JUL 2 8 2005

K051527

Thommen Medical AG
510(k) Premarket Notification
SPI® EASY Temporary Cap

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

DEVICE NAME

Classification Name: Abutment, Implant, Dental, Endosseous
Trade/Proprietary Name: SPI® EASY Temporary Cap
Common Name: Endosseous Dental Implant System Component

ESTABLISHMENT REGISTRATION NUMBER

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

DEVICE CLASSIFICATION

Endosseous dental implant abutments are Class II devices (21 CFR 872.3630). 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 raw material from which the SPI® EASY Temporary Cap is made complies with ISO 10993-1.

PREDICATE DEVICE INFORMATION

The predicate devices for this modification are Thommen Medical AG SPI® Dental Implant System Abutments cleared by FDA under K033346, K023645 and K031747, and Straumann USA Abutments cleared by FDA under K041070.

K051527

PACKAGING/LABELING/PRODUCT INFORMATION

Thommen SPI® EASY Temporary Cap will be packaged and sold non-sterile.

INTENDED USE

The Thommen SPI® EASY Temporary 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. It is used to protect the coronal surface of the abutment and to serve as a base for a temporary restoration.

DEVICE DESCRIPTION

Design Characteristics

The Thommen SPI® EASY Temporary Cap is an endosseous dental implant component used for maintaining the gingival contour and as a base for a fabrication of a temporary restoration. It 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 Temporary 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 Temporary Cap has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- is packaged using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2005

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

Re: K051527
Trade/Device Name: SPI® Easy Temporary Cap
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 7, 2005
Received: June 8, 2005

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.

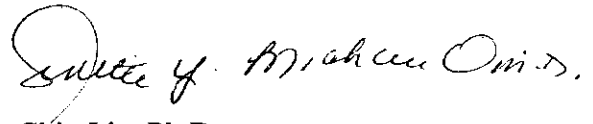
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

Applicant: Thommen Medical AG

510(k) Number (if known): K051527

Device Name: SPI® EASY Temporary Cap

Indications for Use:

The Thommen SPI® EASY Temporary 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. It is used to protect the coronal surface of the abutment and to provide a base for fabrication of temporary restorations.

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, Dental Devices

510(k) Number: K051527