



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 5, 2016

Dentium Co., Ltd
% Younjung Yuk
US Agent
Dentium USA
6761 Katella Ave
Cypress, California 90630

Re: K160483

Trade/Device Name: Burn-out Cylinder and Angled Screw Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 6, 2016
Received: July 7, 2016

Dear Younjung Yuk:

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
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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: K160483

Device Name: Burn-out Cylinder and Angled screw Abutments

Indications for Use:

Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K160483

510(k) Summary

Date: August 5, 2016

1. Company

	Submitter
Name	Dentium Co., Ltd.
Address	150, Eondong-ro, Giheung-gu, Youngin-si, Gyeonggi-do, 446-914, Korea
Phone / Fax	+82 31 207 2200 / +82 31 207 3883
Contact person	Sangpil Yoon spyoon@dentium.com

2. Device Name

Trade / Proprietary name: Burn-out Cylinder and Angled Screw Abutments

Common name: Abutment, Prosthetic Device, Prosthetic Accessories to Dental Implant

Classification name: Endosseous dental implant abutment

Regulation number: 21 CFR 872.3630

Class: II

Panel: Dental

Product code: NHA

3. Predicate Device

- Primary Predicate for Angled Screw Abutment
K141457 - Dentium Implantium® and SuperLine® Abutments
- Reference Device for Burn-out Cylinder
K990342 - Staumann SynOcta Prosthetics®

4. Description

Burn-out Cylinder is a component of a dental implant abutment used in the process of fabricating the dental abutment and the prosthetic restoration. The Burn-out Cylinders are modified by the dental lab and incorporated into the wax framework pattern which is cast into a final gold alloy form. Burn-out Cylinder is made with PMMA (Poly(Methyl Methacrylate)) and is available in three cylinder diameters (4.5mm, 5.5mm and 6.5mm) with two connection designs (Hex and Non-Hex).

Angled Screw Abutment is a dental abutment intended for multi-unit loaded restorations and combined with the burn-out cylinder for increasing the post height to be 4mm at minimum when used for single-unit loading. Angled Screw Abutment is fabricated from Grade 4 pure titanium and partially TiN coated. Angled Screw Abutments in this submission are available in three connection designs (Hex, Long Hex and Non-Hex), two diameters (4.5mm and 5.5mm) and two angulations (15° and 30°). The Dentium angled screw abutments were originally cleared under 510(k) K141457. All subject device abutments are compatible with Implantium dental implants of Dentium Co., Ltd. Abutments are supplied non-sterile and autoclaved by the end user.

5. Indication for Use

Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.

6. Substantial Equivalence

- Angled Screw Abutment

	Angled Screw Abutment (Subject Device)	Dentium Implantium® / SuperLine® Abutments (Primary Predicate)	Similarities / Differences of Devices
Company Name	Dentium Co., Ltd.	Dentium Co., Ltd.	Same
510(k) Number	New Device	K141457	-
Indications for use	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.	Dentium Prosthetics are intended for use as an aid in prosthetic rehabilitation.	Same
Materials	Pure Ti-G4 (ASTM F67)	Pure Ti-G4 (ASTM F67)	Same
Shape			Same

Angle	15° to 30°	15° to 30°	Same
Length	7.4 to 9.4mm	6.4 to 7.87mm	Slight difference Length
Diameter	4.5 to 5.5mm	4.5 to 5.5mm	Same
Gingiva Height (G/H)	2.0 to 3.0mm	1.0 to 1.5mm	Slight difference Gingiva Height
Coating	TiN coated	TiN coated	Same
Use	Prescription	Prescription	Same

- Burn-out Cylinder

	Burn-out Cylinder (Subject Device)	SynOcta Prosthetics®	Similarities / Differences of Devices
Company Name	Dentium Co., Ltd.	Staubmann	-
510(k) Number	New Device	K990342	-
Indications for use	Burn-out Cylinders are intended for use as an aid in prosthetic rehabilitation.	The prosthetic accessories to dental implants are used either in the process of fabricating the prosthetic restoration for the implant or as part of the prosthetic restoration.	Same
Materials	PMMA	PMMA	Same
Shape			Slight difference Shape
Length	12mm	10mm	Slight difference Length
Diameter	4.5~6.5mm	4.8~6.5mm	Slight difference Diameter
Use	Prescription	Prescription	Same

Raw material, mechanical and physical properties, shape, and intended use are similar to the predicated devices. The differences between Dentium Angled screw abutments and Burn-out cylinder (subject device) and predicate devices are different from the slight mechanical and physical characteristics. However, the slight differences do not affect the application

of the device. Therefore, we state that Burn-out Cylinder and Angled Screw Abutment are substantial equivalent with the predicate devices.

7. Identification of the Risk

Risk analysis was performed according to Guidance for Industry and FDA staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments issued on May 12, 2004 and ISO 14971:2007, “Medical devices – Application of risk management to medical devices”. All risks identified have been mitigated based on performance testing results and any residual risk is within acceptable levels.

8. Device Characteristics

Burn-out Cylinder is fabricated from PMMA (Poly(Methyl Methacrylate)) and is available in three cylinder diameters (4.5mm, 5.5mm and 6.5mm) with two connection designs (Hex and Non-Hex).

Angled Screw Abutment is fabricated from Grade 4 pure titanium and partially TiN coated. Angled Screw Abutments in this submission are available in three connection designs (Hex, Long Hex and Non-Hex), two diameters (4.5mm and 5.5mm) and two angulations (15° and 30°). All abutments are made with Dentium’s universal conical connection so that they securely mate with any Dentium Implantium® Fixtures.

9. Performance Testing

Non-clinical testing was performed in accordance with FDA Guidance “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments” and it consisted of testing finished assembled implant/abutment systems of the worst case scenario, through Reliability Calculation and Testing, as well as Fatigue Strength Testing and Static Load Failure Testing.

The proposed combination of the Angled Screw Abutment and Burn-out Cylinder was evaluated using the following performance bench testing to confirm the performance characteristics:

-ISO Fatigue: ISO 14801:2007

Static Compressive mean and Fatigue Limit were evaluated per ISO 14801. Fracture or cracks or severe distortion of any parts were not detected at the fatigue limit and passed 5,000,000 cycles.

Biocompatibility and sterility of the subject device is demonstrated by testing included in the previously cleared primary predicate K141457.

10. Conclusions

All of the data consistent with the recommendations in the FDA guidance document Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments demonstrated that the Dentium Angled Screw abutment and Burn-out Cylinder are substantially equivalent to the predicate device.