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510 (K) SUMMARY

JUN 21 2007

510 (K) SUMMARY. SAFETY AND EFFECTIVENESS INFORMATION
ENDOSSEOUS DENTAL IMPLANT ANGLED ABUTMENTS

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	Leyre Zúñiga Hernando Quality and Regulatory Affairs Pharmacist
SUMARY PREPARATION DATE:	February 2007
ESTABLISHMENT REGISTRATION No:	3004417597
PROPRIETARY NAME:	*Endosseous dental implant angled Abutment*
COMMON NAME:	Endosseous dental implant abutment
CLASSIFICATION NAME:	Endosseous dental implant abutment (Sec. 872.3630)
PRODUCT CODE:	NHA
DEVICE CLASSIFICATION:	Class II

PREDICATE DEVICE
The modified *Endosseous dental implant angled abutments* are claimed to be substantially equivalents in material, design, and function to BTI Endosseous dental implant abutments cleared by FDA under 510 (k) K022258 on Sep 11, 2003 and 510 (k) 053355 on Mar 14, 2006 and in function and design to SFB & CFB Angled Abutments cleared by FDA under 510 (K) K062749 on Nov 29, 2006 and SynOcta® Angled Abutments cleared by FDA under 510 (K) K994119 on Mar 17, 2000.

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DEVICE DESCRIPTION

BTI Endosseous dental implant angled abutments consist of 15 degree angled abutments. The artificial tooth abutments are designed to fit and function on the internal and external BTI conexion implants.

They can be used in singled and multi-unit restorations where angled correction is required.

The angled abutments differ from the BTI predicate abutments in that the abutments are angled. The angled abutments provide for more flexibility in the implant placement and restoration process.

INTENDED USE

Endosseous dental implant angled abutments are premanufactured prosthetic component directly connected to the Endosseous dental implant and are intended for use as aids in prosthetic rehabilitation.

SUBSTANTIAL EQUIVALENCE

The *Endosseous dental implant angled abutments* are considered to be substantially equivalent to the ease abutments previously cleared under K022258/K053355, K062749 and K994119.

CONCLUSION

The *Endosseous dental implant angled abutments* are considered to be substantially equivalent in intended use, material and design to the BTI *Endosseous dental implant titanium abutments* and in intended use and design to *SFB & CFB Angled Abutments* and *SynOcta® Angled Abutments* so we can affirm that Endosseous dental angled implant abutments are as safe and effective as the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Leyre Zúñiga Hernando
Quality and Regulatory Affairs Pharmacist
B.T.I. Biotechnology Institute, S.L.
Leonardo Da Vinci, 14B
01510 Miñano (Álava)
SPAIN

JUN 21 2007

Re: K070533
Trade/Device Name: BTI Endosseous Dental Implant Angled Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 30, 2007
Received: June 7, 2007

Dear Mr. Hernando:

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

K070533

Indications for Use

510(k) Number (if known): _____

Device Name: BTI *Endosseous dental implant angled abutments*

Indications for Use:

Endosseous dental implant angled abutments are premanufactured prosthetic components directly connected to the Endosseous dental implant and are intended for use as aids in prosthetic rehabilitation. They can be used in singled and multi-unit restorations where angled correction is required.

Prescription Use ___X____ (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)

for MSR

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

510(k) Number: K070533