Dentium Co., Ltd.

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

Re: K171622
  Trade/Device Name: Dentium Ti-Base
  Regulation Number: 21 CFR 872.3630
  Regulation Name: Endosseous Dental Implant Abutment
  Regulatory Class: Class II
  Product Code: NHA
  Dated: December 14, 2017
  Received: December 15, 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.

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.

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,

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
**Indications for Use**

510(k) Number *(if known)*

K171622

Device Name

Dentium Ti-Base

Indications for Use *(Describe)*

Dentium Ti-Base abutments are intended for use on Dentium endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in prosthetic rehabilitation.

All digitally designed abutments for use with Dentium Ti-Base abutments are intended to be sent to a Dentium-validated milling center for manufacture.
ADMINISTRATIVE INFORMATION
Manufacturer Name  Dentium Co., Ltd.
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Telephone:  +82-31-207-2200
Fax:   +82-31-207-3883

Official Contact   Byungsun Kim, Team Manager of Regulatory Affairs

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DEVICE NAME AND CLASSIFICATION
Trade/Proprietary Name  Dentium Ti-Base
Common Name   Abutment, implant, dental, endosseous
Classification Name  Endosseous dental implant abutment
Classification Regulations  21 CFR 872.3630
Product Code   NHA
Classification Panel  Dental Products Panel
Reviewing Branch  Dental Devices Branch

PREDICATE DEVICE INFORMATION
Primary Predicate for Ti-Base
K150367, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA

Reference Predicates
K161713, Dentium CAD/CAM Abutments, Dentium Co., Ltd.
K041368, Dentium Company Limited Implantium®, Dentium Co., Ltd.
K160965, Dentium SuperLine® Implants, Dentium Co., Ltd.
INDICATIONS FOR USE
Dentium Ti-Base abutments are intended for use on Dentium endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in prosthetic rehabilitation.

All digitally designed abutments for use with Dentium Ti-Base abutments are intended to be sent to a Dentium-validated milling center for manufacture.

DEVICE DESCRIPTION
Dentium Ti-Base is a patient specific abutment fabricated by Dentium and composed of unalloyed titanium and zirconia ceramic. The Ti-Base has a titanium pre-manufactured precision abutment/implant interface and ceramic superstructure bonded to the post of the titanium base. Ti-Base is used for support of CAD/CAM fabricated zirconia superstructures or for support of hybrid crowns or bridges. Hybrid crowns or bridges and zirconia superstructures are manufactured by a Dentium validated milling center.

Ti-Base Abutments are available in two prosthetic diameters (4.5 and 5.5 mm) and four gingival heights (0.5, 1.0, 1.5, and 2.0 mm). Each of the abutments is available indexed and non-indexed. All subject device abutments are compatible with Dentium Implantium and Dentium Superline 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 and ISO 17665-2 to an SAL of 10⁻⁶, Cytotoxicity testing according to ISO 10993-5 determining the subject device is non-cytotoxic, and dynamic compression-bending testing according to ISO 14801 ensuring 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 is a summary table showing technical comparison between the subject device abutments and the predicate device abutments.

<table>
<thead>
<tr>
<th>Table of Substantial Equivalence – Indications for Use Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subject Device</strong></td>
</tr>
<tr>
<td>Dentium Ti-Base Dentium Co., Ltd.</td>
</tr>
<tr>
<td><strong>Primary Predicate Device</strong></td>
</tr>
<tr>
<td>K150367 Neodent Implant System JGC Indústria e Comércio de Materiais Dentários SA</td>
</tr>
</tbody>
</table>
### Indications for Use Statement

**K161713**
**Dentium CAD/CAM Abutments**
**Dentium Co., Ltd.**

Dentium abutments are intended for use on endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in prosthetic rehabilitation. All digitally designed abutments for use with Dentium CAD/CAM Abutments are intended to be sent to a Dentium-validated milling center for manufacture.

**K041368**
**Dentium Company Limited Implantium**
**Dentium Co., Ltd.**

The Dentium Co., Ltd Implantium is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient’s chewing function. This may be accomplished by either a two-stage surgical procedure or a single surgical procedure. If a single surgical procedure is used, single or multiple implants may be inserted (type I, II or III bone) provided good initial stability (> 40 Ncm) is achieved. Not intended for immediate loading.

**K160965**
**Dentium SuperLine® Implants**
**Dentium Co., Ltd.**

Superline is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient’s chewing function. Superline Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

### Table of Substantial Equivalence – Technological Characteristics

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Subject Device</th>
<th>Primary Predicate Device</th>
<th>Reference Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dentium Ti-Base Dentium Co., Ltd.</td>
<td>Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários SA.</td>
<td>K161713 Dentium CAD/CAM Abutments Dentium Co., Ltd.</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abutment Design</td>
<td>CAD/CAM Ti-Base</td>
<td>CAD/CAM Blank CAD/CAM TiBase</td>
<td>CAD/CAM Blank CAD/CAM Custom Abutment</td>
</tr>
<tr>
<td>Prosthesis</td>
<td>Cement-retained</td>
<td>Cement-retained</td>
<td>Cement-retained</td>
</tr>
<tr>
<td>Attachment</td>
<td>Screw-retained</td>
<td>Screw-retained</td>
<td>Screw-retained</td>
</tr>
<tr>
<td>Restoration</td>
<td>Single-unit, Multi-unit</td>
<td>Single-unit, Multi-unit</td>
<td>Single-unit, Multi-unit</td>
</tr>
<tr>
<td>Abutment/Implant</td>
<td>3.6 - 7.0 mm</td>
<td>3.0 - 6.0 mm</td>
<td>3.6 - 5.0 mm</td>
</tr>
<tr>
<td>Platform Diameter</td>
<td>Up to 30°</td>
<td>Up to 30°</td>
<td>Up to 30°</td>
</tr>
<tr>
<td>Abutment Angle</td>
<td>Internal</td>
<td>Internal</td>
<td>Internal</td>
</tr>
<tr>
<td>Abutment/Implant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interface</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abutment</td>
<td>Unalloyed Titanium ASTM F67</td>
<td>Titanium Alloy ASTM F136</td>
<td>Unalloyed Titanium ASTM F67</td>
</tr>
<tr>
<td>Superstructure</td>
<td>Zirconia ISO 13356</td>
<td>Zirconia ISO 13356</td>
<td>NA</td>
</tr>
</tbody>
</table>

The subject device Ti-Base is substantially equivalent to the predicate Neodent Titanium Base Abutment cleared in K150367 in design, function, material, manufacture and intended use. Both are titanium abutment for support of direct crowns/bridges or CAD/CAM fabricated zirconia copings manufactured by a validated milling center. Differences between the subject device and predicate device are in the design dimensions and implant/abutment interface.
All subject device abutments are by prescription order from a clinician, and have the same implant/abutment interface as the predicate K161713. Subject device abutments are compatible with Dentium Implantium (K041368) and Dentium SuperLine (K160965) dental implants.

The Indications for Use of the subject device is substantially equivalent to the previously cleared Intended Use in K150367. The Indications for Use Statement in K150367 includes two abutment designs (TiBase and Preface) and names the individual restoration options. The Indications for Use Statement for the subject device is for one device and does not list the individual restoration options. Minor differences in wording between the Indications for Use Statements do not affect the intended use of a dental abutment placed on a dental implant for prosthetic restoration.

The Indications for Use of the subject device is substantially equivalent as Dentium CAD/CAM Abutments in K161713, with the only difference being in the proprietary name of the device.

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, gingival height, 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.