DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 2, 2016

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

Re: K160244
Trade/Device Name: VARIOunite
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 3, 2016
Received: May 4, 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,

Tina Kiang
-S

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)*

K160244

Device Name

VARIOunite

Indications for Use *(Describe)*

VARIOflex
Thommen Medical VARIOflex Abutments 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.

VARIOtemp
Thommen Medical VARIOtemp Abutments 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Thommen Medical AG
VARIOunite

May 3, 2016

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	VARIOunite
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

PREDICATE DEVICE

The primary predicate device is K121334, VARIOeco, Thommen Medical AG.
The reference predicate device is K120414, OsseoSpeed™ Plus, Astra Tech AB.

INDICATIONS FOR USE

VARIOflex
Thommen Medical VARIOflex abutments 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.

VARIOtemp
Thommen Medical VARIOtemp abutments 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.

DEVICE DESCRIPTION

VARIOunite is a straight titanium dental implant abutment with retention groves that can be used for either permanent or temporary screw-retained or cement-retained restorations. Labeled as VARIOflex, it is provided with a burn-out sleeve for fabrication of a permanent restoration. Labeled as VARIOtemp, it is provided with a fabrication screw for fabrication of a temporary restoration. VARIOunite can be prepared to the appropriate occlusal height prior to fabrication of the restoration using the retention rings for guidance.

VARIOunite is available with an indexed connection for crowns or a non-indexed connection for bridges. It is available in five platform diameters (3.5, 4.0, 4.5, 5.0 and 6.0 mm) corresponding to existing platform diameters of the Thommen System dental implants.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included 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/TR 17665-2 *Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1,* and biocompatibility evaluation according to ISO 10993-1 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

Clinical data were not submitted in this premarket notification.

EQUIVALENCE TO MARKETED DEVICE

A comparison of the technological characteristics of the subject device and the primary predicate device K121334 is provided in the following table.

Summary Table of Substantial Equivalence

	Subject Device	**Primary Predicate Device**	**Reference Predicate Device**
	Thommen Medical AG VARIOunite K160244	Thommen Medical AG VARIOeco K121334	Astra Tech AB OsseoSpeed Plus K120414
Indications for Use	VARIOflex Thommen Medical VARIOflex abutments 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. VARIOtemp Thommen Medical VARIOtemp abutments 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.	Thommen VARIOeco dental implant abutments 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.	Astra Tech Implant System Plus abutments are intended to be used in conjunction with Astra Tech Implant System Plus in fully or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures.
Design			
Abutment Design	Straight abutment, prepable	Straight abutment, non-prepable	Straight abutment, prepable
Abutment Diameter (mm)	3.5, 4.0, 4.5, 5.0, 6.0	3.5, 4.0, 4.5, 5.0, 6.0	3.0, 3.6, 4.2, 4.8, 5.4
Restoration	Single or multi-unit	Single or multi-unit	Single or multi-unit
Implant Connection	Internal	Internal	Internal
Material			
Abutment	CPTi	CPTi	Titanium Alloy

The subject device VARIOunite abutment is substantially equivalent to the primary predicate, VARIOeco K121334, in basic design and function. Both are straight titanium abutments indicated for screw-retained or cement-retained prostheses, have a precision burn-out sleeve for fabrication of the permanent prosthesis, have the same implant platform diameters, attach to the same corresponding implants in the Thommen Implant System, and are for single or multi-unit restorations. When VARIOunite is provided with a fabrication screw and labeled as VARIOtemp, it is used for a direct temporary restoration where as the primary predicate

VARIOeco uses a separate temporary abutment. VARIOtemp is substantially equivalent to the reference predicate K120414 in abutment design and function. The subject VARIOunite abutment prepable design is substantially equivalent to the prepable design of the reference predicate K120414.

CONCLUSION

Overall, the subject device 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 or very similar materials, and
- has similar packaging and is to be sterilized using the same processes.

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