K102308

NOV 2 2 2010

Dentium

510(k) Summary

28th July, 2010

1. Company

	Submitter
Name	Dentium Co., Ltd.
Address	27-5 Iui-dong, Yeongtong-gu, Suwon-si, Gyeonggi-do, 443-766, Korea
Phone / Fax	+82 31 207 2200 / +82 31 207 3883
Contact person	Lee, Sungwon / R&D swlee@implantium.com

2. Device Name

Proprietary name: SimpleLine II
Common name: Endosseous Dental Implant
Classification name: Implant, Endosseous, Root-Form
DZE, 21CFR872.3640

3. Predicated Device

K060501 Dentium Co., Ltd / Implantium II

4. Description

The SimpleLine II is a dental fixture made of pure titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches.

The SimpleLine II is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The differences between them are shape and shelf life.

The SimpleLine II is substantially equivalent in design, function, surface treatment, material and intended use to the fixture of Dentium Co., Ltd. Implantium II

5. Indication for Use

The SimpleLine II is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetics devices, such as artificial teeth, and to restore the patient's chewing function.

6. Performance Testing

Test performed in air at 24°C, at 14Hz frequency for at least $5x10^6$ cycles. Tilting angles of specimen is 30. Applied loads are 597N, 448N, 299N, 250N. The fatigue limit is over 250N (Fracture or cracks or severe distortion of any parts were not detected. It is the same fatigue limit of predicate device Implantium II.

7. Review

SimpleLine II has the same device characteristics as the predicate device Implantium II. The material, surface treatment is same and the design, use concept is similar.

8. 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 SimpleLine II is safe and effective and substantially equivalent to predicate device 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

Dentium Company, Limited
C/O Mr. Eunk Zyung Son
Dentium USA
6761 Katella Avenue
Cypress, California 90630

NOV 2 2 2010

Re: K102308
Trade/Device Name: SimpleLine II
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: November 9, 2010
Received: November 12, 2010

Dear Mr. Son:

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,

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

K102308

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Dentium

Indications for Use

510(k) Number:

Device Name: SimpleLine II

Indications for Use:

SimpleLine II is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetics devices, such as artificial teeth, and to restore the patient's chewing function. SimpleLine II is for single stage surgery

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)

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

510(k) Number: K102308