



Food and Drug Administration
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April 13, 2016

OT medical GmbH
Ms. Martina Behlau
Quality Manager/Manager Regulatory Affairs
Konsul-Smidt-Straße 8b
Bremen 28217
GERMANY

Re: K151608

Trade/Device Name: 4plus6Line Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 15, 2016
Received: March 16, 2016

Dear Ms. Martina Behlau:

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" (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 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,

Erin I. Keith -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

Indications for Use

510(k) Number (if known)
K151608

Device Name
4plus6Line Abutment System for Endosseous Dental Implant System OT-F2

Indications for Use (Describe)

The 4plus6Line Abutment is a premanufactured prosthetic component intended for use as an aid in prosthetic rehabilitation.

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) PREMARKET NOTIFICATION SUMMARY

K151608

Name/Address of submitter: OT medical GmbH
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Establishment Registration Number: 10033109

Contact Person: Martina Behlau
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Date Summary Prepared: April 11, 2016

Trade Name: 4plus6Line Abutment System

Common name: Dental Abutment

Device Classification Name: Endosseous dental implant abutment

Device Classification Regulation Number: CFR 872.3630

Classification Product code: NHA

Device Regulatory Status: Class II Special Controls

Purpose: The purpose of this 510(k) is to obtain clearance for sale in the U.S.A. for the 4plus6Line Abutment System as an extension of the dental abutments previously cleared in the OT-F² Dental Implant System.

Predicate Devices: K072570 Nobelactive Multi Unit Abutment (primary predicate)
K113113 OT medical Endosseous Dental Implant System as reference predicate
K151432 OT medical NaturalLine Abutment (Endosseous Dental Implant Abutment) as reference predicate for fatigue testing

Device Description: The abutment is available in several diameters and angulations. The straight and the 17° angled versions are available as compatible with implant bodies in diameters of 3.8mm, 4.1, and 5.0. A 30° angled version is also available for the 4.1mm and 5.0 diameter implant bodies. All abutments are made from titanium grad 5 acc. to ASTM F-136. The abutments are compatible with implant bodies contained in the OT-F² Implant System. The abutment system contains both titanium and POM cylinders as well as healing abutments.

Indication for Use: The 4plus6 Line Abutment is a premanufactured prosthetic component intended for use as an aid in prosthetic rehabilitation.

Technological Characteristics: The physical properties and designs of the abutment for the 4plus6Line Abutment System were compared with the legally marketed predicate devices. The technological characteristics were comparable:

Comparison of Properties and Features of OT medical's 4plus6Line Abutment System to Predicate device

	OT-F2 4plus6Line	Multi Unit Abutment (K072570)
Specification of Material	All abutments: Titanium Grade 5 acc. to ASTM-F 136	Angled Abutments: Titanium Grade 5 acc. to ASTM-F 136 Straight abutments and Temporary Coping: Titan Grade 1 (pure Titanium)
Abutment Angle:	0° / 17° / 30°	0° / 17° / 30°
Exterior geometry:	Straight abutments non-engaging	Straight abutments non-engaging
	Angled abutments engaging	Angled abutments engaging
Socket heights	1,5 / 3mm	1,5 / 2,5 / 3,5 / 4,5 mm
surface treatment	Pure machined surface with anodization in the implant-connecting-area	Pure machined surface
Sterilization	0°, 17° and 30° abutments are sterilized by irradiation	0°, 17° and 30° abutments are sterilized by irradiation
	Cylinder Titan is sold unsterile	Temporary Coping is sold unsterile
Accessories for abutments	abutment screw for each abutment included	abutment screw for each abutment included
	Cylinder Titan inclusive Prosthetic screw	Temporary Coping Multi-unit Abutment (with Prosthetic screw)
Indications	The 4plus6 Line Abutment is a premanufactured prosthetic component intended for use as an aid in prosthetic rehabilitation.	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Brief Discussion of Clinical Studies: Clinical studies were not conducted, or deemed necessary, for the purpose of this 510(k) submission.

Non-Clinical Testing:

	Submitted on
<i>Validation Sterilization</i>	
- Microbiological Performance MDS Test 103706-10	Oct. 19, 2011
- Dose mapping	Dec 04, 2012
<i>Packaging validation</i>	
- Ageing Study over 5 years by MDS, Test 094466-10	Oct. 19, 2011
- Ageing Study real time aging 5 years by MDS, Test 142775-10 (dye penetration test)	June 04, 2014
- Ageing Study real time aging 5 years by MDS, Test 151504-10 (microbial properties)	April 09, 2015
Surface analysis:	

- Test Cytotoxicity abutments, MDS report no. 123335-20	July 30, 2012
- Report cleaning validation_2013RV02-2010	Sept 18, 2013

Brief Discussion of Engineering Studies: Engineering studies were conducted as per ISO standard 14801:2003 (E) – (Dentistry – Fatigue test for endosseous dental implants). Testing revealed a stable screw joint at the highest forces tested.

Conclusions Drawn: The OT-F² 4plus6Line Abutment System and associated components have the same intended use as, and technological characteristics similar to, the legally marketed predicate devices. The information and data provided in the submission demonstrates that the proposed device is substantially equivalent to its declared predicate.