



Food and Drug Administration
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October 7, 2016

Institut Straumann AG
% Jennifer Jackson
Director Of Regulatory Affairs And Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K161677

Trade/Device Name: Straumann Sterile Healing Solution
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 5, 2016
Received: September 9, 2016

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. 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 and Part 809); 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 and Part 809), 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K161677

Device Name

Straumann® Sterile Healing Solution

Indications for Use (Describe)

Healing abutments, healing caps and closure screws are intended for use with the implants of the Straumann Dental Implant System to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Fixation caps are used to stabilize bone grafts in cases where bone augmentation is being performed in conjunction with implant placement.

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. 510(k) Summary **K161677****
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- Prepared By:** Christopher Klaczyk
Head of North American Regulatory Affairs
Institut Straumann AG
+41 61 965 1260
- Date Prepared:** October 7, 2016
- Product Code(s):** NHA (21 CFR 872.3630)
- Device Class:** II (21 CFR 872.3630)
- Classification Panel:** Dental
- Classification Name:** Endosseous dental implant abutment (21 CFR 872.3630)
- Proprietary Name:** Straumann® Sterile Healing Solution
- Predicate Device::** K130808, Straumann® Sterile Healing Solution (Institut Straumann)
- Reference Device(s):** K062129, Bone Level Implants (Institut Straumann)
K120951, SMARTbuilder System (Osstem Implant Co.)
- Device Description:** The Straumann Healing Abutments, Healing Caps, and Closure Screws are intended for use with the implants of the Straumann Dental Implant System (SDIS) to protect the inner features of the implant and to maintain, stabilize and form the soft tissue during the healing process. The devices are available in various diameters and heights. They are also not intended for use in immediate loading protocols; none of the devices of the Straumann Sterile Healing Solution are indicated for use in immediate loading protocols as they are intended to protect the internal features of the implant during the healing phase.
- When the implant has sufficient primary stability, the closure caps and fixation caps are used as a means to retain a bone graft

used to augment the bone in the vicinity of the implant. These devices are not intended to be used with granular bone substitute materials or dental membranes.

The subject devices are identified in the table below.

<i>Article Number</i>	<i>Description</i>
024.0000S	RC Healing Abutment, conical, Ø 4.5, H2
024.0001S	RC Healing Abutment, conical, Ø 4.5, H4
024.0002S	RC Healing Abutment, conical, Ø 4.5, H6
024.0003S	RC Healing Abutment, conical, Ø 6.0, H2
024.0004S	RC Healing Abutment, conical, Ø 6.0, H4
024.0005S	RC Healing Abutment, conical, Ø 6.0, H6
024.2100S	NC Closure Screw, H 0
024.2100S-04	NC Closure Screw, H 0 (4-Pack)
024.2105S	NC Closure Screw, H 0.5
024.2105S-04	NC Closure Screw, H 0.5 (4-Pack)
024.2220S	NC Closure & Fixation Cap, Ø 5.5mm, Ti
024.4100S	RC Closure Screw, H 0
024.4100S-04	RC Closure Screw, H 0 (4-Pack)
024.4105S	RC Closure Screw, H 0.5
024.4105S-04	RC Closure Screw, H 0.5 (4-Pack)
024.4220S	RC Closure & Fixation Cap, Ø 5.5mm, Ti
048.324S	NNC Closure Screw, H 0
048.324SV4	NNC Closure Screw, H 0 (4-Pack)
048.325S	NNC Closure Screw, H 0.5
048.325SV4	NNC Closure Screw, H 0.5 (4-Pack)
048.371SV4	RN Closure Cap, H 0, Ti (4-Pack)
048.373SV4	RN Closure Cap, H 1.5 mm, Ti (4-Pack)

Indications For Use: Healing abutments, healing caps and closure screws are intended for use with the implants of the Straumann Dental Implant System to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Fixation caps are used to stabilize bone grafts in cases where bone augmentation is being performed in conjunction with implant placement.

Materials: The material for all Healing Abutments, Closure Caps and Closure Screws is commercially pure Titanium (grade 4) conforming to ISO 5832-2.

Technological Characteristics: A comparison of the relevant technological characteristics between the subject and primary predicate devices is provided in the table that follows.

Feature	Primary Predicate Device Straumann Sterile Healing Solution	Subject Devices Straumann Sterile Healing Solution
Indications For Use K130808	Closure screws, healing caps, and healing abutments, are intended for use with the Straumann dental implant system (sdis) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Customizable healing abutments made of PEEK are for use for up to six months.	Healing abutments, healing caps and closure screws are intended for use with the implants of the Straumann Dental Implant System to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Fixation caps are used to stabilize bone grafts in cases where bone augmentation is being performed in conjunction with implant placement.
Indications For Use K120951	SMARTbuilder System is a metal (Non-resorbable membrane) device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	The Indications for Use differ with the removal of the PEEK abutments. The subject devices do not include PEEK abutments and only include Titanium abutments; therefore the modification of the Indications for Use is acceptable as the PEEK abutment limitation for 6 months does not apply to the subject device
Compatible Implants	Straumann Bone Level implants having the NC and RC implant-to-abutment interface geometries. Straumann Tissue Level implants having the NNC, RN and WN implant-to-abutment interface geometries.	Straumann Bone Level implants having the NC and RC implant-to-abutment interface geometries. Straumann Tissue Level implants having the NNC and RN implant-to-abutment interface geometries.
Material	Commercially pure grade 4 Titanium per ISO 5832-2	Commercially pure grade 4 Titanium per ISO 5832-2
Construction	One-piece solid device.	One-piece solid devices and two-piece device assemblies. Two-piece devices are supported via comparison with components of the Osstem SMARTbuilder System (K120951)
Packaging	Primary barrier package consists of a PETG blister tray with a PETG insert and a Tyvek 1073B lid stock. The primary package is contained within a paperboard shelf box.	Primary barrier package consists of a PETG blister tray with a PETG insert and a Tyvek 1073B lid stock. The primary package is contained within a paperboard shelf box.
Sterility	Provided sterile via gamma irradiation to a Sterility Assurance Level of 10 ⁻⁶ . Cycle validated per ISO 11137-2.	Provided sterile via gamma irradiation to a Sterility Assurance Level of 10 ⁻⁶ . Cycle validated per ISO 11137-2.

- Performance Data:** Test data to support the evaluation of the subject closure cap and fixation cap devices has been included directly or by reference as follows:
- Sterilization validation in accordance with ISO 11137 series of standards.
 - Biocompatibility assessment per the ISO 10993 series of standards.
 - Shelf Life validation in accordance ASTM F1980

No animal or human clinical studies were conducted.

Conclusions: Based upon our assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate devices.