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

November 30, 2016

Dentalpoint AG
% Roshana Ahmed, MA, RAC
Senior Manager, Regulatory Affairs - Medical Devices
Mapi USA, Inc.
2343 Alexandria Drive, Suite 100
Lexington, Kentucky 40504

Re: K163043
Trade/Device Name: Zeramex® P6 Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: October 28, 2016
Received: October 31, 2016

Dear Roshana Ahmed:

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,

Michael J. Ryan -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)*

K163043

Device Name

Zeramex® P6 Dental Implant System

Indications for Use *(Describe)*

The Zeramex® P6 Dental Implant System is intended to be surgically placed in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function.

The Zeramex® P6 Dental Implant System can be used for single or multiple unit restorations.

The Zeramex® P6 implants are intended for delayed loading.

The Zeramex® P6 implants are specially indicated for patients with metal allergies/ intolerances and chronic illness due to metal allergies/intolerances.

The Zeramex® P6 (Ø3.3mm SN) implant may only be used in the anterior teeth in the lower jaw and lateral incisor in the upper jaw.

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.

3.0 510(k) Summary

I. Submitter

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Contact Person: Viktor Lienhard, COO
Date Prepared: November 29, 2016

II. Device

Device Proprietary Name:	Zeramex® P6 Dental Implant System
Common or Usual Name:	Dental Implant System
Classification Name:	Endosseous Dental Implant
Regulation Number:	21 CFR 872.3640
Product Code:	DZE, NHA
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate:

- Zeramex® P6 Dental Implant System, K152385, Dentalpoint AG

IV. Device Description

The Zeramex® P6 Dental Implant System is an endosseous dental implant/abutment system including various sizes of endosseous two piece dental implants, abutments, and accessories. The Zeramex® P6 implants may be restored with cement retained abutments or screw retained abutments, depending on the dentist's preference. The Zeramex® P6 implants are placed using the Zeramex® P6 surgical tools.

The implants, produced from aluminum toughened zirconia, are provided in three diameters (Ø 3.3 mm, 4.1 mm, and 4.8 mm),three lengths (8 mm, 10 mm, and 12 mm). The implants are designed with an internal cylindrical connection. Anti-rotational features include internal triangular designs and external hexagonal connections; the feature used depends on the restoration method selected.

Straight and angular (15^{o}) cement retained and screw retained abutments, provided in small neck (SN; 4.0mm) and regular neck (RN, 4.8mm) sizes, are compatible for use with the Zeramex® P6 implants. The straight and angular abutments are made from the same zirconium materials as the Zeramex® P6 implants.

The cement retained Zeramex® Zeralock™ straight and angular abutments have a cylindrical connector which fits into the internal cylindrical connection of the implant and a hexagonal design which fits into the implant's internal triangular design and locks the abutment into place. This design mitigates rotation in six possible positions.

The screw retained Zeramex® P6 abutments fit on the implant's external hexagonal connection such that rotation is mitigated in six possible positions. The Zeramex® P6 screw retained abutments are affixed to the implant with a carbon fiber reinforced PEEK-Optima™ Ultra (Endolign) screw which fits the internal thread of the implant and provides a secure, screw retained ceramic on ceramic connection.

Locator abutments facilitate removable full restoration of the upper or lower jaw. Three sizes (heights 2/3/5 mm) for each platform (SN 4.0mm and RN 4.8mm) are provided for the Zeramex® P6 Dental Implant System and provide the Zeralock™ connection. The Zeramex® P6 Locators are made from ATZ.

The Zeramex® Zeralock™ cement retained abutments are bonded to the implants using dental cements which have been tested and validated for use with the Zeramex® systems: Panavia™ (K032455) and 3M ESPE RelyX (K111185).

The screw retained abutments are attached to the implants using carbon-fiber reinforced (CFR) VICARBO screws (made of PEEK-Optima™ Ultra (Endolign)), which are provided as straight and angular screws in SN and RN sizes.

Healing caps and gingivaformers are also provided in the system. These components, provided in SN and RN sizes, are manufactured from PEEK and are connected to the implant using a screw. The Zeramex® P6 Gingivaformers are provided in two (2) lengths (3 mm and 4 mm). Provisional restoration components may be used to support temporary crowns after the healing period. The Zeramex® P6 Provisional Restoration SN and RN are made of PEEK. The Zeramex® P6 Provisional Restoration Screw is made of carbon fiber reinforced PEEK.

A closure screw (Ø3.5 mm) may be used in lieu of the healing cap to allow the gingiva to cover the platform during the healing period. This component is manufactured from PEEK.

V. Indications for Use

The Zeramex® P6 Dental Implant System is intended to be surgically placed in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function.

The Zeramex® P6 Dental Implant System can be used for single or multiple unit restorations.

The Zeramex® P6 implants are intended for delayed loading.

The Zeramex® P6 implants are specially indicated for patients with metal allergies/ intolerances and chronic illness due to metal allergies/intolerances.

The Zeramex® P6 (Ø3.3mm SN) implant may only be used in the anterior teeth in the lower jaw and lateral incisor in the upper jaw.

VI. Comparison of Technological Characteristics

The subject device differs from the predicate device as follows:

1. Addition of closure screw
2. Administrative updates to the User Manual
3. Addition of contraindications to the User Manual and IFU
4. Addition of Indication for Use word revision.

The subject and predicate systems include the same components with the exception of the new closure screw, which may be used in lieu of a healing cap. The closure screw is manufactured from the same materials and is subject to the same sterilization methods and parameters as the currently cleared healing caps and gingivaformers. Risk assessment demonstrated that there were no new or revised risks related to the use of the closure screw.

The indications for use statement has been slightly revised to clarify that the Ø3.3mm SN implant should be used in the anterior teeth in the lower jaw and lateral incisor in the upper jaw. The words “lateral incisor” replaces the words “lateral teeth”. This revision does not alter the intended use of the product.

The administrative changes throughout User Manual seek to clarify verbiage to facilitate use of the system in clinical practice; there is no change in the actual instructions for use or

surgical technique from the predicate device. The additional contraindications are consistent with the clinical standard of care and are not due to any adverse events.

These changes do not impact the Substantial Equivalence of the product as they do not impact the intended use of the product and technological characteristics are similar to the predicate device.

VII. Performance Data

New performance data is not required in support of this submission.

The sterilization validation, shelf-life studies, biocompatibility studies, mechanical testing, and clinical studies from K152385 are applicable to this submission. LAL lot release testing was conducted and reviewed under K152385.

VIII. Conclusion

There have been no significant changes to the design of the Zeramex® P6 Dental Implant System components since clearance under K152385. The indications for use statement has been slightly revised to clarify that the Ø3.3mm SN implant should be used in the anterior teeth in the lower jaw and lateral incisor in the upper jaw. This revision does not alter the intended use of the product. Furthermore, additional contraindications have been added to the labeling in line with clinical practice and industry standards.

As demonstrated by risk analysis, the provision of a closure screw for use in lieu of a healing cap does not suggest new uses of the device.

Therefore, it is concluded that the Zeramex® P6 Dental Implant System is substantially equivalent to the predicate devices.

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