DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 10, 2016

Thommen Medical AG
c/o Ms. Linda K. Schulz
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K151984
Trade/Device Name: Milling Abutment for CAD/CAM
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 10, 2016
Received: February 11, 2016

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.

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 Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151984

Device Name

Milling Abutment for CAD/CAM

Indications for Use *(Describe)*

Thommen Milling abutments for CAD/CAM are intended to be used in conjunction with Thommen System dental implants in the maxillary and /or mandibular arch to provide support for crowns, bridges and overdentures.

All digitally designed abutments for use with Thommen Milling abutments for CAD/CAM are intended to be sent to a Thommen validated milling center for manufacture.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Thommen Medical AG

Milling Abutment for CAD/CAM
K151984

March 7, 2016

ADMINISTRATIVE INFORMATION

Manufacturer Name	Thommen Medical AG Neckarsulmstrasse 28 2540 Grenchen, Solothurn Switzerland Telephone: +41 61 965 90 20 Fax: +41 61 965 90 21
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Representative/Consultant	Linda Schulz, BSDH, RDH Floyd G. Larson PaxMed International, LLC 12264 El Camino Real, Suite 400 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:	Milling Abutment for CAD/CAM
Common Name:	Dental implant abutment
Classification Name:	Endosseous dental implant abutment
Classification Regulation:	21 CFR 872.3630, Class II
Product Code:	NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INDICATIONS FOR USE

Thommen Milling abutments for CAD/CAM are intended to be used in conjunction with Thommen System dental implants in the maxillary and /or mandibular arch to provide support for crowns, bridges and overdentures.

All digitally designed abutments for use with Thommen Milling abutments for CAD/CAM are intended to be sent to a Thommen validated milling center for manufacture.

PREDICATE INFORMATION

K122295	CORE 3D Abutment System for Digital Prosthetic Solutions	CORE 3D Protech, S.L.	Primary Predicate
K073713	Blue Sky Bio Dental Implant System	Blue Sky Bio, LLC	Reference Predicate
K031747	SPI® Dental Implant Abutments	Thommen Medical, AG	Reference Predicate
K090154	SPI® Dental Implant, INICELL®	Thommen Medical, AG	Reference Predicate

DEVICE DESCRIPTION

The Milling Abutment for CAD/CAM is an abutment used by a dental laboratory equipped with the 3Shape CAD/CAM System to fabricate a customized abutment made of titanium. Each patient-specific abutment is individually prescribed by the clinician. Minimum wall thickness allowed for the final abutment is 0.4 mm, maximum angulation is 20°, maximum gingival height is 7.0 mm, and total height of the abutment is no greater than 15 mm and no shorter than 4.5 mm. All digitally designed abutments for use with Thommen Milling abutments for CAD/CAM are intended to be sent to a Thommen validated milling center for manufacture. Final abutments are to be sterilized prior to intraoral placement.

Milling Abutment for CAD/CAM is available in five diameters (3.5 mm, 4.0 mm, 4.5 mm, 5.0 mm, 6.0 mm) and two heights (12 mm and 15 mm). The Ø3.5 mm abutment is provided in the 12 mm height. All other diameters are provided in the 15 mm height. Each abutment is supplied with a corresponding screw. Milling Abutment for CAD/CAM is compatible with the Thommen Implant System ELEMENT and CONTACT implants.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included the following: sterilization validation according to ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices* and ISO 17665-2 *Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1;* Biocompatibility evaluation according to ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* which determined that no further biocompatibility testing is required because all

materials and processing are identical to the abutments cleared in K031747; Input/output validation for the Thommen Medical library performed to ensure accuracy and conformance to the parameters outlined for the Thommen Milling Abutment for CAD/CAM. Validation confirmed that accuracy was consistent and parameter limits were maintained in final device manufacturing. Static and dynamic compression -bending testing were performed according to ISO 14801 *Dentistry - Implants - Dynamic fatigue test for endosseous dental implants.*

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent in indications and design principles predicate devices shown above. Below are summary tables showing technical comparison between the subject device and the primary predicate devices.

Subject Device	Primary Predicate Device
Thommen Medical AG Milling Abutment for CAD/CAM K151984	CORE 3D Protech, S.L. Core 3D Abutment System for Digital Prosthetic Solutions K122295
Indications for use	
Thommen Milling abutments for CAD/CAM are intended to be used in conjunction with Thommen System dental implants in the maxillary and /or mandibular arch to provide support for crowns, bridges and overdentures. All digitally designed abutments for use with Thommen Milling abutments for CAD/CAM are intended to be sent to a Thommen validated milling center for manufacture.	The CORE 3D abutment system for digital prosthetic solutions are dental abutments placed into a dental implant to provide support for dental prosthetic restorations. The abutments include: • Titanium Bases to be attached to the underlying implant and upon which a CAD/CAM designed superstructure may be fitted to complete a two-piece dental abutment; • Titanium Abutment Blanks with a pre-machined implant connection where the upper portion may be custom-milled in accordance with a patient-specific design using CAD/CAM techniques • Abutment Screws to permanently fix the abutments to the underlying implant. Core 3D abutments are intended for use to support single-tooth (unit) and multiple-tooth (bridges and bars) prostheses, in the mandible or maxilla for functional and aesthetic restorations. Core 3D abutments designed using CAD/CAM techniques must fulfill the Core 3D allowable range of design specifications and be provided as straight abutments only. Core 3D abutments and are compatible for use with the following dental Implants: • Nobel Biocare Brånemark System (K022582, K934825) • Zimmer Tapered Screwvent (K013227, K061410, K072589)
Design	
CAD/CAM Blank	CAD/CAM Blank, Titanium Base
Cement-retained	Cement-retained
Single-unit, Multi-unit	Single-unit, Multi-unit
3.5 – 6.0	3.5 – 5.7
Internal Hex	Internal Hex, External Hex

The subject device and primary predicate have slightly different Indications for Use language. However, the difference in language does not change the intended use of abutments. Both abutments are being used in conjunction with dental implants for the purpose of supporting dental prostheses and are CAD/CAM custom abutments fabricated at a milling center.

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and diameter, gingival height, and angle of the abutments. The subject and predicate devices are packaged in similar materials and to be sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.