K022038

JUL 15 2002

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: Implant, Endosseous (DZE)
Trade/Proprietary Name: SPI® ONETIME Dental Implant
Common Name: Endosseous Dental Implant

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 "Implant, 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 the Thommen dental implant meets the chemical and mechanical requirements of ASTM F67 and ISO 5832-2.

PREDICATE DEVICE INFORMATION

The principal predicate device for this modification is the Thommen Medical AG HA-Ti Dental Implant, cleared by FDA on July 12, 2001 under K003045. Thommen Medical AG has acquired the rights to the HA-Ti system from HATI Dental AG.

PACKAGING/LABELING/PRODUCT INFORMATION

Thommen SPI® ONETIME implants will be packaged in a radiation sterilizable package consisting of a primary container, with implant and auxiliary parts, sealed with a peel-off wrapping. The sterile packs will be grouped into storage packs. 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® ONETIME Dental Implant is 10^{-6}. The device is not represented to be "pyrogen free."

INTENDED USE

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

DEVICE DESCRIPTION

The two-stage HA-Ti Dental Implant acquired from HATI Dental AG by Thommen Medical AG has been modified to make it a one-piece one-stage transgingival implant and will be marketed as the SPI® ONETIME Dental Implant. Other components of the HA-Ti Dental Implant System have not been modified and are suitable for use with the modified implant, and will be sold under the SPI® Dental Implant System name.

The Thommen SPI® ONETIME Dental Implant is a one-stage root form endosseous dental implant made of commercially pure grade titanium. The implant surface is smooth machined on the transgingival portion and sandblasted and acid-etched in the area designed to contact bone. The implant is offered in three lengths (8 mm, 11 mm, 14 mm, not including the 2.9 mm transgingival portion), with two diameters (4.2 mm, 5.0 mm) for each length. It is constructed of materials that have a long clinical history of proven acceptance and performance.

EQUIVALENCE TO MARKETED PRODUCT

The modified SPI® ONETIME Dental Implant has the following similarities to the predicate HA-Ti Dental Implant:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design, (with the addition of a transgingival portion)
- 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

JUL 15 2002

Mr. Floyd G. Larson
Consultant
PaxMed International
4329 Graydon Road
San Diego, California 92130

Re: K022038
Trade/Device Name: SPI® ONETIME Dental Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: June 21, 2002
Received: June 24, 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

K 022038

Applicant: Thommen Medical AG

510(k) Number: K022038

Device Name: SPI ® ONETIME Dental Implant

Indications for Use:

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

(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 ____

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K022038