K023645

ADMINISTRATIVE INFORMATION

Manufacturer Name: Thommen Medical AG
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Switzerland
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NOV 1 3 2002

Official Contact: Orlando Antunes

Representative/Consultant: Floyd G. Larson
PaxMed International
4329 Graydon Road
San Diego, CA 92130
Telephone (858) 792-1235
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DEVICE NAME

Classification Name: Abutment, Implant, Dental, Endosseous (NHA)
Trade/Proprietary Name: SPI® EASY Dental Implant Abutment
Common Name: Endosseous Dental Implant Abutment

ESTABLISHMENT REGISTRATION NUMBER

Thommen Medical AG has submitted an Establishment Registration to FDA. The Establishment Registration number has not yet been assigned. 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. However, the CP titanium Grade 4 used to manufacture Thommen dental implant abutments meets the chemical and mechanical requirements of ASTM F67 and ISO 5832-2.

PREDICATE DEVICE INFORMATION

The predicate device for this modification is the HA-Ti Dental Implant System, cleared by FDA on January 4, 1991 under K901927 and July 12, 2001 under K003045. Thommen Medical AG has acquired the rights to the HA-Ti Dental Implant System from HATI Dental AG and has renamed it the SPI® Dental Implant System.

PACKAGING/LABELING/PRODUCT INFORMATION

Thommen SPI® EASY Dental Implant Abutments will be packaged and sold non-sterile. The device is not represented to be "pyrogen free." Samples of product labels are shown in Exhibit II, with copies of the prosthetic procedure manual with the instructions for use. All catalogues will be amended to include the modified devices, consistent with the information shown for existing devices.

INTENDED USE

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

DEVICE DESCRIPTION

Thommen SPI® EASY Dental Implant Abutments are endosseous dental implant abutments made of commercially pure grade titanium and intended for cemented restorations. They may be used for cemented single crowns or bridges. The existing abutments are offered in four diameters with lengths from 6.0 mm to 9.0 mm. Straight abutments and abutments with angulation correction of 20° are available. The preangled abutments are also available in the four diameters, with lengths from 6.5 mm to 9.0 mm.

The SPI® EASY abutments added by means of this Special 510(k) all are straight abutments and include lengths of 4.3 mm and 7.0 mm in each of the existing diameters. The shorter abutments are intended to reduce or eliminate the need for the clinician to prepare the abutment for restoration.

All SPI® EASY abutments may be used with all SPI® ELEMENT implants (those covered in the HA-Ti predicate device submissions referred to above), as well as with SPI® ONETIME implants, covered by Thommen Medical AG Special 510(k) K022038.

EQUIVALENCE TO MARKETED PRODUCT

The modified SPI® EASY Dental Implant Abutment has the following similarities to the predicate SPI® System and HA-Ti Dental Implant Abutments:

- 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.

In summary, the modified Thommen SPI® EASY Dental Implant Abutment 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

NOV 13 2002

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

Re: K023645
Trade/Device Name: SPI® EASY Dental Implant Abutment
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE and NHA
Dated: October 28, 2002
Received: October 30, 2002

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.

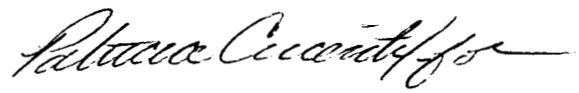
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: Thommen Medical AG

510(k) Number: K023645

Device Name: SPI ® EASY Dental Implant Abutment

Indications for Use:

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

(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: K023645