K061807

510(k) Summary

JUL 3 1 2006

Thommen Medical AG
SPI® ART Abutment

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Thommen Medical AG Hauptstrasse 26d 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, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone (858) 792-1235 Fax (858) 792-1236

DEVICE NAME

Classification Name:	Abutment, Implant, Dental, Endosseous
Trade/Proprietary Name:	SPI® ART Abutment
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 device classification is reviewed by the Dental Devices Branch. The product code for "Abutment, Implant, Dental, Endosseous" is NHA.

INDICATIONS FOR USE

SPI® ART 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.

SPI ART Abutments are contraindicated for free-end bridges or bridges with more than one intermediate pontic element.

DEVICE DESCRIPTION

Thommen SPI ART Abutments are zirconia dental implant abutments for use with the SPI Dental Implant System.

Design

Both the SPI ART Abutment and SPI ART Grinding (Milling) Abutment have the same design as their titanium counterparts, SPI EASY abutments for cemented restoration and SPI RETAIN milling abutments. Each of the SPI ART abutment types comes in two sizes.

Material

SPI ART abutments are made from zirconium oxide (Y-TZP) and are designed specifically for use with ceramic cemented restorations.

EQUIVALANCE TO MARKETED DEVICE

Thommen Medical AG has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the SPI ART Abutment is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2006

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

Re: K061807
Trade/Device Name: SPI® Art Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 23, 2006
Received: June 27, 2006

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 (240) 276-3150 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

K061807

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: SPI® ART Abutment

Indications for Use:

SPI® ART 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.

SPI ART Abutments are contraindicated for free-end bridges or bridges with more than one intermediate pontic element.

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)

Kei Mulay for HSR
...on Sign-Off)
...n of Anesthesiology, General Hospital,
...ation Control, Dental Devices
...Number K061807