Dear Elizabeth Rose:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -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
510(k) Number *(if known)*
K180184

Device Name
Zeramex® XT Dental Implant System

Indications for Use *(Describe)*

The ZERAMEX® XT 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® XT Dental Implant System can be used for single or multiple unit restorations. The ZERAMEX® XT Dental Implants are indicated for delayed loading. The ZERAMEX® XT dental implants are specially indicated for patients with metal allergies/intolerances and chronic illnesses due to metal allergies/intolerances.

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

“As an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
Indications for Use

The NobelPearl 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 NobelPearl Dental Implant System can be used for single or multiple unit restorations.

NobelPearl Dental Implant System are intended for delayed loading.

NobelPearl Dental Implant System are specially indicated for patients with metal allergies/intolerances and chronic illness due to metal allergies/intolerances.

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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  - PRASTaff@fda.hhs.gov

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3.0 510(k) Summary

I. Submitter
Dentalpoint AG
Bodenäckerstrasse 5
Spreitenbach, 8957
Switzerland

Phone: (+41) 44 542 41 71
Fax: (+41) 44 388 36 39

Contact Person: Anja Lieberherr, Quality Management
Date Prepared: November 16, 2018

II. Device

<table>
<thead>
<tr>
<th>Device Proprietary Name</th>
<th>Zeramex® XT Dental Implant System and NobelPearl Dental Implant System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common or Usual Name</td>
<td>Dental Implant System</td>
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<tr>
<td>Classification Name</td>
<td>Endosseous Dental Implant</td>
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<tr>
<td>Regulation Number</td>
<td>21 CFR 872.3640</td>
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<td>Primary Product Code</td>
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<tr>
<td>Secondary Product Code</td>
<td>NHA</td>
</tr>
<tr>
<td>Device Classification</td>
<td>II</td>
</tr>
</tbody>
</table>

III. Predicate Device
Substantial equivalence is claimed to the following primary predicate devices:

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

The following devices are referenced within the submission:

- Zeramex® P6 Dental Implant System, K163043, Dentalpoint AG
- Zeramex® P6 Dental Implant System, K152385, Dentalpoint AG

IV. Device Description
The Zeramex® XT Dental Implant System is an endosseous dental implant/abutment system including various sizes of endosseous two piece dental implants, abutments, and accessories. The Zeramex® XT implants may be restored with screw retained Zeramex® XT abutments. The Zeramex® XT implants are placed using the Zeramex® XT surgical tools.
The NobelPearl Dental Implant System is an endosseous dental implant/abutment system including various sizes of endosseous two piece dental implants, abutments, and accessories. The NobelPearl Dental Implant System may be restored with screw retained NobelPearl abutments. The NobelPearl Dental Implant System are placed using the NobelPearl surgical tools.

The implants, abutments, and surgical tools for the Zeramex® XT and NobelPearl Dental Implant Systems are exactly the same; two trade names are being used for marketing purposes.

The implants, produced from aluminum toughened zirconia (conforming to ISO 6474-1:2010 Implants for Surgery – Ceramic Materials and ISO 6872:2015 Dentistry – Ceramic Materials), are provided sterile in two (2) diameters (Ø 4.2 mm (RB), and 5.5 mm (WB)) and three (3) lengths (8 mm, 10 mm, and 12 mm). The Ø 4.2 mm implant is also provided in 14 mm. The implants are designed with a “bolt-in tube” internal connection which provide anti-rotational features.

Straight and angular (15°) screw retained abutments, provided non-sterile in two sizes (RB; Ø 5.0 mm and SB, Ø 6.0 mm), are compatible for use with the system implants. The straight and angular abutments are made from the same zirconium materials as the system implants.

The screw retained abutments fit within four (4) retention elements and are affixed to the implant with a carbon fiber reinforced PEEK-Optima™ Ultra VICARBO® screw (straight) which fits the internal thread of the implant and provides a secure, screw retained ceramic on ceramic connection.

Healing caps and gingivaformers are also provided in the system. These components, provided in two sizes, are manufactured from PEEK and are connected to the implant using a screw. Provisional restoration components may be used to support temporary crowns after the healing period. The provisional restorations and the provisional restoration screws are made of carbon fiber reinforced PEEK.

V. Indications for Use

Zeramex® XT Dental Implant System

The ZERAMEX® 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® Dental Implant System can be used for single or multiple unit restorations. The ZERAMEX® Dental Implants are indicated for delayed loading. The ZERAMEX® dental implants are specially indicated for patients with metal allergies/intolerances and chronic illnesses due to metal allergies/intolerances.

NobelPearl Dental Implant System
The NobelPearl 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 NobelPearl Dental Implant System can be used for single or multiple unit restorations. NobelPearl Dental Implant System are intended for delayed loading. NobelPearl Dental Implant System are specially indicated for patients with metal allergies/intolerances and chronic illness due to metal allergies/intolerances.

VI. Comparison of Technological Characteristics
The Zeramex® XT and NobelPearl Dental Implant Systems and the predicate devices share the following characteristics:

- two-piece design (K133255 and K163043);
- implant and abutment material of construction (K163043);
- screw material of construction (K133255 and K163043);
- implant lengths (K133255 and K163043);
- implant diameters (K133255);
- abutment angulation (K133255 and K163043);
- screw retained implant/abutment connection (K163043);
- provision of carbon-fiber reinforced PEEK screws (K163043); and
- implant and abutment sterilization methods.

The Zeramex® XT and NobelPearl Dental Implant Systems are technologically different from the predicate devices with respect to the anti-rotational feature. The subject devices feature a “Bolt-In Tube” connection with four (4) retention elements, while the predicate devices have internal cylindrical connections. The Zeramex® P6 Dental Implant System also has an external hexagonal anti-rotational feature.

<table>
<thead>
<tr>
<th>Zeramex® XT and NobelPearl Dental Implant Systems</th>
<th>Zeramex® T Dental Implant System (K133255)</th>
<th>Zeramex® P6 Dental Implant System (K163043)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Dentalpoint AG</td>
<td>Dentalpoint AG</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The ZERAMEX® 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® Dental Implant System can be used for single or multiple unit restorations.</td>
<td>The Zeramex® T 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 chewing function. The Zeramex® T Dental Implant System can be used for single or multiple unit restorations.</td>
</tr>
</tbody>
</table>
The ZERAMEX® Dental Implants are indicated for delayed loading. The ZERAMEX® dental implants are specially indicated for patients with metal allergies/intolerances and chronic illnesses due to metal allergies/intolerances.

The NobelPearl 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 NobelPearl Dental Implant System can be used for single or multiple unit restorations. NobelPearl Dental Implant System are intended for delayed loading. NobelPearl Dental Implant System are specially indicated for patients with metal allergies/intolerances and chronic illness due to metal allergies/intolerances.

Discussion
The technological difference between the subject and predicate devices does not raise new questions. As seen above, the Zeramex® XT and NobelPearl Dental Implant Systems have the same indications for use, materials of construction, design, size, surface treatment, and sterilization methods as the predicate devices. The data within this submission support that the subject devices are substantially equivalent to the identified predicate devices.

VII. Performance Data
As the subject devices are a line extension to the Zeramex® Implant Systems, verification activities, as identified through risk analysis, were conducted to written protocols with pre-defined acceptance criteria.
Fatigue testing in accordance with ISO 14801 Second Edition 2007-11-15 Dentistry-Implants-Dynamic Fatigue Test for Endosseous Dental Implants was conducted on the subject devices, Zeramex® XT and NobelPearl Dental Implant Systems. The fatigue testing as conducted in saline because of the ceramic/polymer device composition.

The following performance tests, conducted on the predicate devices, are being leveraged in support of this submission:

- shelf-life, packaging, and transport validation studies;
- cleaning and sterilization validation;
- biocompatibility;
- bacterial endotoxin testing (LAL Method);
- analysis of surface composition; and
- surface roughness and contact angle testing.

**Clinical Studies**

Data supporting the Zeramex® T Dental Implant System and Zeramex® P6 Dental Implant System are applicable to the subject devices as the products are made from the same materials, undergo the same surface treatments, and have the same outer design. Fatigue testing supports that the subject devices can withstand clinically relevant forces.

**VIII. Conclusion**

Based on the above information, the Zeramex® XT and NobelPearl Dental Implant Systems can be considered substantially equivalent to the identified predicate devices.
Although minor differences in design and technology exist between the subject and predicate devices, substantial equivalence has been demonstrated through a comparison of intended use, design, technological characteristics, and performance evaluations. Therefore, the Zeramex® XT and NobelPearl Dental Implant Systems are substantially equivalent to the predicate devices.