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

August 31, 2015

Hager & Meisinger GmbH
Mr. Wiebke Stolten
Management Regulatory Affairs
Hansemannstrasse 10
Neuss, 41468
GERMANY

Re: K143539
Trade/Device Name: Dental Implant System OKTAGON® Bone Level
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: July 30, 2015
Received: July 31, 2015

Dear Mr. Stolten:

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,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Traditional

Dental Implant System OKTAGON® Bone Level

Section #4
Indications for Use Statement

510(k) Number (if known): K143539

Device Name: Dental Implant System OKTAGON® Bone Level

Indications for use:

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 implants are intended to be used with OKTAGON® Bone Level abutments and prosthetic parts.

Dental Implant Abutments Bone Level are intended to provide support for prosthetic reconstructions. Prosthetic applications can include individual crowns, bridges, partial or total prostheses.

Abutments can be used in single tooth replacements and multiple tooth restorations. The Abutments are intended to be compatible to OKTAGON® Bone Level implants with diameters 3.3mm, 4.1mm and 4.8mm and with the lengths 8mm, 10mm, 12mm and 14mm.

The Oktagon Bone Level System is intended for delayed loading, or for immediate loading when good primary stability is achieved and with appropriate occlusal load.

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Traditional K143539
Dental Implant System OKTAGON® Bone Level

Section #5
510(k) Summary

1. Applicant's Name and Address

Hager & Meisinger GmbH
Hansemannstrasse 10
41468 Neuss, Germany
Phone: (0049) 2131 2012-0
Fax: (0049) 2131 2012- 222
Contact Person: Wiebke Stolten
Management product approval and product validation
(Regulatory Affairs)

2. Date prepared

Date prepared: 8th April 2015

3. Name of the device

Trade Name:	Dental Implant System OKTAGON® Bone Level
Common Name:	Endosseous dental implants and abutments
Classification Name:	Endosseous dental implants
Product Code:	DZE and NHA
Regulation No:	872.3640
Class:	II
Panel:	Dental

4. Predicate Devices:

510(k) No.	Manufacturer	Trade Name
K122807	Meisinger	Dental Implant OKTAGON
K062129	Straumann	P.004 Implant
K132214	Meisinger	Dental Abutment OKTAGON
K072071	Straumann	P.004 RC Cementable Abutments
K080286	Straumann	P.004 NC Cementable Abutments

5. Device Description:

The Bone Level Implant is an addition to the currently distributed OKTAGON® dental implant system.
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 abutments are available in different versions including the corresponding screws.
The abutments are made of Titanium Grade 4, Titanium Alloy or POM; the connection to the implants is achieved by an internal octagon/nut construction and a metric thread.

The following types of abutments will be available:

- Cover screw
- Healing abutment
- Straight abutment
- Alligator abutment

6. Indications for use:

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 implants are intended to be used with OKTAGON® Bone Level abutments and prosthetic parts.

Dental Implant Abutments Bone Level are intended to provide support for prosthetic reconstructions. Prosthetic applications can include individual crowns, bridges, partial or total prostheses.

Abutments can be used in single tooth replacements and multiple tooth restorations. The Abutments are intended to be compatible to OKTAGON® Bone Level implants with diameters 3.3mm, 4.1mm and 4.8mm and with the lengths 8mm, 10mm, 12mm and 14mm.

The Oktagon Bone Level System is intended for delayed loading, or for immediate loading when good primary stability is achieved and with appropriate occlusal load.

7. Perfomance tests and used standards

Performance tests (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".

The following standards have been followed for the development, production, performance and safety testing of Dental Implant System OKTAGON® Bone Level: ISO 14801, ISO 7405, ISO 10993-1, ISO 5832-2, ASTM F67, ISO 11137-1, ISO 14971, ISO 11137-2, ISO 10993-5, ANSI/AAMI ST79, ISO 11607-1:2009, ASTM F88/F88M-09, ASTM F1929-98 (2004), ISO 5832-3, ASTM F136.

The following standards have been followed sterilization validation for the accessories: ISO 17665-1, ISO 17665-2.

8. Basis for substantial equivalence

The intended use for Dental Implant System OKTAGON® Bone Level is identical to the named predicated devices.

Overview Implants:

Manufacturer	Hager & Meisinger GmbH	Hager & Meisinger GmbH	Straumann AG
510(k) Number	K143539	K122807	K062129
Intended Use	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 OKTAGON® system Bone Level is intended for delayed loading, 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® abutments and prosthetic parts.	The P.004 is intended for immediate, delayed, or conventional placement in the anterior maxillary an/or mandibular arches to support crowns, bridges or overdentures in edentulous or partially edentulous patients.
Description	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.	The Dental Endosseous Implant OKTAGON® is a root-form design 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	The P.004 is an addition to the currently distributed Straumann Dental Implant System. The P.004 implant is a solid screw with a SLA (grit blasted then acid etched) or SLA surface. The implants are composed of Grade 4 commercially pure Titanium and are available in a range of lengths and diameters.

	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.	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.	
Material	Titanium Grade 4	Titanium Grade 4	Titanium Grade 4
Surface endosseous	Micro-structured (grit blasted and acid etched)	Micro-structured (grit blasted and acid etched)	grit blasted then acid etched
Length	8mm to 14mm endosseous length	8mm to 14mm endosseous length	8mm to 14mm endosseous length
Diameter	3.3 to 4.8 mm endosseous	3.3 to 4.8 mm endosseous, Ø 6.5 coronal (at 4.8mm endosseous)	3.3 to 4.8 mm endosseous

The implants have the same material composition and the same surface treatments. In addition, the implants are of the same, root-form design.

Overview Abutments:

Manufacturer	Hager & Meisinger GmbH	Hager & Meisinger GmbH	Straumann AG	Straumann AG
510(k) Number	K143539	K132214	K072071	K080286
Indications for Use	Dental Implant Abutments Bone Level are intended to provide support for prosthetic reconstructions. Prosthetic applications can include individual crowns, bridges, partial or total prostheses. Abutments can be used in single tooth replacements and multiple tooth restorations.	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions. Prosthetic applications can include individual crowns, bridges, partial or total prostheses.	Abutments are placed into dental implants to provide support for prosthetic restorations such as crowns, bridges and overdentures. Abutments can be used in single tooth replacements and multiple tooth restorations.	Abutments are placed into dental implants to provide support for prosthetic restorations such as crowns, bridges and overdentures. Abutments can be used in single tooth replacements and multiple tooth restorations.
Description	The OKTAGON® Dental Implant System is an integrated system of endosseous dental implants which are designed to support prosthetic devices for partially of fully edentulous patients. The devices covered in this	The OKTAGON® Dental Implant System is an integrated system of endosseous dental implants which are designed to support prosthetic devices for partially of fully edentulous patients. The devices	The Straumann P.004 Dental Implant System is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially or fully edentulous patients. The	The Straumann P.004 Dental Implant System is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially or fully edentulous patients. The

510(k) Traditional K143539
Dental Implant System OKTAGON® Bone Level

Section #5
510(k) Summary

Manufacturer	Hager & Meisinger GmbH	Hager & Meisinger GmbH	Straumann AG	Straumann AG
510(k) Number	K143539	K132214	K072071	K080286
	submission are abutments in different version including the corresponding screws.	covered in this submission are abutments.	system consists of a variety of dental implants, abutments and surgical and prosthetic parts and instruments.	system consists of a variety of dental implants, abutments and surgical and prosthetic parts and instruments.
Material	Titanium Grade 4, Titanium Alloy, synthetic material	Titanium Grade 4, Titanium Alloy, synthetic material	Not detailed in submission, acc. to catalogue same material used	Not detailed in submission, acc. to catalogue same material used

The intended use for Abutments is identical to the named predicated devices. The abutments have the same indications for use, material composition and the connection to implants is equivalent. In addition the principal design including measurements of abutments is identical to the previously cleared predicated devices.

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