Hager & Meisinger GmbH
Adam Tomczak
Regulatory Affairs
Hansemannstrasse 10
Neuss, 41468
GERMANY

May 10, 2018

Re: K180360
Trade/Device Name: OKTAGON® Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 6, 2018
Received: February 9, 2018

Dear Adam Tomczak:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180360

Device Name
OKTAGON® Implant System

Indications for Use *(Describe)*
Dental implants OKTAGON® 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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510(k) Traditional
OKTAGON® Implant System
Section #5
510(k) Summary

1. Applicant

Hager & Meisinger GmbH
Hansemannstrasse 10
41468 Neuss
Germany
Contact Person: Dr. Adam Tomczak, Regulatory Affairs
Phone: 0049 2131 2012 293
Fax: 0049 2131 2012 223
Date prepared: 9 May 2018

2. Device

Trade Name: OKTAGON® Implant System
Common Name: Dental Implants, Dental Implant Abutments
Classification Name: Endosseous Dental Implants
Product Code: DZE (primary product code), NHA
Regulation No: 872.3640
Class: II
Panel: Dental

3. Predicate Devices

510(k) No.	Manufacturer	Trade Name
Primary predicate device:		
K170287	Hager & Meisinger GmbH	Dental Implants OKTAGON® Bone Level Tapered Design
Reference devices:		
K162073	Hager & Meisinger GmbH	Dental Implants OKTAGON® Tissue Level and Bone Level
K143539	Hager & Meisinger GmbH	Dental Implant System OKTAGON® Bone Level

4. Device Description

Endosseous Dental Implants

The proposed implants represent a line extension of dental implants OKTAGON®, which have been previously cleared in the submissions K170287, K162073 and K143539. The proposed implants have a root-form design and are made of Titanium Grade 4 conforming to ASTM F67-13. The surface is microstructured in the endosteal section by blasting with high-grade corundum and acid-etching.

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Tissue Level Conical Implants have a conical shape, and the endosteal body of Bone Level Tapered Design Implants is cylindrical in the coronal region and conical in the apical region.

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. OKTAGON® Implant System includes four variations of the prosthetic connection:

- Tissue Level Implants: Regular Platform (RP) and Wide Platform (WP)
- Bone Level Implants: Regular Connect (RC) and Narrow Connect (NC)

This submission contains the following implants:

Ref. No.	Description	Prosthetic connection	Diameter [mm]	Length [mm]
31147	TL Conical Implant	RP	4.1	8.0
31175	TL Conical Implant	RP	4.1	12.0
24005	BLT Implant	RC	4.8	8.0
24006	BLT Implant	RC	4.8	10.0
24007	BLT Implant	RC	4.8	12.0

TL =Tissue Level, BLT = Bone Level Tapered Design

The proposed Tissue Level Conical Implants will increase the range of lengths available for this implant variation. The proposed Bone Level Tapered Design implants will be offered in the same range of lengths as the predicate devices, but with an increased diameter.

Endosseus Dental Implant Abutments

The proposed healing abutments increase the range of diameters available for Bone Level Narrow Connect implants. They are manufactured from Titanium Grade 4, and are intended to close the implant and shape the surrounding soft tissue during the healing phase. No occlusal loading is intended.

Ref. No.	Description	Prosthetic connection	Diameter [mm]	Gingiva height [mm]
22070	Healing Abutment	NC	5.5	2.0
22071	Healing Abutment	NC	5.5	3.5
22072	Healing Abutment	NC	5.5	5.0

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5. Indications for Use

Dental implants OKTAGON® 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.

6. Performance testing

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include:

- Sterilization validation according to ISO 11137-1 and 11137-2 (referenced from K143539; a revalidation report can be found in Section 14 Sterilization and Shelf Life of this submission).
- Sterilization validation according to ISO 17665 and ST79 (referenced from K143539). Based on the design, it was determined that the proposed abutments do not represent a new sterilization validation challenge. Thus, no additional testing was required.
- Sterile barrier system validation according to ISO 11607 (referenced from K143539). The packaging of the subject device and the reference device K143539 is the same, thus no additional testing was required.
- Biocompatibility assessment according to ISO 10993-1 and cytotoxicity testing according to ISO 10993-5 (referenced from K143539). The subject device uses the same materials and manufacturing methods as the reference device K143539. Furthermore, the intended use, the sterilization methods and the tissue contact are identical. Thus, no additional testing was required.
- Fatigue testing according to ISO 14801 and FDA Special Controls Guidance Document *Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments* (referenced from K143539, K162073 and K170287). Based on the same design and comparative surface area analysis, it was determined that the proposed implants do not represent a new worst case. Thus, no additional testing was required.

No animal testing or human clinical trials have been conducted.

7. Basis for substantial equivalence

A comparison of the indications for use and the technological characteristics between the subject device and the predicate devices is provided in the table below:

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510(k) Number	K180360	K143539 (Primary Predicate Device)	K162073	K170287 (Primary Predicate Device)
Manufacturer	Hager & Meisinger GmbH	Hager & Meisinger GmbH		
Indications for Use	Dental implants OKTAGON® 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 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.	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® respectively Bone Level abutments and prosthetic parts. The OKTAGON Implant System is intended for delayed loading, or for immediate loading when good primary stability is achieved and with appropriate occlusal load.	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.
Description	The proposed implants represent a line extension of Dental Implants OKTAGON®, which have been previously cleared in the submissions K143539, K162073 and K170287. The proposed implants have a root-form design and are made of Titanium Grade 4 conforming to ASTM F67-13. The surface is microstructured in the endosteal section by blasting with high-grade corundum and acid-etching. Tissue Level Conical Implants have a	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	The Dental Implants OKTAGON® Tissue Level and Bone Level follow a root-form design and are made of commercially pure Titanium Grade 4 conforming to ASTM-F67. The surface is microstructured in the endosteal section and the surface has been blasted with high-grade corundum and afterwards acid-etched. The implant shoulder of Dental Implants OKTAGON® Tissue Level and Bone Level is polished.	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

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510(k) Number	K180360	K143539 (Primary Predicate Device)	K162073	K170287 (Primary Predicate Device)
	conical shape, and the endosteal body of Bone Level Tapered Design Implants is conical in the coronal region and cylindrical in the apical region. 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. The proposed healing abutments increase the range of diameters available for Bone Level Narrow Connect Implants. They are manufactured from Titanium Grade 4, and are intended to seal the implant and shape the surrounding soft tissue during the healing phase. No occlusal loading is intended.	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	The prosthetic connection is achieved with the help of an inner cone with an additional octagonal antirotation device. A sterile cover screw is enclosed with the implant so that an immediate occlusion of the internal thread is possible after successful insertion.	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.
Material	Titanium Grade 4	Implants: Titanium Grade 4 Abutments: Titanium Grade 4, Ti6Al4V, POM	Titanium Grade 4	Titanium Grade 4
Endosseous Surface	Micro-structured (grit blasted and acid etched)	Micro-structured (grit blasted and acid etched)		
Connection	Inner cone with octagonal anti-rotation device	Inner cone with octagonal anti-rotation device		
Length	8/ 10/ 12 mm	8/ 10/ 12/ 14 mm	8/ 10/ 12 mm	8/ 10/ 12 mm
Endosseous Diameter	4.1/ 4.8 mm	3.3 /4.1/ 4.8 mm	3.75 / 4.1 mm	3.3 / 3.75/ 4.1 mm

8. Conclusion

The subject device and the predicate devices have identical intended use and technological characteristics, and are made of identical materials. Based on the assessment of applicable performance data, the subject device does not raise new performance or safety issues. Thus, we concluded that the subject device is substantially equivalent to the legally marketed predicate devices listed above.