510(k) Summary

APR 2 0 2011

THOMMEN MEDICAL AG
SPI® Titanium Base for CAD/CAM
K102804

April 19, 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
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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® Titanium Base for CAD/CAM
Common Name:	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 Titanium Base for CAD/CAM abutments are intended to be used in conjunction with Thommen implants and the 3M ESPE Lava™ System in the maxillary and/or mandibular arch to provide support for crowns and bridges.

K102804

DEVICE DESCRIPTION

Titanium Base for CAD/CAM provides a foundation for a customized CAD/CAM abutments and restorations. It is suitable for precision fit custom abutments or crown and bridge restorations fabricated with CAD/CAM technology provided separately by 3M ESPE as the Lava System. The Titanium Base for CAD/CAM in conjunction with the 3M ESPE Lava System is not intended to be used to fabricate angled abutments. Titanium Base for CAD/CAM is made from commercially pure titanium, grade 4 conforming to ASTM F67, and the corresponding abutment screw (cleared under K031747) is made of titanium alloy, Ti-6Al-7Nb conforming to ASTM F1295.

EQUIVALENCE TO MARKETED DEVICE

Thommen Medical AG demonstrated that, for the purposes of FDA's regulation of medical devices, SPI® Titanium Base for CAD/CAM 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:

Altatec GmbH, CAMLOG Implant System Modified Implants and Abutments, cleared under K083496, Altatec GmbH, CAMLOG Implant System Abutments, cleared under K073553;

FRIADENT GmbH, FRIADENT PLUS Dental Implant Systems, cleared under K040170;

Implant Innovations, Inc., 3i Patient-Specific Dental Abutments and Overdenture Bars, cleared under K032263; and

Sybron Implant Solutions GmbH, Pitt-Easy Dental Implant System, cleared under K083297.

The subject device and the predicate devices are all made of commercially pure titanium or titanium alloy. The subject and predicate devices encompass the same range of physical dimensions, including sizes and configuration. All of the devices consist of a titanium base/post used in CAD/CAM fabrication of custom dental implant abutments/restorations and an abutment screw. The custom CAD/CAM component is bonded to the titanium base. The subject and predicate devices are packaged in similar materials and sterilized using similar methods. Any differences in technological characteristics do not raise new issues of safety or efficacy. Information provided to demonstrate substantial equivalence included a detailed list of subject and predicate device characteristics.

Overall, SPI® Titanium Base for CAD/CAM 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.

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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 Linda K. Schulz
PaxMed International, LLC
Regulatory Affairs
11234 El Camino Real, Suite 200
San Diego, California 92130

APR 20 2011

Re: K102804
Trade/Device Name: SPI® Titanium Base for CAD/CAM
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: April 15, 2011
Received: April 18, 2011

Dear Mrs. 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 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

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: _____