results confirmed that the software is performed as designed. Performance test of image reconstruction verification was executed using an acrylic phantom with markers of known position. The testing results confirmed that the correction of the image reconstruction algorithm is verified to the acceptable criterion. The stability test was performed to confirm that the software is stable under long-time operation.

Validation:

The pre-clinical testing using partially edentulous and fully edentulous patient data was performed to verify safety and effectiveness as intended. The testing results confirmed that the software is performed to meet the user needs listed in SRS document. The usability test was also performed to validate user interface (UI) design. The test was conducted by an independent usability lab. Ten experienced dentists from the dentistry department of two university hospitals were participated in the test. The testing results confirmed that the UI design is acceptable for safety and effectiveness per *IEC62366::2007 "Medical devices – Application of usability engineering to medical devices"*

5.9 Safety Information

ImplantMax Software is a stand-alone software device for visualization of digital medical images. The device does not contact the patient, nor does it control any life sustaining devices.

All potential hazards have been identified and analyzed. The result of the analysis indicates that the device is of moderate level of concern per *"Guidance for*

the Content of Premarket Submission for Software Contained in Medical Devices”.

5.10 Conclusion

The information provided in this submission demonstrates that ImplantMax Software is substantially equivalent to the predicate device. The results of software validation indicate that the software is safe and effective for its intended use.