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

September 15, 2016

Dentium Co., Ltd.
Sangpil Yoon
Regulatory
150, Eondong-ro, Giheung-gu
Gyeonggi-do 443-270
KOREA

Re: K160828
Trade/Device Name: Dentium Implantium® & SuperLine® Prosthetics
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 5, 2016
Received: August 9, 2016

Dear Sangpil Yoon:

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" (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 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,

Michael J. Ryan -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: K160828

Device Name: Dentium Implantium® & SuperLine® Prostehtics

Indications for Use:

Dentium Implantium® & SuperLine® 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	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:	Dentum Implantium® / SuperLine® Prosthetics
Common name:	Prosthetic Device
Classification name:	Abutment, Implant, Dental, Endosseous
Regulation number:	872.3630
Class:	II
Panel:	Dental
Product code:	NHA

3. Predicate Device

K052957 - Implantium Prosthetics

K112045 - SimpleLine II Abutment System

4. Description

Dentium Implantium® / SuperLine® Prosthetics are intended for use as an aid in prosthetic rehabilitation. They consist of Dual Milling Abutment, Dual Abutment, Angled Abutment, Temporary Abutment, Direct-Casting Abutment and Metal Casting Abutment.
They are supplied non-sterile and sterilized by the recommended sterilization method in user's manual.

The materials of the Implantium & SuperLine Prosthetics are as follows;
Pure Titanium Grade 4: Dual Milling Abutment, Dual Abutment, Angled Abutment and Temporary Abutment,
Co-Cr-Mo alloy (conform to ASTM F799) and Polyacetal (POM): Metal Casting Abutment,
Gold Alloy and Polyacetal (POM): Direct Casting Abutment.

5. Indication for Use

Dentium Implantium® / SuperLine® Prosthetics are intended for use as an aid in prosthetic rehabilitation.

6. Substantial Equivalence

- Dual Milling Abutment, Dual Abutment, Angled Abutment, Temporary Abutment

  - Angled abutments are only available at 15 degree and 25 degree angles.
  - All other abutments are cast straight. (0 degrees)

	Implantium® / SuperLine® Prosthetics (Subject Device)	Implantium Prosthetics (Primary Predicate)	Similarities / Differences of Devices
Company Name	Dentium Co., Ltd.	Dentium Co., Ltd.	Same
510(k) Number	New Device	K052957	-
Classification and Product Code	Class II; 872.3630; NHA	Class II; 872.3630; NHA	Same

Indications for use	Dentium Implantium®/ SuperLine® Prosthetics is intended for use as an aid in prosthetic rehabilitation	Implantium® SuperLine® Prosthetics is intended for use as an aid in prosthetic rehabilitation	Same

Shape Material Coating Dimension	Dual Milling Abutment  Pure Titanium Grade4 Non-coated Total Length: 14.7mm Diameter: 4.0~6.5mm Hex Height: 1.15mm	Dual Milling Abutment  Pure Titanium Grade4 Partially TiN coated Total Length: 12.7~14.7mm Diameter: 4.0~6.5mm Hex Height: 0.93mm	New devices are designed to add various Hex Height options. Detailed SE discussions mentioned as belows.
	Dual Abutment  Pure Titanium Grade4 Non-coated Total Length: 9.2~13.7mm Diameter: 4.5~6.5mm Hex Height: 1.15mm	Dual Abutment  Pure Titanium Grade4 Partially TiN coated Total Length: 9.2~13.7mm Diameter: 4.5~6.5mm Hex Height: 0.93mm	New devices are designed to add various Hex Height options. Detailed SE discussions mentioned as belows.
	Angled Abutment  Pure Titanium Grade4 Non-coated Total Length: 15.31mm Diameter: 4.5~5.5mm Hex Height: 1.15mm	Angled Abutment  Pure Titanium Grade4 Partially TiN coated Total Length: 13.3mm Diameter: 4.5~5.5mm Hex Height: 0.93mm	New devices are designed to add various Total Length & Hex Height options. Detailed SE discussions mentioned as belows.
	Temporary Abutment  Pure Titanium Grade4 Non-coated Total Length: 13.7mm Diameter: 4.5mm Hex Height: 1.15mm	Temporary Abutment  Pure Titanium Grade4 Non-coated Total Length: 13.7mm Diameter: 4.5mm Hex Height: 0.93mm	New devices are designed to add various Hex Height options. Detailed SE discussions mentioned as belows.

- Metal Casting Abutment, Direct Casting Abutment

	Implantium® / SuperLine® Prosthetics (Subject Device)	SimpleLine II Abutment System (Primary Predicate)	Similarities / Differences of Devices
Company Name	Dentium Co., Ltd.	Dentium Co., Ltd.	Same
510(k) Number	New Device	K112045	-

Classification and Product Code	Class II; 872.3630; NHA	Class II; 872.3630; NHA	Same
Indications for use	Dentium Implantium®/ SuperLine® Prosthetics is intended for use as an aid in prosthetic rehabilitation	SimpleLine II Abutment system is intended for use as an aid in prosthetic rehabilitation.	Same
Shape Material Coating Dimension	Metal Casting Abutment  Co-Cr-Mo Non-coated Total Length:18.7mm Diameter: 4.30mm Hex Height: 1.15mm	Metal Casting Abutment  Co-Cr-Mo Non-coated Total Length:19.2 Diameter: 4.50 Hex Height: 0.93mm	New devices are designed to add various Total Length & Diameter & Hex Height options. Detailed SE discussions mentioned as belows.
	Direct Casting Abutment  Gold alloy Non-coated Total Length:19.2 Diameter: 4.50 Hex Height: 1.15mm	Direct Casting Abutment  Gold alloy Non-coated Total Length:18.95 to 19.1 Diameter: 4.50 Hex Height: 0.93mm	New devices are designed to add various Total Length & Hex Height options. Detailed SE discussions mentioned as belows.

Raw material, mechanical and physical properties, shape, and intended use are similar to the predicated devices. The differences between the Implantium® / SuperLine® Prosthetics and predicate devices are the slight mechanical and physical characteristics. However, the slight differences do not affect the application of the device. Therefore, we state that Implantium® / SuperLine® Prosthetics 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

Dentium Implantium® / SuperLine® Prosthetics are supplied in many different shapes and sizes to meet the patient specific needs of our customers. All abutments are made with Dentium's universal conical connection so that they securely mate with any Dentium Implantium® / SuperLine® Fixture(cleared under 510(k) # 041368).

9. Performance Testing

Biocompatibility testing on the proposed Dentium Implantium® / SuperLine® Prosthetics has been completed. Requirements for biological evaluation of the purposed device were based on 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 Dentium Implantium® / SuperLine® Prosthetics were evaluated using the following performance bench testing to confirm the performance characteristics:

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

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

10. Non-clinical Testing

Non-clinical test data was used to evaluate the proposed device's safety and effectiveness, and determine substantial equivalence with predicate devices. Clinical testing was not necessary to establish substantial equivalency of the device.

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.

In addition, sterilization validation information and recommended sterilization method based on ISO 17665-1 is provided in the Information for Use.

The testing performed demonstrated implant to abutment compatibility and has established substantial equivalency of the proposed device with predicate devices.

11. Review

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the Dentium Implantium® / SuperLine® Prosthetics met the established specifications necessary for consistent performance according to its intended use.

Dentium Implantium® / SuperLine® Prosthetics have been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices complying with the applicable International and US regulations.

12. Conclusions

All of the data, consistent with the recommendations in the FDA guidance document Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments, demonstrate that Dentium Implantium & SuperLine Prosthetics are substantially equivalent to the predicate device.