K132214

JUL 07 2014

510(k) Traditional
Dental Endosseous Implant Abutment OKTAGON®

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: 06/11/2014

3. Name of the device

Trade Name:	Dental Implant Abutment OKTAGON®
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:

510(k No.)	Manufacturer	Trade Name
K091701	Straumann	Dental Abutment (Modified Dental Implant Abutment)
K073628	Straumann	Abutment, Dental, Endosseous implants (RN synOcta 1.5 mm Abutment)

5. Device 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 version including the corresponding screws.

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The abutments are made of Titanium Grade 4, Titanium Alloy or POM; the connection to the implants is achieved by an internal octagon and a metric thread.

6. Indications for use:

Dental Implant Abutments 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 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.

7. Performance tests and used standards / Clinical data

For Dental Implant Abutments OKTAGON® a performance test (fatigue test) has been conducted.
The performed test fulfills the requirements listed in ISO 14801 and the Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments, Chapter 8.
The following standards have been considered for Dental Implant Abutments OKTAGON® during development, production and market surveillance: ISO 14801, ISO 7405, ISO 10993-1, ISO 5832-2, ASTM F67, ISO 14971, ISO 5832-3, ASTM F136, AAMI ST79, ISO 17665-1.

8. Basis for substantial equivalence

Manufacturer	Hager & Meisinger GmbH	Straumann AG	Straumann AG
510(k) Number	K132214	K091701	K073628
Indications for Use	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 and bridges. Abutments can be used in single tooth replacements and	Abutments are placed into dental implants to provide support for prosthetic restorations such as crowns and bridges. Abutments can be used in single tooth replacements and

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Manufacturer	Hager & Meisinger GmbH	Straumann AG	Straumann AG
510(k) Number	K132214	K091701	K073628
	Abutments can be used in single tooth replacements and multiple tooth restorations.	multiple tooth restorations.	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 submission are abutments in different version including the corresponding screws.	The Straumann 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 system consists of a variety of dental implants, abutments and surgical and prosthetic parts and instruments. The devices covered in this submission are abutments.	The Straumann 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 system consists of a variety of dental implants, abutments and surgical and prosthetic parts and instruments. The device covered in this submission is an abutment. The coronal portion of the abutment is seated in the implant with a screw. The abutment is used for screw-retained and cemented restorations.
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
Connection	octagonal anti-rotation device	octagonal anti-rotation device	octagonal anti-rotation device

The intended use for Endosseous Dental Implant Abutment OKTAGON® 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 the information provided in the summary, we conclude Dental Implant Abutments OKTAGON® are substantially equivalent to the legally marketed predicate devices described.

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

July 7, 2014

Hager & Meisinger GMbh
Ms. Wiebke Stolten
Management, Regulatory Affairs
Hansemannstrasse 10
Neuss, D-41468
GERMANY

Re: K132214
Trade/Device Name: Dental Implant Abutment OKTAGON®
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implants abutment
Regulatory Class: II
Product Code: NHA
Dated: June 2, 2014
Received: June 3, 2014

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mary [redacted] -S

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

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Section #4
Indications for Use Statement

510(k) Number (if known): K132214

Device Name: Dental Implant Abutment OKTAGON®

Indications for use:

Dental Implant Abutments 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 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.

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)

Sheena A. Green -S
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