510(k) Summary

Thommen Medical AG
SPI® System Dental Implants

ADMINISTRATIVE INFORMATION

DEC 06 2007

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® System Dental Implants
Common Name:	Dental implant
Classification Regulations:	Endosseous dental implant 21 CFR 872.3640, Class II
Product Codes	DZE
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

SPI® System Dental Implants are for one-stage or two-stage surgical procedures. SPI System Dental Implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, four or more implants must be used in immediately loaded cases.

Contraindications for the use of SPI® ELEMENT implant Ø 3.5 mm and SPI® CONTACT implant Ø 3.5 mm:
These implants are not suitable for applications in areas where pronounced rotation and translation movements occur, causing the implant to be subjected to large bending movements.

- Restoration of posterior teeth in the upper and lower jaw
- Single-tooth restoration of canines and central incisors in the upper jaw
- Any application involving retentive anchors

DEVICE DESCRIPTION

Thommen SPI Dental Implants are self tapping, root form, endosseous dental implants made of commercially pure grade titanium. The intended use of the subject endosseous dental implants includes a six week healing period when conventional loading protocols are used, rather than the currently recommended twelve-week minimum healing period, as well as to permit immediate functional loading of single-tooth or multiple unit restorations when good primary stability is achieved.

EQUIVALENCE TO MARKETED PRODUCT

Thommen Medical AG has demonstrated that, for the purposes of FDA's regulation of medical devices, the SPI System Dental Implants 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 06 2007

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

Re: K072649
Trade/Device Name: SPI® System Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: November 29, 2007
Received: November 30, 2007

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.

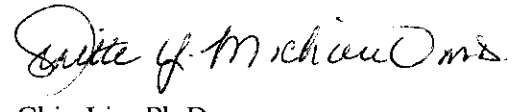
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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

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Indications for Use

510(k) Number (if known):

Device Name: SPI® System Dental Implants

Indications for Use:

SPI® System Dental Implants are for one-stage or two-stage surgical procedures. SPI System Dental Implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, four or more implants must be used in immediately loaded cases.

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Susan Runner

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

510(k) Number: K072649

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)

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