DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 27, 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: K152385
Trade/Device Name: Zeramax® P6 Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: June 6, 2016
Received: June 7, 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 yours,

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)*
K152385

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 teeth 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)

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510(k) Summary

I. Submitter

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Contact Person: Viktor Lienhard, COO
Date Prepared: July 25, 2016

II. Device

Name of Device:	Zeramex® P6 Dental Implant System
Common or Usual Name:	Dental Implant System
Classification Name:	Endosseous Dental Implant (21 CFR 872.3640)
Regulatory Class:	II
Product Code:	DZE, NHA

III. Predicate and Reference Devices

Substantial equivalence is claimed to the following predicate device:

- Zeramex® T Dental Implant System, Dentalpoint AG, K133255

The following devices are cited as reference devices:

- Branemark System Dental Implant Products, Nobel Biocare AB, K022562
- Straumann® Dental Implant System SLActive and Roxolid Product Families, Straumann USA, LLC, K130222
- Procera® Abutment Branemark, Nobel Biocare USA LLC, K042658

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) PEEK-Optima™ Ultra (Endolign) screws (provided as straight and angular screws in SN and RN sizes).

Healing caps and gingiva formers 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 Gingiva formers 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.

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 teeth in the upper jaw.

VI. Comparison of Technological Characteristics

The Zeramex® P6 Dental Implant System and the predicate devices share the following characteristics:

- Two-piece design
- Abutments and implants have the same material of construction
- Cement retained abutments are fixed via an adhesive process which affixes the abutment to the implant, in conjunction with the internal cylindrical connection (anti-rotation feature)
- Screw retained abutments which fit on the implant's external hexagonal connection (anti-rotation feature)
- The implants and abutments are provided in similar diameters and lengths as the predicate devices
- Abutments are provided in straight and angled (15º) configurations
- Implant surfaces are treated via grit blasting and acid etching processes

The Zeramex® P6 Dental Implant System is technologically different from the predicate devices as follows:

- Provision of carbon-fiber reinforced PEEK screws for the screw retained abutments

A comparison of the subject and predicate devices is provided in the tables below.

Comparison of Dental Implants

	Zeramex® P6 Dental Implant System	**Zeramex® T Dental Implant System (K133255)**	**Straumann® Dental Implant System (K130222)**	**Branemark System Dental Implant Products (K022562)**
Indications for Use Statement	The Zeramex P6 Dental Implant Systems 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 Dental Implants are specially indicated for patients with metal allergies/intolerances and chronic illnesses due to metal allergies/intolerances. The Zeramex P6 (Ø3.3) implant may only be used in the anterior teeth in the lower jaw and lateral teeth in the upper jaw.	The Zeramex T Dental Implant Systems 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 T Dental Implant System can be used for single or multiple unit restorations. The Zeramex T implants are intended for delayed loading. The Zeramex T Dental Implants are specially indicated for patients with metal allergies and chronic illnesses due to metal allergies. The Zeramex T (Ø3.5) implant may only be used in the anterior teeth in the lower jaw and lateral teeth in the upper jaw.	Straumann dental implants are indicated for oral endosteal implantation in the upper and lwer jaw arches for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restoration used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).	The Branemark system implants are for single stage or two stage surgical procedures and cement or screw retained restoration. The Branemark system implants are intended for immediate placement and function on single tooth and/or multiple tooth applications recognizing sufficient bone stability (type I or ii bone) and appropriate occlusal loading, to restore chewing function. Multiple tooth applicants may be splinted with a bar.

Design	Two-piece design	Two-piece design	Two-piece design	Two-piece design
Implant Material	Zirconia	Zirconia	Grade 4 Titanium	Titanium
Implant Lengths	8 mm 10 mm 12 mm	8 mm 10 mm 12 mm 14 mm	6 mm 8 mm 10 mm 12 mm 14 mm	7 mm 8.5 mm 10 mm 11.5 mm 13 mm 15 mm 18 mm
Implant Diameter	3.3 mm 4.1 mm 4.8 mm	3.5 mm 4.2 mm 5.5 mm	3.3 mm 4.1 mm 4.8 mm	3.3 mm 3.75 mm 4 mm 5 mm
Implant Surface Treatment	Grit blasted, acid etched	Grit blasted, acid etched	Grit blasted, acid etched – SLA or SLActive	Machined or modified (TiUnite) Surface
Anti-Rotation Features	Internal cylindrical connection with internal triangular design (used for cemented abutments) and external hexagonal connections (used for screw retained abutments)	Internal cylindrical connection with internal triangular design	Internal octagon connection	Internal tri-channel or external hexagonal connection
Sterilization	Steam, SAL 10^{-6}	Steam, SAL 10^{-6}	Gamma	Gamma

Comparison of Abutments

	Zeramex® P6 Dental Implant System	**Zeramex® T Dental Implant System (K133255)**	**Procera® Abutment Branemark (K042658)**
Indications for Use Statement	The Zeramex P6 Dental Implant Systems 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	The Zeramex T Dental Implant Systems 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 T Dental Implant System can be used for single or multiple unit restorations. The Zeramex T implants are intended for	Nobel Biocare's Procera Abutment Branemark is indicated for the treatment of partially edentulous patients requiring a prosthetic device. In addition to the Branemark implant, the abutments' hexagon connector fits the external hexagon of the following endosseous implants: 3i 3.75mm, Lifecore Biocmedical Restore 3.75mm, Zimmer Dental Taperlock 4.0mm, and Sterngold Implamed 3.75mm.

	Zeramex P6 Dental Implants are specially indicated for patients with metal allergies/intolerances and chronic illnesses due to metal allergies/intolerances. The Zeramex P6 (Ø3.3) implant may only be used in the anterior teeth in the lower jaw and lateral teeth in the upper jaw.	delayed loading. The Zeramex T Dental Implants are specially indicated for patients with metal allergies and chronic illnesses due to metal allergies. The Zeramex T (Ø3.5) implant may only be used in the anterior teeth in the lower jaw and lateral teeth in the upper jaw.	
Abutment Material	Zirconia	Zirconia	Zirconia Titanium Alumina
Abutment Angulation	Straight Angled, 15º	Straight Angled, 15º	Straight Angled, 10º and 15º
Connection to Implant	Cement Retained (internal cylindrical connection with hexagonal design) & Screw Retained (external hexagon connection)	Cement Retained (internal cylindrical connection with hexagonal design)	- Screw Retained (external hexagon connection)
Screw Material	Carbon-Fiber Reinforced PEEK	N/A	Titan 6Al7Nb (TAN) Screw
Sterilization	End User Sterilized	End User Sterilized	End User Sterilized

Discussion

There is only a slight difference between the indications for use statement of the Zeramex® P6 Dental Implant System and the Zeramex® T Dental Implant System which is the addition of the term “intolerances”. The addition of patients with metal intolerances to the previous indication for patients with metal allergies does not change the intended use of the device for patients for which traditional titanium implant systems may not be appropriate.

The ZERAMEX® P6 Implants feature the same material, same connection concept (internal cylinder with triangular anti-rotation feature), same surface treatment, and similar abutments as the previously cleared ZERAMEX® T system for cemented abutments.

As seen above, the differences between the subject and primary predicate is the provision of screw retained abutments, addition of an external hexagon anti-rotation feature for the screw-retained abutments, the inclusion of a carbon-fiber reinforced PEEK abutment fixation screw, and the reduction of the implant body diameter from 3.5 to 3.3mm.

The implants are similar in shape and diameter as the previously cleared Straumann® Implants. The ZERAMEX® P6 Implants additionally feature an external hexagon connection similar to the previously cleared Branemark Implants.

The connecting abutment features a fitting hexagon and is of same material as the previously cleared Procera® Abutment.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Studies

- Cleaning and Sterilization Validation according to ISO 17665-1, ISO 17665-2, ISO 11737-1 and ISO 11737-2.
- Shelf-life, Packaging, and transport validation according to ASTM F1980, ASTM F88, ASTM F1886, ASTM F1929, ISO 11607-1, and ISO 11607-2.
- Biocompatibility in accordance with ISO 10993-5
- Surface chemical and roughness analysis by XPS, SEM, and contact angle
- Fatigue testing in accordance with ISO 14801 for new as well as artificially aged samples of the submission device

Clinical Studies

Retrospective clinical data on implants and prosthetics was obtained on 19 patients who received a total of 35 screw retained abutments. Follow up data was obtained on 15 of those patients (representing 27 screw retained abutments), with ≥ 6 month follow up data on eight (8) patients, and ≥ 1 year follow up data on three (3) patients.

Patients were between the ages of 36 and 69 years old, with no local risk factors. Implants were placed in the maxilla and mandible using a 2-step loading process with the time to loading ranging from 12 to 24 weeks.

Bone quantity ranged very heavy bone to soft bone, with all patients presenting with good bone quality.

No post-operative complications or adverse events were reported for any of the patients at the implant placement and loading phases. Follow up data (n = 15 patients, 27 implants/abutments) shows that there were no post-operative complications defined as anesthesia or paresthesia, mandibular fracture, loss of alveolar ridge height, adverse impact on adjacent teeth, abnormal or prolonged pain, failure to maintain adequate oral hygiene, fistula, infection, or osteomyelitis. No adverse reactions (infection, pain, altered sensation, temporomandibular joint problems, implant loss prior to loading, loss of loaded implant, implant breakage, or abutment breakage) were reported. In addition, there were no reports of screw movement, fracture, or replacement.

Conclusion

Although differences in design and technology exist between the subject and predicate devices, these differences are supported by the biocompatibility, fatigue, and retrospective clinical study data described above. Therefore, it is concluded that the Zeramex® P6 Dental Implant System is substantially equivalent to the predicate devices.