MAR - 5 2004

K034014

ADMINISTRATIVE INFORMATION

Manufacturer Name: Thommen Medical AG
Hauptstrasse 87
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
4329 Graydon Road
San Diego, CA 92130
Telephone (858) 792-1235
FAX (858) 792-1236

DEVICE NAME

Classification Name: Implant, Dental, Endosseous (DZE)

Trade/Proprietary Name: SPI® CONTACT Dental Implant

Common Name: Endosseous 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 as a Class III device (21 CFR 872.3640). The product code for "Implant, Dental, Endosseous" is DZE.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards applicable to endosseous dental implants have been established by FDA. However, CP titanium Grade 4 used to manufacture Thommen dental implants meet the chemical and mechanical requirements of ASTM F 67 and ISO 5832-2.

PACKAGING/LABELING/PRODUCT INFORMATION

Thommen SPI® CONTACT Dental Implants will be packaged in a radiation sterilizable container. Sterilization will be accomplished by means of Co^{60} gamma irradiation at a nominal dose of 25 kGy (2.5 Mrad). Sterilization will be validated by the bioburden method, according to ISO 11137 (*Sterilization of Health Care Products – Radiation Sterilization*). The sterility assurance level (SAL) that Thommen Medical AG intends to meet for the SPI® CONTACT Dental Implant is 10^{-6}. The device is not represented to be "pyrogen free."

INTENDED USE

The Thommen SPI® CONTACT Dental Implant is intended to be surgically placed, either immediately or delayed, in the bone of the maxillary and/or mandibular arch to provide support for crowns, bridges or overdentures. SPI® CONTACT 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.

Contraindications for the use of 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 moments.

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

DEVICE DESCRIPTION

Design Characteristics

Thommen SPI® CONTACT Dental Implants are threaded, tapered, endosseous dental implants made of commercially pure titanium and intended for use with the SPI® System abutments and instruments. The implants are offered in lengths ranging from 9.5 mm to 17 mm, with diameters from 3.5 mm to 6 mm.

Material Composition

SPI® CONTACT Dental Implants are made of pure titanium according to ASTM F 67 Grade 4/ ISO 5832-2 GR4B. The surface of the threaded portion of the SPI® CONTACT Dental Implant is sandblasted and acid etched. The 1.5 mm collar is smooth machined for subgingival and transgingival use.

EQUIVALENCE TO MARKETED PRODUCT

For the purposes of FDA's regulation of medical devices, the SPI® CONTACT Dental Implant is substantially equivalent in indications and design principles to the following predicate devices: the HA-Ti Dental Implant System, cleared by FDA on January 4, 1991 under K901927 and July 12, 2001 under K003045; the Thommen SPI® Onetime Dental Implant, cleared on July 15, 2002 under K022038; the Thommen SPI® Element Dental Implant, cleared on March 4, 2003 under K030689; the Straumann ITI TE Dental Implant, cleared on March 31, 2003 under K030007; the Steri-Oss Replace Dental Implant cleared on March 5, 1997 under K964220 and the Bränemark Replace Select Dental Implant, cleared on October 11, 2002 under K022562.

The SPI® CONTACT Dental Implant 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 materials, and
- is packaged and sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2004

Thommen Medical, AG
C/O Ms. Floyd G. Larson
President
Paxmed International
4329 Graydon Road
San Diego, California 92130

Re: K034014
Trade/Device Name: SPI Contact dental Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: December 22, 2003
Received: December 24, 2003

Dear Ms. Larson:

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 (301) 594-4613. 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/dsma/dsmamain.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): K034014

Device Name: SPI® CONTACT Dental Implant

Indications For Use:

The Thommen SPI® CONTACT Dental Implant is intended to be surgically placed, either immediately or delayed, in the bone of the maxillary or mandibular arch to provide support for crowns, bridges or overdentures. SPI® CONTACT 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.

Contraindications for the use of SPI® CONTACT implants 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 moments.

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

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K034014