June 21, 2021

Dental Wings GmbH
℅ Jennifer Jackson
Director of Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K193301
Trade/Device Name: coDiagnostiX
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZJ, LLZ
Dated: May 26, 2021
Received: May 27, 2021

Dear Jennifer Jackson:

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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193301

Device Name
coDiagnostiX

Indications for Use *(Describe)*

coDiagnostiX is an implant planning and surgery planning software tool intended for use by dental professionals who have appropriate knowledge in the field of application. The software reads imaging information output from medical scanners such as CBCT or CT scanners.

It is indicated for pre-operative simulation and evaluation of patient anatomy, dental implant placement, surgical instrument positioning, and surgical treatment options, in edentulous, partial edentulous or dentition situations, which may require a surgical guide. It is further indicated for the user to design such guides for, alone or in combination, the guiding of a surgical path along a trajectory or a profile, or to help evaluate a surgical preparation or step.

coDiagnostiX software allows for surgical guide export to a validated manufacturing center or to the point of care. Manufacturing at the point of care requires a validated process using CAM equipment (additive manufacturing system, including software and associated tooling) and compatible material (biocompatible and sterilizable). A surgical guide may require to be used with accessories.

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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5 Section 5: 510(k) Summary - coDiagnostiX

5.1 Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of: Dental Wings GmbH Düsseldorfer Platz 1 09111 Chemnitz Germany
Contact Person:	Jennifer M. Jackson, MS Director of Regulatory Affairs and Quality Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023
Date of Submission:	June 17, 2021

5.2 Name of the Device

Trade Names:	coDiagnostiX
Common Name:	Dental Surgery Planning Software
Classification Name:	Bone cutting instrument and accessories
Regulation Number:	21 CFR 872.4120
Device Classification:	II
Product Code:	DZJ
Secondary Product Code(s):	LLZ
Review Panel:	Dental

5.3 Predicate Device(s)

Primary Predicate:

- K130724 – coDiagnostiX Implant Planning Software

Reference Devices:

- K182789 – KLS Martin Individual Patient Solution (IPS) Planning System
- K112280 – Straumann® CARES® Screw-retained Bridge Ti, Straumann® CARES® Dolder® Bar Ti

5.4 Description

The main uses and capabilities of the coDiagnostiX software are unchanged from the primary predicate version.

As in the primary predicate version, it is a software for dental surgical treatment planning. It is designed for the evaluation and analysis of 3-dimensional datasets and the precise image-guided and reproducible preoperative planning of dental surgeries.

The first main steps in its workflow include the patient image data being received from CBCT (Cone Beam Computed Tomography) or CT. The data in DICOM format is then read with the coDiagnostiX DICOM transfer module according to the standard, converted into 3-dimensional datasets and stored in a database.

The pre-operative planning is performed by the computation of several views (such as a virtual Orthopantomogram or a 3-dimensional reconstruction of the image dataset), by the analysis of the image data, and the placement of surgical items (i.e. sleeves, implants) upon the given views. The pre-operative planning is then followed as decided by the user by the design of a corresponding surgical guide that reflects the assigned placement of the surgical items.

Additional functions are available to the user for refinement of the preoperative planning, such as:

- Active measurement tools, length and angle, for the assessment of surgical treatment options;
- Nerve module to assist in distinguishing the *nervus mandibularis* canal;
- 3D sectional views through the jaw for fine adjustment of surgical treatment options;
- Segmentation module for coloring several areas inside the slice dataset, e.g., jawbone, native teeth, or types of tissue such as bone or skin, and creating a 3D reconstruction for the dataset;
- Parallelizing function for the adjustment of adjacent images; and
- Bone densitometry assessment, with a density statistic in areas of interest.

All working steps are automatically saved to the patient file. One patient file may contain multiple surgical treatment plan proposals which allows the user to choose the ideal surgical treatment plan. The output file of the surgical guide and/or the guided surgical protocol is then generated from the final surgical treatment plan.

coDiagnostiX software allows for surgical guide export to a validated manufacturing center or to the point of care. Manufacturing at the point of care requires a validated process using CAM equipment (additive manufacturing system, including software and associated tooling) and compatible material (biocompatible and sterilizable). A surgical guide may require to be used with accessories.

The changes with respect to the coDiagnostiX predicate device version are to expand on the different surgical planning tools that can be considered as part of the predicate's general implant planning and surgical planning indications for use. The three tools are:

a) Planning of a surgical path along a trajectory - this provides for a path to be determined that defines the alignment orientation of a surgical item (e.g., an implant and/or instrument).

b) Planning of a surgical path along a profile – this provides for a profile surface to be determined to guide the orientation of a surgical instrument along a profile.

c) Planning of a form suitable to evaluate surgical preparation or other surgical steps - this provides for a procedure to be planned with the corresponding design of a form with geometric features to evaluate the results of a surgical procedure or step.

Such planning may include the design of drill guides (planning a), cutting guides (planning b) and evaluation guides (planning c). Drill guides are manufactured from acrylate, whereby the drilling area is protected by metal. The same applies for the evaluation guides. Cutting guides are manufactured from commercially pure titanium and – if piezo-surgical instruments are applied – acrylate. Note that only cutting guides are subject of this submission. Drill guides and evaluation guides are mentioned for informational purposes only. They are not subject to the premarket clearance in this K193301 submission. Manufacturing takes place at Straumann's validated manufacturing center or at the point of care. Manufacturing at the point of care requires a validated process using CAM equipment (additive manufacturing system, including software and associated tooling) and compatible material (biocompatible and sterilizable). A surgical guide may require to be used with accessories. Accessories are included or referenced in the surgical item library, as well as items which are required to be known for the surgery planning.

These changes were accommodated by changes to the GUI, adding items to the surgical item libraries, and the product's instructions for use to clarify and explain the use of the general surgery planning tool specificities. There are no changes to the base software functionalities or architecture as compared to the predicate device coDiagnostiX software.

5.5 Indications for Use of the Subject Device:

coDiagnostiX is an implant planning and surgery planning software tool intended for use by dental professionals who have appropriate knowledge in the field of application. The software reads imaging information output from medical scanners such as CBCT or CT scanners.

It is indicated for pre-operative simulation and evaluation of patient anatomy, dental implant placement, surgical instrument positioning, and surgical treatment options, in edentulous, partial edentulous or dentition situations, which may require a surgical guide. It is further indicated for the user to design such guides for, alone or in combination, the guiding of a surgical path along a trajectory or a profile, or to help evaluate a surgical preparation or step.

coDiagnostiX software allows for surgical guide export to a validated manufacturing center or to the point of care. Manufacturing at the point of care requires a validated process using CAM

equipment (additive manufacturing system, including software and associated tooling) and compatible material (biocompatible and sterilizable). A surgical guide may require to be used with accessories.

5.6 Substantial Equivalence Determination:

The general intended use is identical for both the subject device and primary predicate device. As to the indications for use, the general planning tools indication has been modified for the subject device coDiagnostiX as compared to its predicate device version (K130724), to also indicate three specific planning tool principles or approaches that are available with the software. The subject device also specifies the indicated patient conditions: for use in edentulous, partial edentulous, and dentition conditions. However, this is already included in the labelling of the primary predicate (K130724). Finally, the alternate workflow involving the printouts and manufacturing method using the manually operated gonyX has been removed.

Similarities and Differences to the Predicate Device

The predicate device coDiagnostiX software version (K130724) is identical or similar to the subject device' technological characteristics with regards to the software, hardware, interface requirements, as well as inputs and outputs. The surgical item library has been updated. For manufacturing at the point of care, the acrylate has been replaced by a similar acrylic resin. Central manufacturing of guides made of acrylic resin and commercially pure titanium have been added.

A technological difference is that the subject device proposes the usage of piezo-surgical cutting instruments with acrylic guides. The potential impact on substantial equivalence of this technological difference is addressed by risk analysis and testing. With the non-clinical data obtained this method is considered equivalent to the usage of a state of the art cutting device with a metal guide and does not present any new significant questions of safety or effectiveness.

Reference Devices

KLS Martin Individual Patient Solution (IPS) Planning System (K182789) has been included as reference device to leverage the increased specificity of general tool indication as part of surgery planning and surgical treatment options. KLS Martin Individual Patient Solution (IPS) Planning System is using the same technologies and methods as the subject device and is describing surgical planning tool specificities for maxillofacial treatments, which include the treatments in the oral-maxillofacial region of the subject device.

Straumann® CARES® Screw-retained Bridge Ti, Straumann® CARES® Dolder® Bar Ti (K112280) has been included as reference device to leverage individual customized titanium guides made of commercially pure titanium using subtractive manufacturing method (centralized milling).

The table below summarizes the similarities and differences between the proposed device, the predicate device, and the reference devices with respect to the intended uses and indications for use, and the device features and specifications:

Item	coDiagnostiX K193301 (Subject Device)	coDiagnostiX K130724 (Predicate Device)	IPS K182789 (Reference Device)	SRBB K112280 (Reference Device)
Indications for Use	coDiagnostiX is an implant planning and surgery planning software tool intended for use by dental professionals who have appropriate knowledge in the field of application. The software reads imaging information output from medical scanners such as CBCT or CT scanners. It is indicated for pre-operative simulation and evaluation of patient anatomy, dental implant placement, surgical instrument positioning, and surgical treatment options, in edentulous, partial edentulous or dentition situations, which may require a surgical guide. It is further indicated for the user to design such guides for, alone or in combination, the guiding of a surgical path along a trajectory or a profile, or to help evaluate a surgical preparation or step. coDiagnostiX software allows for surgical guide export to a validated manufacturing center or to the point of care. Manufacturing at the point of care requires a validated process using CAM equipment (additive manufacturing system, including software and associated tooling) and compatible material (biocompatible and sterilizable). A surgical guide may require to be used with accessories.	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.	The KLS Martin Individual Patient Solutions (IPS) Planning System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the IPS Planning System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, guides, splints, and case reports for use in maxillofacial surgery. The IPS Planning System is also intended as a pre-operative software tool for simulating / evaluation surgical treatment options.	Straumann CARES Screw-retained Bridge Ti and Straumann CARES Dolder Bar Ti are indicated for use as bares and bridges that attach to dental implants (Straumann implant Regular Neck (RN(Ø4.8mm and Wide Neck (WN) Ø6.5mm) in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function. The Straumann CARES Screw-retained Bridge Ti can be designed for specific patient size and spans thar are attached to 2 to 16 implants. The Straumann CARES Dolder Bar Ti can be designed for specific patient sizes and spans that are attached to 2 to 10 implants.
Classification	21 CFR 872.4120, Class II 21 CFR 892.2050, Class II	21 CFR 892.2050, Class II	21 CFR 872.4120, Class II 21 CFR 892.2050, Class II	21 CFR 872.3630, Class II
Product Code(s)	DZJ, LLZ	LLZ	DZJ, LLZ	NHA
Product Code Name	Bone Cutting Instruments and Accessories System, Image Processing, Radiological	System, Image Processing, Radiological	Bone Cutting Instruments and Accessories System, Image Processing, Radiological	Endosseous Dental Implant Abutment
General Description	Dental Surgery Planning System	Dental Surgery Planning System	Dental Surgery Planning System	Implant Restoration
Prescription Use	Yes	Yes	Yes	Yes
Core Component	Stand-alone software	Stand-alone software	Stand-alone software	Bar, Bridge
Target Population	General public	General public	Pediatric & Adults	N/A

Item	coDiagnostiX K193301 (Subject Device)	coDiagnostiX K130724 (Predicate Device)	IPS K182789 (Reference Device)	SRBB K112280 (Reference Device)
Patient condition	For edentulous, partial edentulous or dentition situations	For edentulous, partial edentulous or dentition situations	Non-specific	For edentulous or partial edentulous.
Main Features/ Tools	CAD tools to manipulate/modify/ render/import/export/sectioning patient models (teeth, upper/lower jaws), surgical item models, areas of interest. Includes: - Panoramic curve - Nerve detection - Virtual structures - Orient images to occlusal plane - Surgical item libraries - Bone density analyses, geometric measurements	CAD tools to manipulate/modify/ render/import/export/sectioning patient models (teeth, upper/lower jaws), surgical item models, areas of interest. Includes: - Panoramic curve - Nerve detection - Virtual structures - Orient images to occlusal plane - Surgical item libraries - Bone density analyses, geometric measurements	CAD tools to manipulate/modify/ render/import/export/sectioning patient models (teeth, upper/lower jaws), surgical item models, areas of interest. Includes: - Panoramic curve - Nerve detection - Virtual structures - Orient images to occlusal plane - Surgical item libraries - Bone density analyses, geometric measurements - Orthognathic modelling	N/A
Anatomical site	Oral-maxillofacial regions	Oral-maxillofacial regions	Cranio-maxillofacial regions	N/A
Specialty of application / Surgical Planning Tool Specificities	Surgery treatment planning Specificities as per surgical planning tool with treatment examples in the user manual: • Planning of a surgical path along a trajectory • Planning of a surgical path along a profile • Planning to help evaluate a surgical preparation or step Applicable in: • Restorative Dentistry (including Endodontics and Implantology) • Oral Surgery • Maxillofacial Surgery • Periodontics • Orthodontics	Surgery treatment planning Specificities with treatment example implantation in the user manual. Applicable in: • Restorative Dentistry (including Implantology)	Surgery treatment planning Specificities with treatment example bone reconstruction, orthognathic procedures, implant design and model creation in the user manual. Applicable in: • Maxillofacial Surgery	N/A
Physical output design per Planning	Yes	Yes	Yes	N/A

Item	coDiagnostiX K193301 (Subject Device)	coDiagnostiX K130724 (Predicate Device)	IPS K182789 (Reference Device)	SRBB K112280 (Reference Device)
Minimum System Requirements	PC with specified requirements on hardware, operating system and security (in user manual)	PC with specified requirements on hardware, operating system and security (in user manual)	PC with specified requirements on hardware, operating system and security (in user manual)	N/A
Interface Requirements	Desktop Application	Desktop Application	Web Application	N/A
DICOM Standard Compliant	Yes	Yes	Yes	N/A
Image Import	- DICOM standard format data from CBCT or CT, - STL standard format from impression and/or surface scanners	- DICOM standard format data from CBCT or CT - STL standard format from impression and/or surface scanners	- DICOM standard format data from CBCT or CT - STL standard format from impression and/or surface scanners	N/A
Export	STL file format	STL file format	STL file format	N/A
Printouts	Report/plan with patient information, screenshots, plan results	Report/plan with patient information, screenshots, plan results	Report/plan with patient information, screenshots, plan results	N/A
Guide Material	Acrylate CP Titanium	Acrylate Polystyrene	Polyamid, Titanium Alloy (Ti-6Al-4V), CP Titanium Methacrylate (splints)	CP Titanium (no guide design, but bridge and bar on implant)
Guide Function	Cutting guide (CP Titanium or Acrylate)	Drill guide, Evaluation Guide	Marking/Cutting Guide (Polyamid, Titanium Alloy (Ti-6Al-4V), CP Titanium) Splints (Methacrylate)	N/A (no guide design)
Sterilization	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)
Manufacturing Method	Acrylate: Additive (Digital Light Processing (DLP)) CP Titanium: Subtractive	Acrylate: Additive (Polyjet) Polystyrene: gonyX (manually operated)	Acrylate: Additive (Stereolithography (SLA)) Polyamide: Additive (Selective Laser Sintering (SLS)) Titanium Alloy: Additive (Selective Laser Melting (SLM)) CP Titanium: Subtractive (traditional)	CP Titanium: Subtractive (traditional)

Item	coDiagnostiX K193301 (Subject Device)	coDiagnostiX K130724 (Predicate Device)	IPS K182789 (Reference Device)	SRBB K112280 (Reference Device)
Guide Specifications	Design Volume: Min: patient specific Max: 200 mm x 200 mm x 100 mm	Not provided	Length: Min: 15 mm Max: 350 mm; Width: Min: 7 mm Max: 200 mm; Thickness: Min: 1 mm Max: 5 mm; Degree of curvature (in-plane): Min: 90° Max:180°; Degree of curvature (out of plane): Min: 60° Max: 180°	N/A
	No. of supporting points: Min: 3, arranged in a triangle	Not provided	No. of holes: Min: 2 Max: Depends on length and screw hole spacing	N/A
	Supporting points distance: Max: 40 mm	Not provided	Screw hole spacing: ≥ 4.5 mm	N/A
	Cutting bar dimensions: Height/Thickness: ≥ 3 mm Width: ≥ 4 mm	Not provided	Length: Min: 15 mm Max: 350 mm; Width: Min: 7 mm Max: 200 mm; Thickness: Min: 1 mm Max: 5 mm;	N/A

5.7 Non-Clinical Performance Data

Software verification and validation is conducted to assure requirements and specifications as well as risk mitigations (design inputs) are correctly and completely implemented and traceable to design outputs. Testing required, including functional and usability testing, shows conformity with expected results. The software documentation provides evidence that the software performs as intended and any potential risks are adequately mitigated as specified.

Software verification and validation includes the evidence that the base accuracy is identical as compared to the predicate device given that the base software (CAD type) capabilities, image sources, and output file functions are unchanged from the predicate device version of coDiagnostiX. This is similar as to the reference device KLS Martin Individual Patient Solution (IPS) Planning System (K182789) and adequate for the respective new tool specificities and related example uses applicable under those predicate and reference devices, given they involve the same base software capabilities (CAD type) and CBCT or CT image sources, as well as the same type of output files.

Guide material types, specific compositions with its properties are similar and provided for the finished material by the material manufacturers. Stability testing is conducted to validate those properties under expected conditions of use. Results demonstrate for all guide materials used, that the properties are not degraded by sterilization or storage, with the shelf-life validated for 10 months. The material compositions are safe for the devices intended use.

Biocompatibility testing is conducted in accordance with ISO 10993-1 for the acrylates, including an assessment of the impact of material reuse. For titanium the evaluations from the reference device (K112280) are leveraged. Biocompatibility testing includes test results provided by material manufacturers, development partners and own testing. The evaluations conducted are within the acceptance criteria defined by the standard. The results demonstrate that there is no evidence that the guides applied as intended are hazardous. It adequately addresses biocompatibility. Similar testing and confirming results are available for the reference devices.

Sterilization validation is performed for steam sterilization for the acrylate guides in accordance with ISO 17665-1 to a sterility assurance level (SAL) of 10-6 using the biological indicator (BI) overkill method. For titanium guides the sterilization validations from the reference device (K112280), which are identical in formulation, manufacturing process and post-processing procedures, are leveraged. In addition, accuracy and stability testing was conducted after sterilization. The acceptance criteria are met. The results demonstrate that the guides are safe to sterilize for their intended use.

Process performance qualifications of the manufacturing process are conducted to assure a guide of a certain material can safely and effectively be manufactured (with the compatible 3D manufacturing system). Worst case testing of representative guide designs is utilized, including an assessment of the influence of build orientation and build location in the build space as well as of material reuse. Expected results are met. This process performance qualifications includes

centralized manufacturing and point of care procedures. The validated materials and manufacturing processes are safe and effective for their intended use.

6 Conclusion

The coDiagnostiX software has the same intended use and similar technological characteristics as the primary predicate device. The changes to increase the tool indication specificities, together with the minor updates in the software, the labeling, and the expansion of validated material and manufacturing process capabilities do not change the intended use or the applicable fundamental technology, and do not raise any new questions of safety or effectiveness. Additionally, the non-clinical testing supports that the software and its outputs, perform in accordance with the intended us and are safe and effective, and perform as well as the predicate device. The subject device has been shown to be substantially equivalent to the predicate device.