510(k) Summary

Thommen Medical AG
SPI® VARIO Angled Abutment
K111984

October 27, 2011

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Thommen Medical AG Hauptstrasse 26d CH-4437 Waldenburg, Switzerland Telephone: +41 61 965 90 20 Fax: +41 61 965 90 21
Official Contact:	Minna Buser, RA Manager
Representative/Consultant:	Linda K. Schulz, BSDH, RDH Kevin A. Thomas, PhD PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: lschulz@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

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

K111984

INTENDED USE

Thommen SPI® VARIO 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 crowns or bridges.

DEVICE DESCRIPTION

SPI® VARIO Angled Abutments are titanium dental implant abutments for use with the SPI® Dental Implant system. They connect with the internal hex feature of the implant, have a precision fit interface with the prosthetic attachment, and are intended for screw retained restorations in single unit and small multi-unit solutions. SPI VARIO Angled Abutments are designed for correction of implant divergence and can be used in combination restorations with SPI VARIO abutments.

EQUIVALENCE TO MARKETED DEVICE

Thommen Medical AG submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices SPI® VARIO Angled Abutment is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Thommen Medical AG, SPI® Dental Implant Abutments cleared under K031747
Thommen Medical AG, SPI® VARIOmulti Abutment cleared under K072856
Thommen Medical AG, SPI® VARIOmulti Angled Abutment cleared under K090153

The subject device and the predicate devices have the same intended use, the same technological characteristics, are made of the same materials, and encompass the same range of physical dimensions. The subject and predicate devices are packaged in similar materials and sterilized using similar methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy.

Performance testing was provided to demonstrate substantial equivalence and included methods described in ISO 14801.

Overall, SPI® VARIO 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 or very similar materials, and
- has similar packaging and is 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
Regulatory Affairs Consultant
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

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Re: K111984
Trade/Device Name: SPI® VARIO Angled Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: October 27, 2011
Received: October 28, 2011

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,

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

K111984

Indications for Use

510(k) Number: K111984

Device Name: SPI® VARIO Angled Abutment

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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)

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

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