DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

September 29, 2017

Re: K171795
Trade/Device Name: Thommen Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 31, 2017
Received: September 1, 2017

Dear Linda 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 (DICE) 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 (DICE) 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,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting 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)*

K171795

Device Name

Thommen Implant System

Indications for Use *(Describe)*

Implant:
The ELEMENT PF 3.0 is suitable for use in one-stage or two-stage surgical techniques for restoring chewing function. The ELEMENT PF 3.0 is suitable for immediate implantation and restoration in case of replacement of several teeth; prerequisites are good primary stability and appropriate occlusal loading. The ELEMENT PF 3.0 must only be used for replacement of the lateral incisors of the upper jaw and the central and lateral incisors of the lower jaw.

VARIOunite PF 3.0:
Thommen Medical VARIOunite abutments PF 3.0 are only used in conjunction with the ELEMENT PF 3.0 and are for fabrication of provisional and final crowns in the anterior maxilla and mandible (upper lateral incisors, lower anterior teeth).
Digitally designed abutments for use with Thommen VARIOunite are intended to be sent to a Thommen validated milling center for manufacture.

VARIOunite:
Thommen Medical VARIOunite 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.
Digitally designed abutments for use with Thommen VARIOunite 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.

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

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510(k) Summary

Thommen Medical AG

Thommen Implant System
K171795

September 29, 2017

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 K. Schulz, BSDH, RDH Kevin A. Thomas, PhD 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 kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Thommen Implant System
Common Name	Dental implant Dental implant abutment
Classification Name	Implant, endosseous, root form Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640, Class II
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate
K093615, SPI® Dental Implant ELEMENT, Thommen Medical AG

Reference Predicates
K160244, VARIOunite, Thommen Medical AG
K102804, SPI® Titanium Base for CAD/CAM, Thommen Medical AG
K151984, Milling Abutment for CAD/CAM, Thommen Medical AG
K121334, VARIOeco, Thommen Medical AG
K120414, OsseoSpeed™ Plus, Astra Tech AB

INDICATIONS FOR USE

Implant:
The ELEMENT PF 3.0 is suitable for use in one-stage or two-stage surgical techniques for restoring chewing function. The ELEMENT PF 3.0 is suitable for immediate implantation and restoration in case of replacement of several teeth; prerequisites are good primary stability and appropriate occlusal loading. The ELEMENT PF 3.0 must only be used for replacement of the lateral incisors of the upper jaw and the central and lateral incisors of the lower jaw.

VARIOunite PF 3.0:
Thommen Medical VARIOunite abutments PF 3.0 are only used in conjunction with the ELEMENT PF 3.0 and are for fabrication of provisional and final crowns in the anterior maxilla and mandible (upper lateral incisors, lower anterior teeth).
Digitally designed abutments for use with Thommen VARIOunite are intended to be sent to a Thommen validated milling center for manufacture.

VARIOunite:
Thommen Medical VARIOunite 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.
Digitally designed abutments for use with Thommen VARIOunite are intended to be sent to a Thommen validated milling center for manufacture.

DEVICE DESCRIPTION

ELEMENT Ø 3.0 is a self-tapping, root form, endosseous dental implant made of commercially pure titanium. It is provided in two surfaces (TST and INICELL) and five lengths (8.0, 9.5, 11.0, 12.5, and 14 mm). Subject device components available for the ELEMENT Ø 3.0 implant are the healing cap, gingiva former and VARIOunite abutments. VARIOunite abutments can be used for temporary restorations, permanent restorations, or CAD/CAM zirconia superstructures. The indications for previously cleared VARIOunite abutments have been expanded to include angulation of the CAD/CAM zirconia superstructures.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: radiation sterilization validation to an SAL of 10^{-6} according to ISO 11137-1, ISO 11137-2; Steam sterilization validation to an SAL of 10^{-6} according to ISO 17665-1 and ISO 17665-2; biocompatibility evaluation according to ISO 10993-1 by reference to K093615, K160244, K102804 and K121334; *Limulus* amebocyte lysate (LAL) endotoxin testing in accordance with FDA Guidance documents *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile;* shelf life testing for detecting seal leaks according to ASTM F88/F88M, seal strength testing according to ASTM F1886/1886M, seal integrity testing according to ASTM F1929, dye penetration testing according to ASTM F3039, testing for packaging of terminally sterilized medical devices according to ISO 11607-1, and ISO 11607-2, and mechanical testing according to ISO 14801 to ensure that the subject device is strong enough for its intended use.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent in indications and design principles to the predicate devices shown above. Below are summary tables comparing the Indications for Use and the technological characteristics of the subject device and the predicate devices.

Comparison of Indications for Use Statements

	Indications for Use Statement
Subject Device	
Thommen Implant System Thommen Medical AG	Implant: The ELEMENT PF 3.0 is suitable for use in one-stage or two-stage surgical techniques for restoring chewing function. The ELEMENT PF 3.0 is suitable for immediate implantation and restoration in case of replacement of several teeth; prerequisites are good primary stability and appropriate occlusal loading. The ELEMENT PF 3.0 must only be used for replacement of the lateral incisors of the upper jaw and the central and lateral incisors of the lower jaw. VARIOunite PF 3.0: Thommen Medical VARIOunite abutments PF 3.0 are only used in conjunction with the ELEMENT PF 3.0 and are for fabrication of provisional and final crowns in the anterior maxilla and mandible (upper lateral incisors, lower anterior teeth). Digitally designed abutments for use with Thommen VARIOunite are intended to be sent to a Thommen validated milling center for manufacture. VARIOunite: Thommen Medical VARIOunite 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. Digitally designed abutments for use with Thommen VARIOunite are intended to be sent to a Thommen validated milling center for manufacture.
Primary Predicate	
K093615 SPI® Dental Implant ELEMENT Thommen Medical AG	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
Reference Predicates	
K160244 VARIOunite Thommen Medical AG	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.
K102804 SPI® Titanium Base for CAD/CAM Thommen Medical AG	Thommen Titanium Base for CAD/CAM abutments are intended to be used in conjunction with Thommen implants and the 3M ESPE Lava™ System in the maxillary and/or mandibular arch to provide support for crowns and bridges.
K151984 Milling Abutment for CAD/CAM Thommen Medical AG	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.
K121334 VARIOeco Thommen Medical AG	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.

	Indications for Use Statement
120414 OsseoSpeed™ Plus Astra Tech AB	Implants: The Astra Tech Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • replacing single and multiple missing teeth in the mandible and maxilla, • immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge, • especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective, • immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm, or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate. The intended use for OsseoSpeedTM Plus 3.0S is limited to replacement of maxillary lateral incisors and mandibular incisors. Abutments: Astra Tech Implant System Plus abutments are intended to be used in conjunction with Astra Tech Implant System Plus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures. Atlantis Abutments: The Atlantis™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous; patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous; implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous; patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant.

Comparison of Technological Characteristics

	Subject Device	**Primary Predicate Device**	**Reference Predicate Devices**				
	Thommen Implant System Thommen Medical AG	K093615 SPI® Dental Implant ELEMENT Thommen Medical AG	K160244 VARIOunite Thommen Medical AG	K102804 SPI® Titanium Base for CAD/CAM Thommen Medical AG	K151984 Milling Abutment for CAD/CAM Thommen Medical AG	K121334 VARIOeco Thommen Medical AG	K120414 OsseoSpeed™ Plus Astra Tech AB
Design							
Implant Body Diameter (mm)	3.0	3.5, 4.0, 4.5, 5.0, 6.0	NA	NA	NA	NA	3.0, 3.6, 4.2, 4.8, 5.4
Implant Length (mm)	8, 9.5, 11, 12.5, 14	6.5, 8.0, 9.5, 11, 12.5	NA	NA	NA	NA	6.0, 8.0, 9.0, 11, 13, 15, 17
Abutment Diameter (mm)	3.0, 3.5, 4.0, 4.5, 5.0, 6.0	6.0	3.5, 4.0, 4.5, 5.0, 6.0	3.5, 4.0, 4.5, 5.0, 6.0	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
Abutment Design	Straight or Angled (max 20°)	Straight	Straight	Straight or Angled (max 20°)	Straight or Angled (max 20°)	Straight	Straight or Angled (max 30°)
Restoration	Single or multi-unit	Single or multi-unit	Single or multi-unit	Single or multi-unit	Single or multi-unit	Single or multi-unit	Single or multi-unit
Implant Connection	Internal	Internal	Internal	Internal	Internal	Internal	Internal
Material							
Implant	CP Titanium	CP Titanium	NA	NA	NA	NA	CP Titanium

	Subject Device	**Primary Predicate Device**	**Reference Predicate Devices**				
	Thommen Implant System Thommen Medical AG	K093615 SPI® Dental Implant ELEMENT Thommen Medical AG	K160244 VARIOunite Thommen Medical AG	K102804 SPI® Titanium Base for CAD/CAM Thommen Medical AG	K151984 Milling Abutment for CAD/CAM Thommen Medical AG	K121334 VARIOeco Thommen Medical AG	K120414 OsseoSpeed™ Plus Astra Tech AB
Abutment	CP Titanium Titanium Alloy	CP Titanium	CP Titanium	CPTitanium	CPTitanium	CP Titanium	Titanium Alloy Zirconia, Gold, PEEK
Screw	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy

Subject device implants and healing caps are substantially equivalent to K093615 implants and healing caps in body and cover design, connection design, material, surface, and intended use. The subject device ELEMENT Ø 3.0 mm implant is 0.5 mm narrower than the predicate ELEMENT Ø 3.5 mm implant. The hex interface remains the same. The ELEMENT Ø 3.0 mm implant is substantially equivalent to the OsseoSpeed™ Plus Ø 3.0 mm implant (K120414) in diameter, length, and intended use.

Subject device VARIOunite and Gingiva Former abutments are substantially equivalent to K160224 and K120414 abutments in material, design and function. The expanded indication for VARIOunite to be used as a TiBase with CAD/CAM zirconia superstructure is substantially equivalent to that of SPI® Titanium Base for CAD/CAM (K102804) using the same materials and processes. The subject device is substantially equivalent to K151984 in that all digitally designed abutments for use with Thommen VARIOunite are intended to be sent to a Thommen validated milling center for manufacture.

Small differences in language in the Indications for Use Statements among the subject device, the predicate devices do not change the intended use. All are implant systems placed in the maxilla or mandible to support single or multi-unit prostheses and restore chewing function.

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 angle of the abutments. The subject and predicate devices are packaged in similar materials and are to be sterilized using similar methods.

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