

510(k) Summary

Thommen Medical AG SPI® VARIOmulti Abutment

File # 5

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: Orlando Antunes

Representative/Consultant: Linda K. Schulz or
Floyd G. Larson
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
flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: SPI® VARIOmulti 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 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, bridges or overdentures.

DEVICE DESCRIPTION

SPI® VARIOmulti 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. VARIOmulti Abutments are appropriate for supporting laboratory cast frameworks as well as machined titanium frameworks using the Nobel Biocare Procera® Implant Bridge Titanium.

EQUIVALENCE TO MARKETED PRODUCT

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



FEB 15 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K072856
Trade/Device Name: SPI[®] VARIOmulti Abutment
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 6, 2008
Received: February 7, 2008

Dear Ms. Linda K. 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.

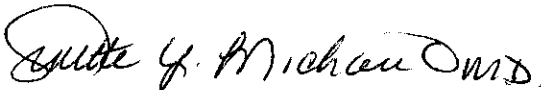
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.
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):

Device Name: SPI® VARIOmulti Abutment

Indications for Use:

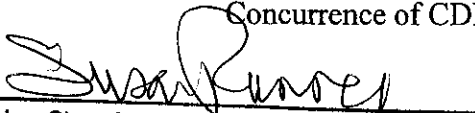
Thommen SPI® VARIOmulti Abutments are intended to be used in conjunction with SPI® System dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures.

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)



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

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