DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 24, 2017

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

Re: K162073
Trade/Device Name: Dental Implants OKTAGON Tissue Level and Bone Level
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: January 31, 2017
Received: February 3, 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,

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 Statement

510(k) Number (if known): K162073

Device Name: Dental Implants OKTAGON® Tissue Level and 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 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.

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) Summary

K162073

1. Applicant' s Name and Address

Contact Person: Dr. Melanie May
Regulatory Affairs

Phone No.: +49 2131 2012 292
Fax No.: +49 2131 2012 223
Email: melanie.may@meisinger.de

Hager & Meisinger GmbH
Hansemannstrasse 10
41468 Neuss
Germany

2. Date prepared

Date prepared: February 22nd, 2017

3. Name of the device

Trade Name: Dental Implants OKTAGON® Tissue Level and Bone Level
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
K122807 (Primary Predicate Device)	Hager & Meisinger GmbH	Dental Implant OKTAGON®
K143539 (Reference Predicate Device)	Hager & Meisinger GmbH	Dental Implant System OKTAGON® Bone Level

5. Device Description

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 micro-structured 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 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 are the following implant variations:

BL NC Ø3.75 mm, L 8 mm
BL NC Ø3.75 mm, L 10 mm
BL NC Ø3.75 mm, L 12 mm

TL RP Ø3.75 mm, L 8 mm
TL RP Ø3.75 mm, L 10 mm
TL RP Ø3.75 mm, L 12 mm

TL RP Conical Ø4.1 mm, L 10 mm

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 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.

7. Performance 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 Implants OKTAGON®: 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).

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

8. Technological Characteristics

Manufacturer	Hager & Meisinger GmbH	Hager & Meisinger GmbH	Hager & Meisinger GmbH
510(k) Number	K162073	K122807 (Primary Predicate Device)	K143539 (Reference Predicate Device)
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® 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 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® abutments and prosthetic parts.	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.
Implant Variations	BL NC Ø3.75 mm, L 8 mm BL NC Ø3.75 mm, L 10 mm BL NC Ø3.75 mm, L 12 mm TL RP Ø3.75 mm, L 8 mm TL RP Ø3.75 mm, L 10 mm TL RP Ø3.75 mm, L 12 mm TL RP Conical Ø4.1 mm, L 10 mm	TL RP Ø3.3 mm, L 8 mm TL RP Ø3.3 mm, L 10 mm TL RP Ø3.3 mm, L 12 mm TL RP Ø3.3 mm, L 14 mm TL RP Ø4.1 mm, L 8 mm TL RP Ø4.1 mm, L 10 mm TL RP Ø4.1 mm, L 12 mm TL RP Ø4.1 mm, L 14 mm TL RP Ø4.8 mm, L 8 mm TL RP Ø4.8 mm, L 10 mm TL RP Ø4.8 mm, L 12 mm TL RP Ø4.8 mm, L 14 mm TL RP TD Ø4.1 mm, L 10 mm TL RP TD Ø4.1 mm, L 12 mm TL WP Ø4.8 mm, L 8 mm TL WP Ø4.8 mm, L 10 mm TL WP Ø4.8 mm, L 12 mm	BL NC Ø3.3 mm, L 8 mm BL NC Ø3.3 mm, L 10 mm BL NC Ø3.3 mm, L 12 mm BL NC Ø3.3 mm, L 14 mm BL RC Ø4.1 mm, L 8 mm BL RC Ø4.1 mm, L 10 mm BL RC Ø4.1 mm, L 12 mm BL RC Ø4.1 mm, L 14 mm BL RC Ø4.8 mm, L 8 mm BL RC Ø4.8 mm, L 10 mm BL RC Ø4.8 mm, L 12 mm BL RC Ø4.8 mm, L 14 mm
Accessories	A sterile cover screw is enclosed with the implant so that an immediate occlusion of the internal thread is possible after successful insertion.	A sterile cover screw is enclosed with the implant so that an immediate occlusion of the internal thread is possible after successful insertion.	A sterile cover screw is enclosed with the implant so that an immediate occlusion of the internal thread is possible after successful insertion.
Features			
Length	8, 10, 12 mm	8, 10, 12, 14 mm	8, 10, 12, 14 mm
Diameter	Ø3.75 mm, Ø4.1 mm	Ø3.3 mm, Ø4.1 mm, Ø 4.8 mm	Ø3.3 mm, Ø4.1 mm, Ø 4.8 mm
Material (Implant and Cover Screw)	Pure titanium Grade 4 conforming to ASTM Standard Specification F67	Pure titanium Grade 4 conforming to ASTM Standard Specification F67	Pure titanium Grade 4 conforming to ASTM Standard Specification F67
Surface Treatment	The surface is micro-structured in the endosteal section and the	The surface is micro-structured in the endosteal section and the	The surface is micro-structured in the endosteal section and the

Manufacturer	Hager & Meisinger GmbH	Hager & Meisinger GmbH	Hager & Meisinger GmbH
	implant shoulder is polished. The implant surface has been blasted with high-grade corundum and afterwards acid-etched.	implant shoulder is polished. The implant surface has been blasted with high-grade corundum and afterwards acid-etched.	implant shoulder is polished. The implant surface has been blasted with high-grade corundum and afterwards acid-etched.
Implant-to-abutment connection	Inner cone with octagonal anti-rotation device	Inner cone with octagonal anti-rotation device	Inner cone with octagonal anti-rotation device
Packaging	Implants are sold in plastic tubes, fastened on a titanium support with apre-assebled insertion system. The tube with the implant is double-wrapped in blister packaging.	Implants are sold in plastic tubes, fastened on a titanium support with apre-assebled insertion system. The tube with the implant is double-wrapped in blister packaging.	Implants are sold in plastic tubes, fastened on a titanium support with apre-assebled insertion system. The tube with the implant is double-wrapped in blister packaging.
Sterilization	Gamma Irradiation, min. 25 kGy. The validation fulfills the requirements of ISO 11137-1 and 11137-2.	Gamma Irradiation, min. 25 kGy. The validation fulfills the requirements of ISO 11137-1 and 11137-2.	Gamma Irradiation, min. 25 kGy. The validation fulfills the requirements of ISO 11137-1 and 11137-2.
Shelf Life	5 years	5 years	5 years

The Dental Implants OKTAGON® Tissue and Bone Level are an addition to the currently distributed Dental Implant OKTAGON and to the Dental Implant System OKTAGON Bone Level.

The subject devices differ in that of an additional diameter of Ø3.75 mm and a conical design.

As the subject devices are comparable to the predicate devices in the intended use, material composition, surface treatment, the implant-to-abutment connection, the principal root-form design and the performance characteristics (e.g. strength and function) no new aspects regarding the substantial equivalence arise.

9. Conclusion

Based on these observations, we conclude that the Dental OKTAGON® Tissue Level and Bone Level implants are substantially equivalent to the identified predicate devices.