510(k) Summary

JAN 10 2007

Special 510(k): Device Modification

SPI® ELEMENT Platform Ø 4.0 mm

ADMINISTRATIVE INFORMATION

Sponsor Name:	Thommen Medical AG Haupstrasse 26d CH-4437 Waldenburg, Switzerland Telephone: +41 61 965 90 20 Fax: +41 61 965 90 21
Official Contact:	Orlando Antunes
Representative/Consultant:	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

DEVICE NAME

Classification Name:	Implant, Endosseous, Root-Form Abutment, Implant, Dental, Endosseous
Trade/Proprietary Name:	SPI® ELEMENT Platform Ø 4.0 mm
Common Name:	Dental implant

ESTABLISHMENT REGISTRATION NUMBER

The Establishment Registration number for Thommen Medical AG is 3003836985. The Owner/Operator number is 9051144.

DEVICE CLASSIFICATION

FDA has classified endosseous dental implants and abutments as Class II devices (21 CFR 872.3640 and 21 CFR 872.3630). The product code for Implant, Endosseous, Root-Form is DZE and the product code for "Abutment, Implant, Dental, Endosseous" is NHA.

INTENDED USE

The Thommen SPI® ELEMENT Dental Implant is intended to be surgically placed, either immediately after extraction or following healing, in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. SPI® Dental Implants can be loaded immediately if they are splinted with a bar on four implants in the mandibular arch or six implants in the maxillary arch.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards applicable to endosseous dental implants have been established by FDA. The SPI ELEMENT dental implants meet the chemical and mechanical requirements of ASTM F 67 *Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)* and ISO 5832-2 *Implants for surgery -- Metallic materials -- Part 2: Unalloyed titanium.*

DEVICE DESCRIPTION

The Thommen SPI® ELEMENT Platform Ø 4.0 mm is a root form endosseous dental implant made of commercially pure grade 4 titanium. The implant surface is smooth machined on the transgingival portion and sandblasted and acid-etched in the area designed to contact bone.

PACKAGING/LABELING/PRODUCT INFORMATION

Thommen SPI® ELEMENT Platform Ø 4.0 mm will be packaged in a radiation sterilizable package consisting of a primary container, with implant and auxiliary parts, sealed with a peel-off wrapping. Sterilization will be accomplished by means of Co^{60} gamma irradiation at a nominal dose of 25 kGy (2.5 Mrad).

EQUIVALENCE TO MARKETED PRODUCT

The SPI® ELEMENT Platform Ø 4.0 mm has the following similarities to the predicate SPI® ELEMENT Dental Implant:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design, (with the addition of a new platform diameter),
- incorporates the same materials, and
- is packaged and sterilized using the same materials and processes.

In summary, the Thommen SPI® ELEMENT Platform Ø 4.0 mm described in this submission is, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2009

Thommen Medical, AG
C/o Mr. Floyd G. Larson
President
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K070007
Trade/Device Name: SPI® ELEMENT Platform Ø 4.0 mm
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: December 29, 2006
Received: January 3, 2007

Dear Mr. Larson:

This letter corrects our substantially equivalent letter of January 10, 2007.

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 (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.

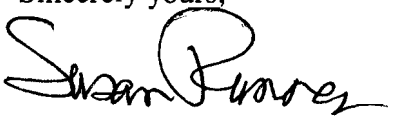
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,



Susan Runner, D.D.S., MA

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

Applicant: Thommen Medical AG

510(k) Number (if known): K070007

Device Name: SPI® ELEMENT Platform Ø 4.0 mm

Indications for Use:

The Thommen SPI® ELEMENT Dental Implant is intended to be surgically placed, either immediately after extraction or following healing, in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. SPI® Dental Implants can be loaded immediately if they are splinted with a bar on four implants in the mandibular arch or six implants in the maxillary arch.

Prescription Use ✓ 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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number K070007