Dentium

K052823

FEB 2 1 2006

6761 Katella Avenue
Cypress, CA 90630
(714) 890-6666 • (714) 890-6360 fax

## 2. 510(k) Summary

| | |
|---|---|
| Date: | 29 September 2005 |
| Applicant: | Dentium Inc.<br>6761 Katella Avenue<br>Cypress, CA 90630 |
| Owner/Operator #: | 9072183 |
| Contact person: | Klaas Besseling |
| Phone numbers:<br>(Contact person) | (949) 466-7472 mobile<br>(949) 448-0312 fax |
| Email address: | kbesseling@spherelink.com |
| Device name: | Implantium abutments |
| Common name: | Endosseous dental implant abutments |
| Classification: | Class II |
| Product Code: | NHA |
| Regulation number: | 21CFR872.3630 |
| Predicate devices: | Implantium, K041368<br>Nobel Biocare Brånemark; K042658 |
| Device description: | The Implantium abutments are devices made of pure titanium, titanium alloys, and plastic. The abutments in this 510(k) submission are supplemental to the previously cleared Implantium devices (K041368) and are designed to be used with the Implantium fixtures. These abutments are placed in the fixtures as a support for fitting prosthetic teeth. This submission includes four differently sized ball abutment kits for overdenture retention, and six different temporary abutments for placement of temporary restorations. |
| Intended use: | The Implantium abutments are intended to be used with the Implantium root-form endosseous dental implant to aid in prosthetic rehabilitation including overdenture retention. After the root-form endosseous dental implant is surgically placed, the endosseous dental implant abutment device is attached to it. |

**Conclusion**

To the best of our knowledge, the devices are substantially equivalent to the predicate devices, and no additional risks are created.

## 4. Indications for use

K052823

**510(k) number:**

**Device name:** Implantium abutments

**Intended use:** The Implantium abutments are intended to be used with the Implantium root-form endosseous dental implant to aid in prosthetic rehabilitation including overdenture retention. After the root-form endosseous dental implant is surgically placed, the endosseous dental implant abutment device is attached to it.

Concurrence of CDRH, Office of Device Evaluation

Prescription use X or Over-The-Counter use _____
(Per 21CFR801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1 2006

Mr. Klaas Besseling
Director
Dentium, Incorporated
28711 Jaeger Drive
Laguna Niguel, California 92677

Re: K052823
Trade/Device Name: Implantium Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 13, 2006
Received: February 16, 2006

Dear Mr. Besseling:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital ,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

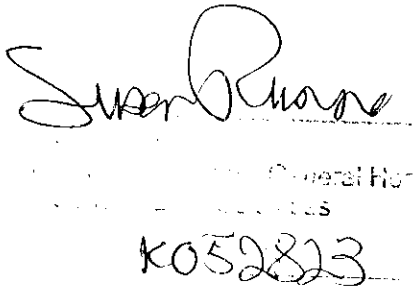
# 4. Indications for use

**510(k) number:**

**Device name:** Implantium abutments

**Intended use:** The Implantium abutments are intended to be used with the Implantium root-form endosseous dental implant to aid in prosthetic rehabilitation including overdenture retention. After the root-form endosseous dental implant is surgically placed, the endosseous dental implant abutment device is attached to it.

Concurrence of CDRH, Office of Device Evaluation



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Prescription use X (Per 21CFR801.109) or Over-The-Counter use _____