

K093615

MAR - 4 2010

**510(k) Summary
Thommen Medical AG
SPI® Dental Implant, ELEMENT
February 25, 2010**

ADMINISTRATIVE INFORMATION

Manufacturer Name: Thommen Medical AG
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Official Contact: Orlando Antunes

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Telephone: +1 (858) 792-1235
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: SPI® Dental Implant, ELEMENT
Common Name: Endosseous dental implant;
Endosseous dental implant abutment
Classification Regulations: 21 CFR 872.3640
21 CFR 872.3630
Product Code DZE
NHA
Classification Panel: Dental Products Panel
Reviewing Branch: Dental Devices Branch

INTENDED USE

SPI® Dental Implant, ELEMENT is for one-stage or two-stage surgical procedures. SPI Dental Implant, ELEMENT 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.

Contraindications for the use of SPI ELEMENT 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 SPI® Dental Implant System implants has been modified to include new sizes and corresponding abutments that will be marketed as the SPI® Dental Implant, ELEMENT. All features other than these implant sizes remain the same as the currently marketed SPI® ELEMENT 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, ELEMENT is substantially equivalent in indications and design principles to predicate devices (K090154, K051502, K050712, K050258, K033984, K010185, K926501), each of which has been determined by FDA to be substantially equivalent to preamendment devices. A comparison of the surface area of the Thommen Medical 6.5mm implant with that of a predicate short implant (Straumann Standard Implant 6.0 mm) showed that the Thommen Medical implant has a greater surface area than the predicate. Overall, the SPI Dental Implant, ELEMENT 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.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Thommen Medical, AG
C/O Ms. Linda K. Schulz
Senior Regulatory Affairs Specialist
Paxmed International, LLC
11234 EL Camino Real, Suite 200
San Diego, California 92130

MAR - 4 2010

Re: K093615
Trade/Device Name: SPI[®] Dental Implant, ELEMENT
Regulation Number: 21CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product: DZE
Dated: February 25, 2010
Received: February 1, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

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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" (21 CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm> 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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093615

Indications for Use

510(k) Number (if known): _____

Device Name: SPI® Dental Implant, ELEMENT

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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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RS Betz MD5 for Dr. K. P. Mulry
(Division Sign-Off)
Division of Anesthesiology, General Hospital
infection Control, Dental Devices

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