DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 21, 2016

Hager & Meisinger GmbH
Dr. Melanie May
Regulatory Affairs
Hansemannstrasse 10
Neuss, 41468
Germany

Re: K160132
Trade/Device Name: Endosseous Dental Implant Abutments OKTAGON® Bone Level
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 20, 2016
Received: October 20, 2016

Dear Dr. 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 yours,

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

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)*
K160132

Device Name
Endosseous Dental Implant Abutments OKTAGON® Bone Level

Indications for Use *(Describe)*
Indications for Use (Describe)
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 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.

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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510(k) Traditional K160132
Endosseous Dental Implant Abutments OKTAGON® Bone Level

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- 223
Contact Person: Dr. Melanie May
Product approval and product validation (Regulatory Affairs)

2. Date prepared

Date prepared: November 17th, 2016

3. Name of the device

Trade Name:	Endosseous Dental Implant Abutments OKTAGON® Bone Level
Common Name:	Endosseous dental implant abutments
Classification Name:	Endosseous dental implant abutment
Product Code:	NHA
Regulation No:	872.3630
Class:	II
Panel:	Dental

4. Predicate Devices:

Predicate Device	510(k) No.	Manufacturer	Trade Name
Primary Predicate	K143539	Meisinger	Dental Endosseous Implant System OKTAGON® Bone Level
Reference Predicate	K132214	Meisinger	Dental Abutment OKTAGON®

5. Device Description:

510(k) Traditional K160132
Endosseous Dental Implant Abutments OKTAGON® Bone Level

510(k) Summary

The Dental Implant System OKTAGON® Bone Level 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 submission are angled abutments and an addition to the currently available Dental Implants and Abutments OKTAGON® Bone Level.

The abutments are made of Titanium Grade 4, the alligator abutments and screws are made of Titanium Alloy (TiAl6V4); the connection to the implants is achieved by an internal octagon/nut construction and a metric thread.

The abutments are available in the following variations including the corresponding screws:

Article No.	Variation	Description	Material		Connection to Implant	Intended Use
			Abutment	Screw		
22025	NC	Abutment, Angled, 18°, Ø3.5mm, L 6.0 mm, H1.5mm, cementable, incl. basic screw 22030	Titanium Grade 4	Titanium Alloy (TiAl6V4)	Octagonal, fixating by screw	For crowns and bridges
22026	NC	Abutment, Angled, 18°, Ø3.5mm, L 6.0 mm, H3.0mm, cementable, 22030	Titanium Grade 4	Titanium Alloy (TiAl6V4)	Octagonal, fixating by screw	For crowns and bridges
22030	NC	Basic screw for NC abutment	Titanium Alloy (TiAl6V4)	-	-	For use with abutments
22041	NC	Alligator Abutment Angled, 15°, H3.0mm	Titanium Alloy (TiAl6V4)	-	Conical, fixating by screw	Overdenture Prosthetic
22042	NC	Alligator Abutment Angled, 15°, H4.0mm	Titanium Alloy (TiAl6V4)	-	Conical, fixating by screw	Overdenture Prosthetic
22103	RC	Abutment, Angled, 18°, Ø5.0mm, L 8.0 mm, H1.5mm, cementable,	Titanium Grade 4	Titanium Alloy (TiAl6V4)	Octagonal, fixating by screw	For crowns and bridges
22105	RC	Abutment, Angled, 18°, Ø5.0mm, L 8.0 mm, H3.0mm, cementable, incl. basic screw 22122	Titanium Grade 4	Titanium Alloy (TiAl6V4)	Octagonal, fixating by screw	For crowns and bridges

510(k) Summary

Article No.	Variation	Description	Material		Connection to Implant	Intended Use
			Abutment	Screw		
22122	RC	Basic screw for RC abutment	Titanium Alloy (TiAl6V4)	-	-	For use with abutments
22129	RC	Alligator Abutment Angled, 15°, H3.0mm	Titanium Alloy (TiAl6V4)	-	Conical, fixating by screw	Overdenture Prosthetic
22130	RC	Alligator Abutment Angled, 15° H4.0mm	Titanium Alloy (TiAl6V4)	-	Conical, fixating by screw	Overdenture Prosthetic
22131	RC/NC	Basic Screw for Alligator	Titanium Alloy (TiAl6V4)	-	-	Overdenture Prosthetic

6. 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. 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 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.

7. Performance tests and used standards

The following standards have been followed for the development, production, performance and safety testing of Dental Implant Abutment OKTAGON® Bone Level:

- Fatigue Testing according to ISO 14801
- Evaluation of Biocompatibility according to ISO 10993-1, ISO 7405
- Cytotoxicity Testing according to ISO 10993-5

510(k) Summary

- Sterilization validation according to ISO 17665-1, ISO 17665-2 and ANSI/ AAMI ST 79
- Material Specification according to ASTM F136, ASTM F67, ISO 5832-2, ISO 5832-3
- Risk Management according to ISO 14971

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".

The biocompatibility was evaluated according to ISO 10993-1. The evaluation shows, that the subject device is comparable in intended use, design and materials to the legally market predicate devices. There are no known negative biological effects of dental implants made of Titanium Grade 4. Thus the requirements of ISO 10993-1 are fulfilled.

8. Basis for substantial equivalence

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

Manufacturer	Hager & Meisinger GmbH	Hager & Meisinger GmbH	Hager & Meisinger GmbH
510(k) Number	Subject device K160132	Primary Predicate K143539	Reference Predicate K132214
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. 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 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.	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. 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 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.	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 can be used in single tooth replacements and multiple tooth restorations. The Dental Implant Abutments OKTAGON® are intended to be compatible to OKTAGON® implants (Dental Implant OKTAGON®) with diameters 3.3mm, 4.1mm and 4.8mm in the variation Regular Platform, Wide Platform and Tapered Design with the lengths 8mm, 10mm, 12mm and 14mm.
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 submission are abutments in different versions including the	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 submission are abutments in different versions including the	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 submission are abutments.

510(k) Summary

Manufacturer	Hager & Meisinger GmbH	Hager & Meisinger GmbH	Hager & Meisinger GmbH
510(k) Number	Subject device K160132	Primary Predicate K143539	Reference Predicate K132214
	corresponding screws.	corresponding screws.	
Diameter, Length (L), Height (H)	**Variation NC:** Angled abutments: Ø3.5, L= 6 mm, H = 1.5 mm and 3.0 mm Alligator abutments: H = 3.0 mm and 4.0 mm **Variation RC:** Angled abutments: Ø5.0 mm, L= 8.5 mm, H = 1.5 mm and 3.0 mm Alligator abutments: H = 3.0 mm and 4.0 mm	**Variation NC:** Abutments: Ø3.5, L= 6 mm, H = 1.0 mm, 2.0, 3.0 and 3.5 mm Alligator abutments: H = 2.0, 3.0, 4.0 and 5.0 mm **Variation RC:** Abutments: Ø5.0 and 6.5, L= 8.5 mm, H = 1.0, 2.0 and 3.0 mm Alligator abutments: H = 1.0, 2.0, 3.0, 4.0 and 5.0 mm	Abutments: Ø2.5-4.8, L= 1.5 - 7.0 mm, Alligator Abutments: H = 1.0, 1.5, 2.0, 3.0 and 4.0 mm
Angulation	18° for Abutments, 15° for angled Alligator	0° for Abutments, 15° for angled Alligator	Max. 20°
Material	Titanium Grade 4 (abutments), Titanium Alloy (alligator abutments and screws)	Titanium Grade 4 (abutments), Titanium Alloy (alligator abutments and screws), synthetic material (plastic copings made of POM)	Titanium Grade 4 (abutments), Titanium Alloy (alligator abutments and screws), synthetic material (plastic copings made of POM)

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 Abutment OKTAGON® Bone Level is substantially equivalent to the legally marketed predicate devices described.