K112045

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Dentium

510(k) Summary

2011.12.02

1. Company and Correspondent making the submission

Company	Dentium Co., Ltd.
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2. Device Name

Proprietary name: SimpleLine II Abutment System
Common name: Abutment
Classification name: Abutment, Dental, Endosseous implant
NHA, 21CFR872.3630

3. Predicated Device

Implantium Prosthetics, Dentium Co., Ltd. (K070228, K052957)

Implantium, Dentium Co., Ltd. (K041368)

4. Device Description

SimpleLine II Abutment system is intended for use as an aid in prosthetic rehabilitation. It consists of Cover screw, Healing Abutment, Solid Abutment, Dual Abutment, Abutment Screw, SCA Abutment, Dual Milling Abutment, Angled Abutment (15° and 25°), Direct casting Abutment-Gold, Metal-Casting Abutment-Co-Cr, Temporary Abutment-Ti and Screw Abutment. All of abutment designs are based on existing Implantium that are cleared for marketing in the United States. The materials of the SimpleLine II Abutment System is Ti-6Al-4V ELI alloy(ASTM F136), Pure Titanium Gr4(ASTM F67). Gold alloy, Co-Cr-Mo (ASTM F799), Ti-Gr2(ASTM F67).
The Angled Abutments are available in diameters of 3.8, 4.3, 4.5, 5.5 and 6.5mm with 15° and 25° angles to the axis of the implant.

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5. Substantial Equivalence:

Trade name	SimpleLine II Abutment	Implantium Prosthetics	Implantium Prosthetics	Implantium
Manufacturer	Dentium Co., Ltd.	Dentium Co., Ltd.	Dentium Co., Ltd.	Dentium Co., Ltd.
510(k) Number	New device	K052957	K070228	K041368
Materials	Titanium, Titanium Alloy, Co-Cr, Gold Alloy	Titanium, Titanium Alloy, Gold Alloy	Titanium, Titanium Alloy	Titanium, Titanium Alloy
Form	Abutment, Dental, Endosseous implants	Abutment, Dental, Endosseous implants	Abutment, Dental, Endosseous implants	Implant, endosseous, root-form
Indications for use	Intended for use as an aid in prosthetic rehabilitation.	SAME	SAME	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.
Use	Prescription	Prescription	Prescription	Prescription

The comparison between SimpleLine II Abutment and other predicated devices is claimed to be substantially equivalence in terms of indication for use, materials, product form, technology, and performance specifications.

The difference between SimpleLine II Abutment and predicate devices are the product shape and slight mechanical and physical characteristics. However, the slight differences do not affect to the application of the device. Therefore, we state that SimpleLine II Abutment system is substantially equivalent to the predicate devices.

6. Indication for Use

The SimpleLine II Abutment system is intended for use as an aid in prosthetic rehabilitation.

7. Performance Testing

Biocompatibility testing on the proposed SimpleLine II Abutment has been completed. Requirements for biological evaluation of the proposed device were based on the

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ISO7405(2008), "Dentistry-Evaluation of biocompatibility of medical devices used in dentistry." 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 SimpleLine II Abutment was evaluated using the following performance bench testing to confirm the performance characteristics:

-ISO Static compressive
-Torque Force
-ISO Fatigue
-Adaptation Accuracy

8. Review

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the SlimpleLine II Abutment system met the established specifications necessary for consistent performance according to its intended use.

SimpleLine II Abutment system has 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.

9. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Dentium Co., Ltd. concludes that the SimpleLine II Abutment System is substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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Republic of KOREA 443-270

JAN 2 6 2012

Re: K112045
Trade/Device Name: SimpleLine II Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: NHA
Dated: January 13, 2012
Received: January 17, 2012

Dear Mr. Choi:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Susan Reuse

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number: K112045

Device Name: SimpleLine II Abutment system

Indications for Use:

The SimpleLine II Abutment System is 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)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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