FEB 2 4 2011

510(K) SUMMARY

510(K) Number K K10 3280

5.1 Applicant's Name:
BHdental Ltd.
4 Hayetsira st.
Nesher 36882 Israel.
Tel/fax: +972 4 820 2882

5.2 Contact Person:
Eilat Ezra
Duet Medical Consulting Ltd.
21 Hanafa Street
Zur- Moshe 42810, ISRAEL
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Email: eilat@duet-medical.com

5.3 Date Prepared: October 2010

5.4 Trade Name: BHdental Implant System

5.5 Classification Name: Implant, Endosseous, Root-Form

5.6 Medical Specialty: Dental

5.7 Product Code: DZE

5.8 Device Class: Class II

5.9 Regulation Number: 872.3640

5.10 Review Panel: Dental

5.11 Predicate Devices:

- Alpha-Bio Tec® Dental Implant System (Alpha-Bio Tec Ltd) cleared under K063364; product code DZE (Implant, Endosseous, Root-Form)
- ONEPLANT Dental Implant System (WARANTEC Co., Ltd.) cleared under K081748; product code DZE (Implant, Endosseous, Root-Form) and NHA (Abutment, Implant, Dental, Endosseous)
- MIS Dental Implant System (MIS - Implant Technologies Ltd.) cleared under K040807; product code DZE (Implant, Endosseous, Root-Form)

- Osseospeed TM Profile System (ASTRA Tech AB) cleared under K080156, K091239) ; product code DZE (Implant, Endosseous, Root-Form)
- ARSD Dental Implants (ARDS Ltd.) cleared under K071803 ;product code DZE (Implant, Endosseous, Root-Form)
- NobleActive internal Connection Implant (Nobel Biocare AB) cleared under K071370;product code DZE (Implant, Endosseous, Root-Form); product code NHA (Abutment, Implant, Dental, Endosseous).

5.12 Intended Use / Indication for Use:

The BHdental 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 chewing function. The BHdental Implant System is also indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

5.13 Device Description:

The BHdental Implant System consists of one and two stage endosseous form dental implant, internal and external hexagonal; internal octagonal hexagonal; cover screws and healing caps; abutment systems, superstructures and surgical instruments.

5.14 Substantial Equivalence:

The proposed BHdental Implant System has similar indications for use, technological characteristics, mode of operation and performance specification as the predicates Alpha-Bio Tec® Dental Implant System (K063364), ONEPLANT Dental Implant System (K081748) and MIS Dental Implant System (K040807).

The proposed device has the same intended use as the predicate Alpha-Bio Tec® Dental Implant System and MIS Dental Implant System and is placed using the same methodology as all of the predicate devices. Both the proposed and predicate devices function in the same manner providing support for prosthetic devices in the upper or lower jaw.

Performance Testing

A series of safety and performance testing were performed to demonstrate that the BHdental Implant System does not raise any new issues of safety and efficacy. These tests include: fatigue, corrosion resistance, sand blasting process and biocompatibility.

The device complies with the following standards:

1. FDA Guidance - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments
2. ISO 14801:2007 "Dentistry-Implants-Dynamic fatigue test for endosseous dental implants"
3. ISO 5832-3:1996 - Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
4. ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
5. ASTM F899 Standard Specification for Wrought Stainless Steels for Surgical Instruments
6. ISO 7405:2008 - Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry
7. ASTM F746-04 (Reapproved 2009)- Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials
8. ISO 10993 -1:2003 - Biological evaluation of medical devices -Part 1: Evaluation and testing

All these tests demonstrate that the BHdental Implant System is substantially equivalent to its predicates without raising new issues of safety or effectiveness.

Summary

Based on the performance testing results, and compliance to performance standards BHdental Ltd. believes that the Implant System is substantially equivalent to its predicates without raising new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

BHdental, Limited
C/O Mr. Eilat Ezra
Duet Medical Consulting, Limited
21 Hanafa Street
Zur-Moshe
ISRAEL 42810

FEB 24 2011

Re: K103280
Trade/Device Name: BHdental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Implant, Endosseous, Root-Form
Regulatory Class: II
Product Code: NHA, DZE
Dated: February 16, 2011
Received: February 22, 2011

Dear Mr. Ezra:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
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 (if known): K103280

Device Name: BHdental Implant System

Indications for Use:

The BHdental 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 chewing function. The BHdental Implant System is also indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Prescription Use __√_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K103280