DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

May 24, 2017

Hager & Meisinger GmbH
Melanie May
Regulatory Affairs
Hansemannstrasse 10
Neuss, 41468
GERMANY

Re: K170287
Trade/Device Name: Dental Implants OKTAGON® Bone Level Tapered Design
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: May 4, 2017
Received: May 8, 2017

Dear Melanie May:

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,

Lori A. Wiggins -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

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)*
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Device Name
Dental Implants OKTAGON® Bone level Tapered Design

Indications for Use *(Describe)*
The Dental Implants OKTAGON® Bone Level Tapered Design are surgically placed in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients. The implants are intended to be used with OKTAGON® abutments and prosthetic parts. The implants are intended for delayed loading in a two-stage surgery or for immediate loading when good primary stability is achieved and with appropriate occlusal load.

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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Dental Implants OKTAGON® Bone Level Tapered Design

510(k) Summary

1. Applicant's Name and Address

Hager & Meisinger GmbH
Hansemannstrasse 10
41468 Neuss
Germany
Phone: *0049 2131 2012 292*
Fax: *0049 2131 2012 223*
Contact Person: *Dr. Melanie May*
Regulatory Affairs

2. Date prepared

Date prepared: *05/23/2017*

3. Name of the device

Trade Name: *Dental Implants OKTAGON® Bone level Tapered Design*
Common Name: *Endosseous dental implants*
Classification Name: *Endosseous dental implants*
Product Code: *DZE*
Regulation No: *872.3640*
Class: *II*
Panel: *Dental*

4. Predicate Devices:

510(k) No.	Manufacturer	Trade Name
K143539	*Hager & Meisinger GmbH*	*Dental Implant System OKTAGON® Bone Level*
K140878	*Straumann USA,LLC*	*Straumann® Bone Level Tapered Implants*

5. Device Description:

The Dental Implants OKTAGON® Bone Level Tapered Design are an addition to the currently distributed Dental Implant System® OKTAGON Bone Level. The implants can be used for immediate or early implantation after loss or extraction of natural teeth.

The endosteal implant body of the subject device has a conical shape in the coronal region and is cylindrical in the apical region. The apical cylindrical part of the implant is relevant for the given endosteal diameter of 3.3 to 4.1 mm. The implants are made of commercially pure Titanium Grade 4 conforming to ASTM- F67. The surface is micro-structured in the endosteal part and has been blasted with high-grade corundum and afterwards acid-etched. The implant shoulder is polished.

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The prosthetic connection is achieved with the help of an inner cone with an additional octagonal anti-rotation device. A sterile cover screw is enclosed with the implant so that an immediate occlusion of the internal thread is possible after successful insertion.

The submission contains the following tapered design implant variations:

BLT NC Ø 3.3 mm, L 8.0 mm
BLT NC Ø 3.3 mm, L 10.0 mm
BLT NC Ø 3.3 mm, L 12.0 mm

BLT NC Ø 3.75 mm, L 8.0 mm
BLT NC Ø 3.75 mm, L 10.0 mm
BLT NC Ø 3.75 mm, L 12.0 mm

BLT NC Ø 4.1 mm, L 8.0 mm
BLT NC Ø 4.1 mm, L 10.0 mm
BLT NC Ø 4.1 mm, L 12.0 mm

6. Indications for Use:

The Dental Implants OKTAGON® Bone Level Tapered Design are surgically placed in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients. The implants are intended to be used with OKTAGON® abutments and prosthetic parts. The implants are intended for delayed loading in a two-stage surgery or for immediate loading when good primary stability is achieved and with appropriate occlusal load.

7. Performance tests and used standards

Information regarding biocompatibility testing, sterility validation and shelf life was leveraged from the predicate device K143539.

The following standards have been followed for the development, production, performance and safety testing of the subject devices.

- *Fatigue Testing according to ISO 14801*
- *Evaluation of Biocompatibility according to ISO 10993-1, ISO 7405*
- *Cytotoxicity Testing according to ISO 10993-5*
- *Sterilization Validation for implants and accessories according to ISO 11137-1, ISO 11137-2,*

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- *Sterile Barrier Testing according to ASTM F88/F88M-09 and ASTM F1929-98*
- *Packaging of sterilized implants according to ISO 11607-1*
- *Material Specification according to ASTM F67*
- *Risk Management according to ISO14971*

In order to demonstrate substantial equivalence performance tests (breakage and fatigue tests) have been conducted fulfilling the requirements of ISO 14801 and the FDA's "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments".

8. Basis for substantial equivalence

The intended use for Dental Implant OKTAGON® Bone Level Tapered Design is identical to the named predicated devices. The implants have the same material composition and the same surface treatments. In addition, the implants are of the same, root-form design

Since the Dental Implants OKTAGON® Bone Level Tapered Design and the predicate implants have the same design, are made of the same materials (see table), exhibit the same performance characteristics (e.g. strength and function), and are furthermore intended for the same use, no new performance or safety issues are raised.

Manufacturer	*Hager & Meisinger GmbH*	*Hager & Meisinger GmbH*	*Straumann USA, LLC*
510(k) Number	*unknown*	*K143539 (Primary Predicate Device)*	*K140878 (Reference Predicate Device)*
Intended Use	*The Dental Implants OKTAGON® Bone Level Tapered Design are surgically placed in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients. The implants are intended to be used with OKTAGON® abutments and prosthetic parts. The implants are intended for delayed loading in a two-stage surgery or for immediate loading when good primary stability is achieved and with appropriate occlusal load.*	*The implants are surgically placed in the maxillary and/ or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients. The parts are intended to be used with OKTAGON® Bone Level abutments and prosthetic parts. The Dental Implant system OKTAGON® Bone Level is intended for delayed loading, or for immediate loading when good primary stability is achieved and with appropriate occlusal load.*	*Straumann® dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate*

Manufacturer	*Hager & Meisinger GmbH*	*Hager & Meisinger GmbH*	*Straumann USA, LLC*
			occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.
Description	*The endosteal implant body of the subject device has a conical shape in the coronal region and is cylindrical in the apical region. The apical cylindrical part of the implant is relevant for the given endosteal diameter of 4.1 mm. The implants are made of commercially pure Titanium Grade 4 conforming to ASTM-F67. The surface is micro-structured in the endosteal part and has been blasted with high-grade corundum and afterwards acid-etched. The implant shoulder is polished.* *The prosthetic connection is achieved with the help of an inner cone with an additional octagonal anti-rotation device.* *A sterile cover screw is enclosed with the implant so that an immediate occlusion of the internal thread is possible after successful insertion.* *Subject to this submission is a tapered design implant variation of 4.1 mm, which is available in a range of endosseous lengths.*	*The root-form designed implant is made of commercially pure Titanium Grade 4 conforming to ASTM Standard Specification F67. The surface is micro-structured in the endosteal section and the implant shoulder is polished. The implant surface has been blasted with high-grade corundum and afterwards acid-etched.* *The prosthetic connection is achieved with the help of an inner cone with an additional octagonal anti-rotation device.* *A sterile locking screw is enclosed with the implant so that an immediate occlusion of the internal thread is allowed after successful insertion.* *The endosseous dental implants are available in a range of endosseous diameters and lengths.*	*The devices represent a line extension of the previously cleared Bone Level implants of the Straumann Dental Implant System (K062129, K083550 and K121131).* *The apical part of the implants has a tapering thread form and three cutting flutes.* *The implants are made of Titanium Grade 4 respectively Titanium-13Zirconium alloy (Roxolid®). The surface finishes are either SLA (grit blasted then acid etched) or SLAactive* *The implant-to-abutment connection (NC, RC) is achieved by an inner cone with octagonal anti-rotation device.* *The devices are available in the endosseous diameters 3.3, 4.1 and 4.8 mm.*

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Manufacturer	*Hager & Meisinger GmbH*	*Hager & Meisinger GmbH*	*Straumann USA, LLC*
Material	*Titanium Grade 4*	*Titanium Grade 4*	*Titanium Grade 4, Titanium-13Zirconium alloy (Roxolid®)*
Surface endosseous	*Micro-structured (grit blasted and acid etched)*	*Micro-structured (grit blasted and acid etched)*	*SLA (grit blasted then acid etched), SLA active*
Connection	*Inner cone with octagonal anti-rotation device*	*Inner cone with octagonal anti-rotation device*	*Inner cone with octagonal anti-rotation device*
Length	*8 to 12 mm*	*8 to 14mm*	*8 to 16 mm*
Endosseous Diameter	*3.3 to 4.1 mm*	*3.3 to 4.8 mm*	*3.3 to 4.8 mm*

Based on these observations, we conclude that the Dental Implant OKTAGON® Bone Level Tapered Design are substantially equivalent to the legally marketed predicate devices described.