

## 510(k) Summary

Thommen Medical AG  
Special 510(k): Device Modification

SPI® VARIOmulti Angled Abutment

## ADMINISTRATIVE INFORMATION

Manufacturer Name: Thommen Medical AG  
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Official Contact: Orlando Antunes

Representative/Consultant: Linda K. Schulz or  
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PaxMed International, LLC  
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## DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: SPI® VARIOmulti Angled Abutment  
Common Name: Dental implant abutment  
Classification Regulations: Endosseous 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 an external hex prosthetic attachment, and are used for multi-unit, screw-retained, prefabricated restorations. The system includes dedicated prosthetic components.

## EQUIVALENCE TO MARKETED PRODUCT

Thommen Medical AG demonstrated that, for the purposes of FDA's regulation of medical devices, the SPI® VARIOmulti Angled Abutments are substantially equivalent in indications and design principles to predicate devices that have been determined by FDA to be substantially equivalent to preamendment devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 27 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Thommen Medical, AG  
C/o Ms. Linda K. Schulz, RDH, BSDH  
PaxMed International, LLC  
11234 El Camino Real, Suite 200  
San Diego, California 92130

Re: K090153  
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: January 20, 2009  
Received: January 22, 2009

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Ginette Y. Michaud, M.D.

Acting Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090153

Device Name: SPI® VARIOmulti Angled Abutment

Indications for 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.

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

Susan Penner

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

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