DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 12,2014

Dentium Company Limited
C/O Ms. Sheryl Higgins
US Agent
6761 Katella Avenue
Cypress, CA 90630

Re: K141457
Trade/Device Name: Dentium Implantium® and SuperLine® Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: October 14, 2014
Received: October 15, 2014

Dear Ms. Higgins:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith, M.S.
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: K141457

Device Name: Dentium Implantium® / SuperLine® 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)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

1. Company

	Submitter
Name	Dentium Co., Ltd.
Address	440, Changnyong-daero, Iui-dong, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea, 443-270
Phone / Fax	+82 31 207 2200 / +82 31 207 3883
Contact person	Sheryl Higgins / US Agent 714-226-0229 x107 shiggins@dentiumusa.com

2. Device Name

Proprietary name:	Dentium Implantium® / SuperLine® Abutments
Common name:	Abutment, Prosthetic Device
Classification name:	Abutment, Implant, Dental, Endosseous NHA, 21 CFR 872.3630

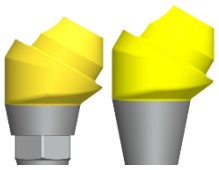
3. Predicated Device

k041368 - Dentium Co. Ltd., Implantium
k052823 - Implantium Abutments
k052957 - Implantium Prosthetics
k112045 - SimpleLine II Abutment System

4. Description

Dentium Implantium and SuperLine Abutments are intended for use an aid in prosthetic rehabilitation. The abutments were originally cleared under 510(k) k041358. The modified designs proposed in this submission consist of the

Angled Screw Abutment, Cover Screw, and Screw Abutment Cylinders. Abutments are supplied non-sterile and autoclaved by the end user.

Name	Class	Material	Dia (mm)	G/H (mm)	Connection	Angle	Figure	Model Number
Angled Screw Abutment	II	Pure Ti-G4 (ASTM F67) TiN Coated	4.5 to 5.5	1.0 to 1.5	Hex and Non-hex	15º to 30°		ASA45151018H ASA45151018N ASA45301018H ASA45301018N ASA55151518H ASA55151518N ASA55301518H ASA55301518N
Screw	II	Ti-6AI-4V ELI alloy (ASTM F136)	1.8 to 2.3	n/a	n/a	n/a		ASASC2023 SRS18T
Cover Screw	II	Ti-6AI-4V ELI alloy (ASTM F136) Annozided	3.6	n/a	n/a	n/a		CS36
Cylinder - Titanium	II	Pure Titanium, Grade 2 (ASTM F67-00)	4.5 to 5.5	n/a	Hex and Non-hex	n/a		STC45SG STC45BG STC55SG STC55BG
Cylinder - Gold	II	Gold Alloy	4.5 to 5.5	n/a	Hex and Non-hex	n/a		SGC45SL SGC45BL SGC55SL SGC55BL
Cylinder - Metal	II	Cobalt-28 Chromium-6 Molybdenum Alloy (ASTM F799)	4.5 to 5.5	n/a	Hex and Non-hex	n/a		SGC45CSL SGC45CBL SGC55CSL SGC55CBL

5. Indication for Use

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

6. Identification of the Risk

Risk analysis was performed according to ISO 14971:2007, “Medical devices - Application of risk management to medical devices”. All risks identified have been mitigated and any residual risk is within acceptable levels.

7. Device Characteristics

Dentium Implantium / SuperLine Abutments are supplied in many different shapes and sizes to meet the patient specific needs of our customers. All abutment are made with Dentium’s universal conical connection so that they securely mate with any Dentium Implantium / SuperLine Fixture.

8. Performance Testing

Biocompatibility testing on the proposed Implantium & SuperLine Abutments have been completed. Requirements for biological evaluation of the purposed device were based on the ISO 10993-1, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.” The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological tissues consistent with its intended use. The following biocompatibility tests were completed:

-ISO Cytotoxicity
-ISO Pyrogenicity
-ISO Intracutaneous reactivity
-ISO Systemic toxicity
-ISO Sensitization

The proposed Implantium & SuperLine Abutments were evaluated using the following performance bench testing to confirm the performance characteristics:

-ISO Static compressive
-Corrosion Testing
-Modified Surface
-ISO Fatigue
-Adaptation Accuracy

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.

9. Reliance on Standards

All testing was performed in compliance with Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.

10. Review

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the Implantium & SuperLine Abutments meet the established specifications necessary for consistent performance according to its intended use.

Implantium & SuperLine Abutments have been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

11. 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 Implantium & SuperLine Abutments are substantially equivalent to the predicate device.