K022258

SEP 11 2003



## 4. 510(k) Summary

**Manufacturer's Information**

Submitter's name: B.T.I. Biotechnology Institute, S.L.
Address: Parque Tecnologico de Alava
Leonardo da Vinci 14B
01510 Miñano (Alava)
España
Contact's name: Alfredo Gómez

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**Device Name**

Common Name: Implant
Trade Name: B.T.I. Dental Implant System
Classification name: Endosseous Implant

**Predicative Device**

The B.T.I. Dental Implant Systems are substantially equivalent to the following device:
*Osseotite Dental Implants manufactured by Implant Innovation Inc,*
. (3I) number K013570.

**Device Description**

The BTI 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 and 4.5 to 5.5 mm for wide platform. Lengths range from 7,0 to 18,0 mm. Narrow platform implants are 3,3 wide in the surgical area, with lengths ranging from 10,0 to 15,0 mm.

**Intended Use**

To replace missing tooth roots for single tooth, partial tooth and fully edentulous patients.
It is designated to become osseointegrated elements allowing the attachment of a partial or a complete prosthodontic appliance.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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B.T.I. Biotechnology Institute S.L.
C/O Mr. Alfredo Gomez
Quality Assurance and Certifications Deputy Manager
Parque Tecnologico de Alava
Leonardo Da Vinci, 14B
01510 Minano (Alava)- ESPANA

Re: K022258
Trade/Device Name: B.T.I Biotechnology Institute, S.L. Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: June 11, 2003
Received: June 13, 2003

Dear Mr. Gomez:

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 (301) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022258

Device Name: BTI 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulay for MSR

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

510(k) Number: K 022258

(Optional Format 3-10-98)