K092248

REVISED 510(k) Summary

Thommen Medical AG
Special 510(k): Device Modification

SPI® Customizable Gingiva Former

SEP 25 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 Email: lschulz@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	SPI® Customizable Gingiva Former
Common Name:	Endosseous dental implant abutment
Classification Regulations:	Abutment, Implant, Dental, Endosseous 21 CFR 872.3630, Class II
Product Code:	NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch
Establishment Registration Number:	3003836985
Owner/Operator Number:	9051144

INTENDED USE

The SPI® Customizable Gingiva Former is intended to be used in conjunction with SPI® System dental implants to provide temporary support for crowns or bridges in the maxillary and/or mandibular arch.

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DEVICE DESCRIPTION

The Thommen SPI® Customizable Gingiva Former is a temporary endosseous dental implant component made from an acrylic-based polymer with a titanium base at the implant/abutment interface for a stable, precise connection. The SPI® Customizable Gingiva Former is used for maintaining gingival contour and as a base for fabrication of a temporary restoration.

EQUIVALENCE TO MARKETED PRODUCT

Predicate devices: K051527, K033346, K023645 and K031747.

The SPI® Customizable Gingiva Former has the following similarities to the unmodified predicate devices:

- has the same intended use,
- uses the same operating principle,
- uses the same or similar materials
- incorporates the same basic design, and
- is packaged using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 25 2009

Thommen Medical, AG
C/O Ms. Linda K. Schulz
Regulatory Affairs Specialist
PaxMed Interational, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K092248
Trade/Device Name: SPI® Customizable Gingiva Former
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: September 17, 2009
Received: September 18, 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

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

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REVISED Indications for Use

Applicant: Thommen Medical AG

510(k) Number (if known):

Device Name: SPI® Customizable Gingiva Former

Indications for Use:

The SPI® Customizable Gingiva Former is intended to be used in conjunction with SPI® System dental implants to provide temporary support for crowns or bridges in the maxillary and/or mandibular arch.

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)

Kevin Mulley for MSP

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

510(k) Number: K092248