510(k) Summary – K130724

JUN 2 8 2013

1. **Applicant's Name and Address**

Straumann US (on behalf of Institut Straumann AG)
60 Minuteman Rd.
Andover, MA 01810
Telephone Number: 800-448-8168, ext 2513
Fax Number: 978-747-0023
Contact Person: Elaine Alan
Regulatory Project Manager

2. **Date of Submission**: March 15, 2013

3. **Name of the Device**

Trade Name:	coDiagnostiX Implant Planning Software
Common Name:	Dental 3D diagnosis and implant planning software
Classification Name:	Image Processing System
Regulation Number:	§892.2050

4. **Legally Marketed Device to which Equivalence is Claimed (Predicate Device)**

K071636, IVS coDiagnostiX

5. **Description of the Device**

coDiagnostiX Implant Planning Software is designed for diagnosis of 3dimensional datasets and precise image-guided and reproducible pre-operative planning of dental implants. The software is provided in three configurations: station, client or server. Patient image data is received from various sources such as CT or DVT scanning. The scanned data will be read with the coDiagnostiX DICOM transfer module using the DICOM format, converted into 3dimensional datasets and stored in a database. Surgical planning is performed through the calculation of special views, analysis of graphic data and the placement of virtual dental implants. Additional functions are available to the user for refinement of the surgical planning, such as:

- Active measurement tools, length and angle, for individual measuring of implant positions
- Nerve module to assist in distinguishing the nervus mandibularis channel
- 3D cut for a 3dimensional cut through the jaw for fine adjustment of the implant position

- Segmentation module for coloring several areas inside the slice dataset, e.g., jaw bone, natural tooth series, or types of tissue, e.g., bone, skin, and creating a 3D reconstruction for the dataset
- Parallelizing function for adjustment of adjacent images
- 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

All working steps are saved automatically to the patient file; one patient file may contain multiple surgical plan proposals which allow the user to choose the ideal surgical plan. The guided surgical template plan, STL file and/or guided surgical protocol is generated from the final surgical plan.

6. Intended Use of the Device

coDiagnostiX is an implant planning and surgery planning software tool intended for use by dental professionals who have appropriate knowledge in dental implantology and surgical dentistry. 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 and dental implant placement.

For automated manufacturing of drill guides in the dental laboratory environment, the coDiagnostiX software allows for export of data to 3D manufacturing systems. Alternatively, coDiagnostiX can provide printouts of template plans for the creation of surgical templates using a manually operated gonyX table.

7. Technological Characteristics

coDiagnostiX Implant Planning Software is a dental image diagnosis and implant planning software. A comparison of the technological characteristics of predicate and subject device is below.

FEATURE	PROPOSED DEVICE coDiagnostiX	PREDICATE DEVICE IVS coDiagnostiX
K Number	Subject Submission	K071636
Intended Use	Straumann coDiagnostiX is an implant planning and surgery planning software tool intended for use by dental practitioners with appropriate training in dental implantology. 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. 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 templant plans for the creation of surgical templates using a manually operated gonyX table. The target patient population is the general public. coDiagnostiX is not intended to be used in direct contact with the patient nor is it intended to be used with life sustaining devices.	coDiagnostiX is intended for use by medical trained people as a Windows-based diagnosis and implant planning software. This software is an interface for the transfer of imaging information from medical scanners such as CT or DVT scanners and also a pre-operative software for simulation and evaluation dental implant placement and surgical treatment options. The patient population will be the general public. coDiagnostiX is not intended to be used in direct contact with the patient nor is it intended to be used with life sustaining devices. It is possible to use coDiagnostiX as a pattern for manufacturing drilling templates with conventional rotary tables or gonyX table from IVS Solutions AG in laboratory environment. This drilling template is then used in direct contact with the patient to realize the implant planning with coDiagnostiX.
Minimum System Requirements	OS: Microsoft Windows 7, Windows SP, Vista Processor: Intel Core or AMD Athlon 64 X2 Main memory: 2 GB Hard disk: 1GB free, plus 50 MB per plan Screen resolution: 1024 x 768 pixels DVD drive One free USB port Optional: Microsoft SQL Server Desktop Engine (MSDE) if user selects to use the SQL Server Module The software can also be run on the Apple operating system with minimum system requirements of: Macintosh computer with Intel processor Mac OSX 10.6 or newer "Parallels Desktop" for Macintosh including valid Windows license (software purchased separately)	WIN 98/NT/2000/XP Pentium compatible processor with 800MHz 128 MB RAM 500 MB hard disc 17" color display with 1024x768 resolution and 16.7 million colors CD ROM device USB interface Optional: Microsoft SQL Server Desktop Engine (MSDE) if user selects to use the SQL Server Module The software can also be run on the Apple operating system with minimum system requirements of: Macintosh computer with Intel processor Mac OSX 10.6 or newer "Parallels Desktop" for Macintosh including valid Windows license (software purchased separately)
Target Population	Same	General public
Supported image formats	Same	JPEG, BMP
DICOM compliant	Yes	yes
Image import	Same, plus STL file format	DICOM data from CT/DVT scanner saved on CDROM, PC or network
Image export	STL file format	unknown
Printouts	Same	Report/plan with patient information, screenshot, implant list, template information, gonyX verification

8. Performance Testing

Software verification and validation testing were performed to ensure that the device subject to this 510(k) Premarket Notification functions as intended and that design input matches design output. Testing has been carried out in accordance with the FDA guidance document, *"General Principles of Software Validation: Final Guidance for Industry and FDA Staff,"* issued on January 11, 2002. The proposed software met the acceptance criteria.

9. Conclusion

coDiagnostiX Implant Planning Software has identical intended use, and operational and functional features, and level of concern as the currently cleared software. Results of the software validation indicate that the software performs as intended and that the proposed changes do not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 28, 2013

Straumann USA, LLC
% Ms. Elaine Alan
Regulatory Project Manager
60 Minuteman Road
ANDOVER MA 01830

Re: K130724
Trade/Device Name: coDiagnostiX Implant Planning Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 17, 2013
Received: May 20, 2013

Dear Ms. Alan:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Janine M. Morris
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): K130724

Device Name: coDiagnostiX Implant Planning Software

Indications for Use:

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For automated manufacturing of drill guides in the dental laboratory environment, the coDiagnostiX software allows for export of data to 3D manufacturing systems. Alternatively, coDiagnostiX can provide printouts of template plans for the creation of surgical templates using a manually operated gonyX table.

Prescription Use__X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiologic Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiologic Health

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