K063364

בס"ד

510(K) SUMMARY

Alpha-Bio Tec® Dental Implant System

MAR 1 4 2007

510(k) Number K_____

A. Applicant's Name: Alpha-Bio Tec Ltd
7, Embar st.
Industrial Zone Kiryat Arie
POB 3936 ZIP 49130
Petach-Tikva, Israel
Tel: +972-3-9291000 / 9390668
Fax: +972-3-9235055
e-mail: ophir@alpha-bio.net; Daniela@alpha-bio.net
Web site: www.alpha-bio.net

B. Contact Person: Daniela Ben Shabat
Alpha-Bio Tec Ltd
7, Embar st.
Industrial Zone Kiryat Arie
POB 3936 ZIP 49130
Petach-Tikva, Israel
Tel: +972-3-9291000 / 9390668
Fax: +972-3-9235055
e-mail: Daniela@alpha-bio.net
Web site: www.alpha-bio.net

C. Date Prepared: March 2006

D. Trade Name: Alpha-Bio Tec®

E. Classification:

Name: implant, endosseous, root-form
Product Code: DZE
Regulation No: 872.3640
Class: II
Panel: Dental

Subsequent Product Code:
Name: Abutment, implant, dental, endosseous
Product Code: NHA
Regulation No: 872.3630
Class: II
Panel: Dental

F. Predicate Devices: The Alpha-Bio Tec® is substantially equivalent to 3i® K022009;K022113; Zimmer Tapered screw vent K013227; MIS Implant Technologies Ltd K040807, K003191 ; Biohorizons K041938; K032351; NobelDirect™ K041876; IMTEC K031106 K023067; Branemark K022562, Straumann K033984; K013798; SWISSPLUS IMPLANT CORE VENT CORP K002188 in terms of intended use, indications for use, technological characteristics, performance and user interface.

The predicate device is Class II medical devices.

A discussion of substantial equivalence is provided in Section 3 of this submission.

G. Device Description: The Alpha-Bio Dental Implant System® consists of one and two stage endosseous form dental implants, internal and external hexagonal; internal octagonal hexagonal; one piece implants system; cover screws and healing caps; abutment systems and superstructures; surgical instruments.

H. Intended Use / Indication for Use: The Alpha-Bio Dental Implant System® is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Alpha-Bio Dental Implant System® is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

I. Performance Standards: No performance standards have been established for such devices under Section 514 of the Federal Food, Drug, and Cosmetic Act.

The device complies with the following recognized standards:

- ISO 7405:1997, Dentistry - Preclinical Evaluation .
- of Biocompatibility of Medical Devices Used in Dentistry - Test Methods for Dental
- F136–02a: 2004 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).
- ASTM F1350-02, 2002 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673).

- ISO 13402:1995, Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion and thermal exposure.
- UL 544 (1998):, Standard for Medical and Dental Equipment - Ed. 4.0.

J. Substantial Equivalence: There are no unique applications, indications, materials or specifications presented below. Evidence of equivalence has been demonstrated through:

- The Alpha-Bio Tec® intended use and indications for use were previously cleared by FDA for the predicate device.
- The technical characteristics of the Alpha-Bio Tec® are similar to those of the predicate device.
- Safety and performance testing.

Therefore, the Alpha-Bio Tec® Dental Implant System is substantially equivalent to its predicate devices as cited above and raises no new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alpha-Bio Tec Limited
C/O Mr. Daniel J. Manelli
Attorney
Manelli & Fisher, P.L.L.C.
5335 Wisconsin Avenue, NW Suite 440
Washington, DC 20015

MAR 14 2007

Re: K063364
Trade/Device Name: Alpha-Bio Tec® Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 9, 2007
Received: March 12, 2007

Dear Mr. Manelli:

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

INDICATIONS FOR USE

510(K) Number: K063364

Device Name: Alpha-Bio Tec® Dental Implant System

Indications for Use:

The Alpha-Bio Dental Implant System® is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

Two stage: ATID, DFI, SPI, SFB, ATIE OF, ITO, SPR

One stage: ITO, SPR

One stage and One Piece: ARRP, ARPB, ARRC 3 mm diameter implants are intended only for the incisors and cuspids of the maxilla and mandible they are also Indicated for denture stabilization using multiple implants

One stage and One Piece for temporary or long-term use: ARR, ARB, ARS, ARBS are self tapping titanium threaded screws indicated for long term intra bony applications. They permit immediate splint stability and long-term fixation of new or existing crown, bridge and prosthesis, and protection of graft sites.

DFI, SPI, ARRP, ARPB and ARRC designs are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

SPI and SFB designs are indicated for immediate loading in single tooth restorations when good primary stability is achieved and with appropriate occlusal loading.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evacuation

Susan Runner

K063364

Prescription Use ✓ OR Over the Counter Use ___
(Per 21 CFR 801.109)