K090154

510(k) Summary

Thommen Medical AG
SPI® Dental Implant, INICELL®

JUL 27 2009

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:	Linda K. Schulz or Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	SPI® Dental Implant, INICELL®
Common Name:	Endosseous dental implant
Classification Regulations:	Implant, Endosseous, Root-Form 21 CFR 872.3640, Class II
Product Code	DZE
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

SPI® Dental Implant, INICELL® is for one-stage or two-stage surgical procedures. SPI Dental Implant, INICELL is intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, four or more implants must be used in immediately loaded cases.

K090154

Contraindications for the use of SPI ELEMENT INICELL implant Ø 3.5 mm and SPI CONTACT INICELL implant Ø 3.5 mm:
These implants are not suitable for applications in areas where pronounced rotation and translation movements occur, causing the implant to be subjected to large bending movements.

- Restoration of posterior teeth in the upper and lower jaw
- Single-tooth restoration of canines and central incisors in the upper jaw
- Any application involving retentive anchors

DEVICE DESCRIPTION

The design of the Thommen Medical AG endosseous dental implants has been modified to include a new surface treatment that will be marketed as the SPI® Dental Implant, INICELL®. All features other than this surface treatment of the implants remain the same as the TST Surface implants. Other components of the SPI® Dental Implant System have not been modified, are suitable for use with the modified implants, and will be sold under the SPI Dental Implant System name.

EQUIVALENCE TO MARKETED DEVICES

Thommen Medical AG demonstrated that, for the purposes of FDA's regulation of medical devices, the SPI Dental Implant, INICELL 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. Overall, the SPI Dental Implant, INICELL has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials, and
- has similar packaging and is 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

Thommen Medical AG
C/O Linda Schulz, RDH, BSDH
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

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Re: K090154
Trade/Device Name: SPI® Dental Implant, INICELL®
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: July 20, 2009
Received: July 22, 2009

Dear Ms.Schulz:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

for

Susan Runner, D.D.S., M.A.
Acting Division 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

510(k) Number (if known): K090154

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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)

Kevin Marley for WSD
(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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