JUL 2 2003

K031747

ADMINISTRATIVE INFORMATION

Manufacturer Name: Thommen Medical AG
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CH-4437 Waldenburg
Switzerland
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JUL 2 2003

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® Dental Implant Abutments

Common Name: Endosseous Dental Implant Abutment

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 "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, 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 devices for this modification are the HA-Ti Dental Implant System, cleared by FDA on January 4, 1991 under K901927 and SPI Easy Dental Implant Abutment (Thommen A.G.), cleared on November 13, 2002 under K023645. Thommen Medical AG has acquired the rights to the HA-Ti Dental Implant System from HATI Dental and has renamed it the SPI® System.

PACKAGING/LABELING/PRODUCT INFORMATION

Thommen SPI® Dental Implant Abutments will be packaged and sold non-sterile. The device is not represented to be "pyrogen free. All catalogues will be amended to include the modified devices, consistent with the information shown for existing devices.

INTENDED USE

Thommen SPI® 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® 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.

EQUIVALENCE TO MARKETED PRODUCT

The modified SPI® Dental Implant Abutments have the following similarities to the predicate HA-Ti Dental Implant Abutment and Thommen SPI® Dental Implant Abutment:

- have the same intended use,
- use the same operating principle,
- incorporate the same basic design,
- incorporate the same materials, and
- are packaged using the same materials and processes.

In summary, the modified Thommen SPI® Dental Implant Abutments described in this submission are, 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

JUL 2 2003

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

Re: K031747
Trade/Device Name: SPI Dental Implant Abutment
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: NHA
Dated: June 3, 2003
Received: June 5, 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,

Susan Runner, DDS, MA
Interim 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:

Device Name: SPI ® Dental Implant Abutment

Indications for Use:

Thommen SPI® 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 X OR Over-The-Counter Use____

Kevin Mulley for MSR

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

510(k) Number: K031747