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K033346

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:	Abutment, Implant, Dental, Endosseous (NHA)
Trade/Proprietary Name:	SPI® EASY Dental Implant Protective Cap
Common Name:	Endosseous Dental Implant System component

ESTABLISHMENT REGISTRATION NUMBER

Thommen Medical AG has submitted an Establishment Registration to FDA. The Establishment Registration number 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 "Abutment, Implant, Dental, Endosseous" is NHA.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards applicable to endosseous dental implant abutments have been established by FDA. The polyetheretherketone (PEEK) raw material from which the SPI® EASY Dental Implant Protective Cap is made complies with ASTM F2026.

PREDICATE DEVICE INFORMATION

The predicate device for this modification is the SPI® Dental Implant System Gingiva Former, cleared by FDA on July 2, 2003 under K031747 and on November 13, 2002 under K023645.

PACKAGING/LABELING/PRODUCT INFORMATION

Thommen SPI® EASY Dental Implant Protective Cap will be packaged and sold non-sterile. The device is not represented to be "pyrogen free."

INTENDED USE

The Thommen SPI® EASY Dental Implant Protective Cap is intended to be used in conjunction with SPI® System dental implants, which provide support for crowns, bridges or overdentures in the maxillary and/or mandibular arch.

DEVICE DESCRIPTION

The Thommen SPI® EASY Dental Implant Protective Cap is an endosseous dental implant component made from polyetheretherketone (PEEK). The Protective Cap may be used for maintaining the gingival contour, replacing or augmenting the use of the Gingiva Former. If it is used to augment the function of the Gingiva Former, it is placed after the Gingiva Former is removed and the abutment is placed, but before the final restoration is placed. The Protective Cap also serves to protect the coronal aspect of the abutment from damage and the patient's tongue from injury during the time the final restoration is being fabricated.

The Protective Cap will be offered in sizes to fit all SPI® EASY abutments and may be used with all SPI® System dental implants.

EQUIVALENCE TO MARKETED PRODUCT

The SPI® EASY Dental Implant Protective Cap has the following similarities to the predicate SPI® Dental Implant Gingiva Former:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design.

In summary, the Thommen SPI® EASY Dental Implant Protective Cap described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2003

Thommen Medical AG
C/O Mr. Floyd G. Larson
PaxMed International
4329 Graydon Road
San Diego, California 92130

Re: K033346
Trade/Device Name: SPI® EASY Dental Implant Protective Cap
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: NHA
Dated: October 17, 2003
Received: October 20, 2003

Dear Mr. 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

Special 510(k): Device Modification • **SPI® EASY Dental Implant Protective Cap**

Applicant: Thommen Medical AG

510(k) Number:

Device Name: SPI ® EASY Dental Implant Protective Cap

Indications for Use:

The Thommen SPI® EASY Dental Implant Protective Cap is intended to be used in conjunction with SPI® System dental implants, which provide support for crowns, bridges or overdentures in the maxillary and/or mandibular arch.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____

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

510(k) Number: K033346