K070290

510(k) Summary APR 17 2007

Thommen Medical AG
SPI® VECTOdrill™ Ceramic Drills

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 1 (858) 792-1235 Fax 1 (858) 792-1236 email: flarson@paxmed.com

DEVICE NAME

Classification Name:	Accessories, Implant, Dental, Endosseous
Trade/Proprietary Name:	SPI® VECTOdrill™ Ceramic Drills
Common Name:	dental implant drill bit

DEVICE CLASSIFICATION

FDA has classified "Accessories, Implant, Dental, Endosseous" as Class I devices (21 CFR 888.3980), with a product code of NDP.

INDICATIONS FOR USE

SPI® VECTOdrill™ Ceramic Drills are for use in the preparation of the implant site for all SPI® System implants.

DEVICE DESCRIPTION

SPI® VECTOdrill™ ceramic drills are reusable zirconia dental implant drill bits for use with the SPI Dental Implant System. SPI VECTOdrill ceramic drills include a pilot drill and three progressive twist drills. The pilot drill has a sle der, highly efficient tip that initiates

the pilot hole without the need for a round bur. The pilot drill also has the ability to cut laterally, in order to allow slight axial correction. The twist drills do not cut laterally, which helps to avoid enlarging the diameter of the osteotomy site. Each twist drill has an integrated guide at the tip, which is the same diameter as the preceding drill, in order to provide automatic axial guidance.

The pilot drill has a diameter of 2.0 mm and is available in 29.0 mm and 34.0 mm lengths. The twist drill is available in three diameters (2.8 mm, 3.5 mm and 4.3 mm) and two lengths for each diameter (29.0 mm and 34.0 mm).

Both the pilot drill and the twist drill have the proximal end configured to fit into a dental handpiece latch. All SPI VECTOdrills have a length 0.5 mm longer than the corresponding SPI Dental Implants. Each drill has depth markings that correspond to the VECTOdrill depth gauge in increments of 1.5 mm, from 8.0 mm to 17.0 mm. SPI VECTOdrill ceramic drills are intended to be resterilized and reused up to 20 times.

SPI VECTOdrill ceramic drills are made of alumina toughened zirconia (ATZ). SPI VECTOdrill ceramic drills are packed individually in a transparent plastic tube contained in a sealed plastic sleeve and are provided non-sterile.

Testing of SPI VECTOdrill ceramic drills established their ability to retain their cutting ability under aggressive cutting conditions. Testing also resulted in the conclusion that the mechanical properties of SPI VECTOdrill ceramic drills are appropriate for their safe use.

EQUIVALENCE TO MARKETED DEVICE

Thommen Medical AG submits the following information to demonstrate that, for the purposes of FDA's regulation of medical devices, the SPI VECTOdrill ceramic drills are substantially equivalent in indications and design principles to the following predicate device: Thommen Medical AG, SPI VECTOdrill stainless steel drills which are considered Class I, exempt.

The SPI VECTOdrill ceramic drills have the following similarities to the predicate device:

- has the same intended use,
- uses the same operating principle,
- incorporates the same design

In summary, the SPI VECTOdrill ceramic drills described in this submission are, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR 17 2007

Re: K070290
Trade/Device Name: SPI® VECTOdrill™ Ceramic Drills
Regulation Number: 21 CFR 872.3980
Regulation Name: Endosseous Dental Implant Accessories
Regulatory Class: I
Product Code: NDP
Dated: January 29, 2007
Received: January 30, 2007

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.

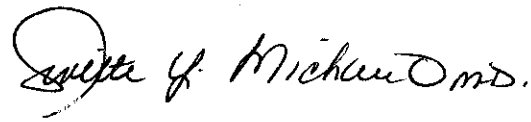
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

K070290

Indications for Use

Applicant: Thommen Medical AG

510(k) Number (if known): _____

Device Name: SPI® VECTOdrill™ Ceramic Drills

Indications for Use:

SPI® VECTOdrill™ Ceramic Drills are for use in the preparation of the implant site for all SPI® System implants.

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)

Susan Runner

...eral Hospital,
...ion Control, ... Devices

...(k) Number K070290