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k053355

Attachment 5

510 (K) SUMMARY

SAFETY AND EFFECTIVENESS INFORMATION

BTI INTERNA
DENTAL IMPLANT SYSTEM

SUBMITTER'S NAME. ADDRESS AND TELEPHONE NUMBER:	B.T.I. Biotechnology Institute, S.L. Parque Tecnológico de Álava Leonardo da Vinci, 14 B Miñano (Álava) 01510 Spain PH: +34 945 297030 FAX: +34 945 297031
CONTACT PERSON	Alfredo Gómez Mengod Quality Assurance Manager
SUMARY PREPARATION DATE:	November 2005
ESTABLISHMENT REGISTRATION No:	3004417597
PROPRIETARY NAME:	BTI INTERNA DENTAL IMPLANT SYSTEM
COMMON NAME:	Dental implant
CLASSIFICATION NAME:	IMPLANT, ENDOSSEOUS, ROOT-FORM

PRODUCT CODE:
DZE

DEVICE CLASSIFICATION:

Class II

PREDICATE DEVICE

The BTI Interna Dental Implant System is claimed to be substantially equivalent in material, design, and function to the BTI Dental Implant System cleared by FDA under 510 (k) *K022258* on Sep 11, 2003

DEVICE DESCRIPTION

The BTI Interna Dental Implant System is designed to server as support for prosthetic devices to restore chewing function. The implants have a surgical diameter range of from 3.3 to 4.0 mm for the universal platform implant. 4.0 for Universal Plus Platform and 4.5 to 5.0 mm for wide platform. Lengths range from 7,0 to 18,0 mm.

INTENDED USE

Dental implant system comprising endosseous titanium implants and prosthetic elements to be attached to the implants, as well as auxiliary elements for surgical and prosthetic procedures.

The intended use of the system is the restoration of missing teeth in partially or fully edentulous patients and/or the fixation of overdentures to restore or enhance the chewing capacity of patients.

SUBSTANTIAL EQUIVALENCE

The BTI Interna Dental Implant System is considered to be substantially equivalent to BTI Dental Implant System

CONCLUSION

The BTI Interna Dental Implant System is considered to be substantially equivalent in design, material and function to the BTI Dental Implant System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2006

Mr. Alfredo Gómez Mengod
Quality Assurance Manager
B.T.I. Biotechnology Institute, S.L.
Parque Tecnológico de Álava
Leonardo da Vinci, 14 B
Miñano (Álava), 01510 Spain

Re: K053355
Trade/Device Name: BTI Interna Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: February 16, 2006
Received: February 21, 2006

Dear Mr. Mengod:

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

Attachment 2

Indications for Use

510(k) Number (if known): **K053355**

Device Name: BTI Interna Dental Implant System

Indications For Use:

Dental implant system comprising endosseous titanium implants and prosthetic elements to be attached to the implants, as well as auxiliary elements for surgical and prosthetic procedures.

The intended use of the system is the restoration of missing teeth in partially or fully edentulous patients and/or the fixation of overdentures to restore or enhance the chewing capacity of patients.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

[illegible], General Hospital
[illegible] Dental Devices

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