Dear Ms. 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 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,

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
Device Name

Dentium CAD/CAM Abutments

Indications for Use (Describe)

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.

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)

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

"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."
510(k) Summary
Dentium Co., Ltd.
Dentium CAD/CAM Abutments
December 14, 2016

ADMINISTRATIVE INFORMATION
Manufacturer Name  Dentium Co., Ltd.
150, Eondong-ro, Giheung-gu
Yongin-si, Gyeonggi-do, 443-270
Republic of Korea
Telephone:  +82-31-207-2200
Fax:   +82-31-207-3883

Official Contact   Sangpil Yoon, Team Manager of Regulatory Affairs

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  Dentium CAD/CAM Abutments
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-Blank
K150203 Medentika CAD/CAM Abutments Medentika GmbH

Primary Predicate for Custom Abutment
K103020 Atlantis™ Abutment for Keystone Implant Astra Tech, Inc.

Reference Predicate
K141457 Dentium Implantium® and SuperLine® Abutments Dentium Co., Ltd.
K070228 Implantium® Prosthetics Dentium Co., Ltd.
K041368 Dentium Company Limited Implantium Dentium Co., Ltd.
K092341 Low Profile Abutment Biomet 3i, Inc.

INDICATIONS FOR USE
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.

DEVICE DESCRIPTION
Dentium CAD/CAM Abutments are titanium abutments to be used in fabricating patient-specific abutments. Each patient-specific abutment is individually prescribed by the clinician. Dentium CAD/CAM Ti-Blank Abutments are abutments with a pre-manufactured precision interface and are used by a validated milling center to fabricate patient-specific abutments. Ti-Blanks are available in three cylinder diameters (10 mm, 14 mm, and 15.8 mm) and three connection designs (Hex, Long Hex, and Non-hex).
Dentium CAD/CAM Custom Abutments are patient-specific abutments fabricated by Dentium. Custom Abutments are available for fabrication in three connection designs (Hex, Long Hex, and Non-hex).
Dentium CAD/CAM Abutments are available for four corresponding implant platform diameters (3.6 mm, 4.0 mm, 4.5 mm, 5.0 mm). Each abutment is supplied with a corresponding abutment screw, cleared previously in K141457. All subject device abutments are compatible with Implantium dental implants.

PERFORMANCE DATA
Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: steam sterilization validation according to ISO 17665-1 and ISO 17665-2, demonstrating a sterility assurance level (SAL) of 10⁻⁶; biocompatibility demonstrated by the referenced Dentium submission, K070228, using the same materials and manufacturing processes as the subject device; and dynamic compression-bending testing according to ISO 14801, showing mechanical performance equivalent to predicate devices.

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 technological characteristics and the Indications for Use of the subject device abutments and the predicate device abutments.
### Subject Device: Dentium Co., Ltd. Dentium CAD/CAM Abutments K161713

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.

### Summary: Table of Substantial Equivalence – Indications for Use

#### Subject Device | Indications for Use
--- | ---
Dentium Co., Ltd. Dentium CAD/CAM Abutments K161713 | 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.

#### Primary Predicate Devices

| Primary Predicate Devices | Indications for Use
--- | ---
Medentika GmbH Medentika CAD/CAM Abutments K150203 (Indications for Use shown are for Medentika PreFace only) | Medentika PreFace CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. The abutments are compatible with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.

| Implant System Compatibility | Series | Implant Diameter (mm) | Platform Diameter (mm)
--- | --- | --- | ---
Nobel Biocare Replace™ Select | E | 3.5, 4.3, 5.0, 6.0 | 3.5, 4.3, 5.0, 6.0
Nobel Biocare NobelActive™ | F | 3.0, 3.5, 4.3, 5.0 | 3.0, 3.5, 3.9 (4.3), 3.9 (5.0)
Biomet 3i Osseotite® Certain® | H | 3.25, 4.0, 5.0 | 3.4, 4.1, 5.0
Biomet 3i Osseotite® | I | 3.25, 3.75, 4.0, 5.0 | 3.4, 4.1, 5.0
Nobel Biocare Bränemark | K | 3.3, 3.75, 4.0, 5.0 | 3.5, 4.1, 4.1, 5.1
Straumann Bone Level | L | 3.3, 4.1, 4.8 | 3.3, 4.1, 4.8
Straumann Standard | N | 3.3, 4.1, 4.8 | 3.5 (NNC), 4.8, 6.5
Zimmer Tapered Screw-vent® | R | 3.3, 3.7, 4.1, 4.7, 6.0 | 3.5, 4.5, 5.7
Astra Tech OsseoSpeed™ | S | 3.0, 3.5, 4.0, 4.5, 5.0 | 3.0, 3.5, 4.0, 4.5, 5.0
Dentsply Friadent® Frialti/XIVE® | T | 3.4, 3.8, 4.5, 5.5 | 3.4, 3.8, 4.5, 5.5

Medentika PreFace is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.

Astra Tech, Inc. Atlantis™ Abutment for Keystone Implant K103020 | 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 or screw retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

This device is compatible with the following manufacturers’ implant systems:

- The titanium abutments are compatible with the Keystone 3.5mm, 4.0mm, 4.1mm and 5.0mm Keystone Implants.
- The zirconia abutments are compatible with the Keystone 3.5mm, 4.0mm, 4.1mm and 5.0mm Keystone Implants.

Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments on small diameter implants are intended for the anterior region only.

#### Reference Predicate Device

| Reference Predicate Device | Indications for Use
--- | ---
Dentium Co. Ltd. Dentium Implantium® and SuperLine® Abutments K141457 | Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation

Dentium Co. Ltd. Implantium Prosthetics K070228 | Implantium Prosthetics is intended for use as an aid in prosthetic rehabilitation.

Biomet 3i, Inc. Low Profile Abutment K092341 | BIOMET 3i Low Profile Abutments are intended for use as accessories to endosseous dental implants to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis is screw retained to the abutment.
### Summary: Table of Substantial Equivalence – Abutment Technological Characteristics

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</tr>
<tr>
<td>Material</td>
<td><strong>CPTi</strong></td>
<td><strong>Titanium Alloy, Y-TZP</strong></td>
</tr>
</tbody>
</table>

The subject device Ti-Blank is substantially equivalent to the predicate K150203 in design, function, manufacture and intended use. Both are cylindrical titanium abutments with a precision implant/abutment interface for use in fabricating a patient-specific abutment at a manufacturer-validated milling center. The subject device is different from the predicate device in implant/abutment interface, specific cylinder size, and specific abutment diameters. However, the subject device sizes are within the size range of the primary predicate.

The subject device Custom Abutment is substantially equivalent to K103020 in design, function, manufacture and intended use. Both are patient-specific abutments fabricated by the manufacturer. The subject device is different from the predicate device in implant/abutment interface, specific abutment sizes and manufacturer. However, the subject device sizes are within the size range of the primary predicate. The final finished Custom Abutment differs from the Ti-Blank and primary predicate in manufacturing flow only.

All subject device abutments and predicate abutments are by prescription order from a clinician, and have the same implant/abutment interface as the reference predicate K141457. All are compatible with Dentium Implantium implants (K041368). Subject device design parameters are substantially equivalent to K150203, K103020, and K092341.

Minor differences in the language or in device-specific details of the indications for use statement for the subject device as compared to the predicate devices do not change the intended use of abutments to be used with endosseous dental implants for prosthetic rehabilitation in the maxilla and mandible. The subject device Indications for Use statement does not include a compatibility table because it is not claiming compatibility with other manufacturers’ devices. Therefore, these minor differences in language do not affect the determination of substantial equivalence.
Mechanical testing performed for the subject device shows that it is strong enough for its intended use and is equivalent to the predicate devices listed above.

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.