K101798

510(k) Summary

SPI® VARIOmulti Angled Abutment
Special 510(k): Device Modification

AUG 19 2010

July 30, 2010

ADMINISTRATIVE INFORMATION

Manufacturer Name:
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	SPI® VARIOmulti Angled Abutment
Common Name:	Dental implant abutment
	21 CFR 872.3630, Class II
Product Code:	NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

Thommen SPI® VARIOmulti Angled Abutments are intended to be used in conjunction with SPI® System dental implants in the maxillary and/or mandibular arch to provide support for splinted crowns, bridges or overdentures.

DEVICE DESCRIPTION

SPI® VARIOmulti Angled Abutments are dental implant abutments for use with the SPI® Dental Implant System. They have an internal connection to the implant and are used for multi-unit, screw-retained, prefabricated restorations. VARIOmulti Angled Abutments are made of titanium and are available in diameters from 3.5 to 4.5 mm with an angle of 30° to the axis of the implant. The system includes dedicated prosthetic components including protective and temporary caps. SPI® VARIOmulti Angled Abutments are compatible with the Nobel Biocare Multi-unit Abutment System.

EQUIVALENCE TO MARKETED PRODUCT

Thommen Medical AG demonstrated that for the purposes of FDA's regulation of medical devices, SPI® VARIOmulti Angled Abutment is substantially equivalent in indications and design principles to the predicate devices, SPI® VARIOmulti Angled Abutment K090153 and SPI® VARIOmulti Abutment K072856.

The subject device has the same intended use as the predicate devices and has the same Indications for Use Statement as the predicate cleared under K090153.

The subject device has the same technological characteristics as the predicate devices. The subject and predicate devices are all fabricated from the same materials (commercially pure titanium conforming to ASTM F67) and share similar design characteristics. All are multi-unit, screw retained dental implant abutments available in diameters of 3.5 to 4.5 mm. The subject and predicate devices are packaged using the same materials and are to be sterilized by the same methods.

PERFORMANCE TESTING

Fatigue testing was performed according to ISO 14801 *Dentistry - Implants - Dynamic fatigue test for endosseous dental implants.* The subject device SPI® VARIOmulti Angled Abutment was determined to have sufficient resistance to fatigue and performed comparably to the predicate device cleared under K090153.

In summary, the SPI® VARIOmulti Angled Abutment has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials, and
- is packaged and sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Thommen Medical, AG
C/O Ms. Linda K. Schulz
Paxmed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

AUG 19 2010

Re: K101798
Trade/Device Name: SPI® VARIOmulti Angled Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 30, 2010
Received: August 02, 2010

Dear Ms. Schulz:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101798

Indications for Use

510(k) Number (if known): K101798

Device Name: SPI® VARIOmulti Angled Abutment

Indications for Use:

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Prescription Use X _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Kai Mulay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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