SECTION 5 - 510(k) Summary (21 CFR 807.92)

JAN 2 1 2014

510(k) Number K132125

1	Submission Owner	A.B. DENTAL DEVICES Ltd. 19 Hayalomim St., Ashdod 77101 ISRAEL Phone : 972-8-8531388 Fax : 972-8-8522562
2	Official Correspondent Contact Person	Sterling Medical Registration Daniela Levy - Regulatory Consultant 22817 Ventura blvd. #161 Woodland Hills, CA 91364 Phone: 1-213-787-3026 Fax: 1-213-447-5297 Email Daniela@sterlingmedicalregistration.com
3	Submission Date	July 7th, 2013
4	Device Trade Name	A.B. DENTAL DEVICES ® Dental Implants System
5	Regulation Description	Root-form Endosseous Dental Implants & Abutments
6	Classification	Device 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

7 Reason for the Premarket Notification Submission : New Device

8 Identification of Legally Marketed Predicate Devices :

A.B. DENTAL DEVICES ® Dental Implants System is substantially equivalent to M.I.S, K092555; Alpha Bio Tec K063364; IMTEC K031106; Nobel Biocare K071370, K102436, K041876; in terms of intended use, indication for use, technological characteristics, performance and user interface.

A.B. DENTAL DEVICES ® Dental Abutments System is substantially equivalent to M.I.S. K040807; Biohorizon K103691; Alpha Bio *Tec* K063364; Zimmer K052600, K061847, K092377; A.B.Dental Devices K051719, K112440; Nobel Biocare K072570,K093643, K031719, K061529, K091904, K061477; Inclusive dental solutions K083480; Zest Anchors K083324; in terms of intended use, indication for use, technological characteristics, performance and user interface.

The predicate devices are a Class II medical device.

9 Device Description: :

A.B. DENTAL DEVICES® Dental Implants System consists of one and two stage endosseous form dental implants, internal hexagonal and one piece implants system;

I2 - Screw Type Implant - Diameter 3.5, Length 8, 10,11.5,13,16

I5 - Conical Implant - Diameter 3.5, Length 8, 10,11.5,13,16

I6 - Narrow Integral Implant - Diameter 2.4, 3, 3.2 Length 10, 11.5, 13, 16

I6b - Ball Attachment Implant - Diameter 2.4 Length 10, 11.5, 13, 16

I6B - Narrow Implant - Diameter 3, 3.2 Length 10, 11.5, 13, 16

I6BI - Narrow Implant - Diameter 3 Length 10, 11.5, 13, 16

Abutments System consists of healing caps, screws, Anti-rotation Abutment, Anatomic Anti-rotation Abutment, Narrow / Wide Anti-rotation Abutment, Zirconium Anatomic Abutment, Temporary PEEK Anatomic Anti-rotation Abutment, Long Angular Abutment 15º, Anatomic Angular Abutment 15º, Ball Attachment Abutment, Angular Ball Attachment 20º, Ball for Angular Adaptor, Titanium Sleeve, Anti-rotation Aesthetic Abutment, Composed Hex/Non Hex Abutment, Angular Adaptor, Locator and other superstructures; impression copy system & surgical instruments are also provided.

10 Intended use / Indication for Use: :

A.B.DENTAL DEVICES® Dental Implants 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. A.B. DENTAL DEVICES® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Two Stage Implants: I2, I5, I6BI.

One Stage: I6, I6b, I6B.

One Stage & One-Piece 3.0 mm diameter implants: I6, I6B, I6BI, are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants.

One stage & One-Piece 2.4 mm diameter implants for temporary use or long term use: I6, I6b, permit immediate splint stability and long term fixation of new or existing crown, bridge and prosthesis.

P14 Angulated Abutment Adapter is to be used with implant diameter 4.2mm and higher.

11 Performance Standards or Special Controls :

- ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.
- ISO 5832-3:1996 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.
- ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants.
- FDA guidance document: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff.

12 Substantial Equivalence :

	Candidate	***Predicate Device***	***Predicate Device***
	A.B. Dental Devices	***Alpha Bio Tec K063364***	
Product Name	I2 - Conical Implant	DFI	
Material	GR-5 Titanium Ti-6Al-4V ELI	GR-5 Titanium Ti-6Al-4V ELI	
Implant Body Contour	Tapered	Tapered	
Implant / Abutment connection	Internal Hex	Internal Hex	
Surface	Calcium Fosfat-Hydroxyapatite	Sand Blast & Acid Etched	
	A.B. Dental Devices	***NobelBiocare K103089***	
Product Name	I5 - Conical Implant	Nobel Active	
Material	GR-5 Titanium Ti-6Al-4V ELI	CP4 Titanium	
Implant Body Contour	Tapered & Conical	Tapered & Conical	
Implant / Abutment connection	Internal Hex	Internal Hex	
Surface	Calcium Fosfat-Hydroxyapatite	TiUnite	
	A.B. Dental Devices	***Alpha Bio Tec K063364***	***Alpha Bio Tec K063364***
Product Name	I6 - Narrow Integral Implant	ARS	ARRP
Material	GR-5 Titanium Ti-6Al-4V ELI	GR-5 Titanium Ti-6Al-4V ELI	GR-5 Titanium Ti-6Al-4V ELI
Implant Body Contour	Tapered & Conical	Tapered	Tapered
Implant / Abutment connection	Onepiece - Implant integrated with abutment	Onepiece - Implant integrated with abutment	Onepiece - Implant integrated with abutment
Surface	Calcium Fosfat-Hydroxyapatite	Acid etched or Sand Blast & Acid Etched	Sand Blast & Acid Etched
	A.B. Dental Devices	***Alpha Bio Tec K063364***	***IMTEC CORP K031106***
Product Name	I6b - Ball Attachment Implantt	ARB/ARSB	IMTEC MDI SENDAX
Material	GR-5 Titanium Ti-6Al-4V ELI	GR-5 Titanium Ti-6Al-4V ELI	GR-5 Titanium Ti-6Al-4V ELI
Implant Body Contour	Tapered & Conical	Straight or Tapered	Straight or Tapered
Implant / Abutment connection	Onepiece - Implant integrated with ball abutment	Onepiece - Implant integrated with ball abutment	Onepiece - Implant integrated with ball abutment
Surface	Calcium Fosfat-Hydroxyapatite	Acid etched or Sand Blast & Acid Etched	Enhanced surface treatment
	A.B. Dental Devices	***Alpha Bio Tec K063364***	
Product Name	I6B - Narrow Implant	ARRC	
Material	GR-5 Titanium Ti-6Al-4V ELI	GR-5 Titanium Ti-6Al-4V ELI	
Implant Body Contour	Tapered & Conical	Tapered	
Implant / Abutment connection	Implant integrated with abutment (+ internal hex)	Implant integrated with abutment (+ internal hex)	
Surface	Calcium Fosfat-	Sand Blast & Acid Etched	

	Hydroxyapatite		
	A.B. Dental Devices	***Nobel Biocare K102436***	***MIS K092555***
Product Name	I6BI - Narrow Implant	NobelActive 3.0	UNO Narrow Implants
Material	GR-5 Titanium Ti-6Al-4V ELI	4 CP Titanium	GR-5 Titanium Ti-6Al-4V ELI
Implant Body Contour	Tapered & Conical	Tapered	Tapered
Implant / Abutment connection	Internal hex	Internal hex	Internal hex
Surface	Calcium Fosfat-Hydroxyapatite	TiUnite	Sand Blast & Acid Etched

Summary of Equivalence:

A.B. DENTAL DEVICES® Dental Implants System shares similarity or very identical to its predicate devices in terms of intended use, indication for use, technological characteristics, performance and user interface.

As demonstrated by the substantial equivalent table, the differences raise no new issues of safety or effectiveness, since A.B. DENTAL DEVICES® Dental Abutments System shares similarity or very identical to its predicate devices.

Non Clinical Testing

Mechanical Testing - A.B. DENTAL DEVICES® has conducted Fatigue – Static & Cycling tests which comply with ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants; The test results have demonstrated the high resistance and high ability with the use of A.B. DENTAL DEVICES® Dental Implant System. Therefore, A.B. DENTAL DEVICES® Dental Implants System raises no new issues of safety or effectiveness than the predicate devices.

Safety & Effectiveness testing

Risk Assessment was conducted and has demonstrated no new safety and/or effectiveness issues than the predicate devices.

<u>Conclusion:</u>

As verified by bench testing, mechanical testing, risk assessment and substantial equivalence, A.B. DENTAL DEVICES® Dental Implant System shares similarity with its predicated devices by term of intended use, raw material and technical design. The fundamental scientific technology of the device is identical or very similar to the referenced predicate devices, thus A.B. DENTAL DEVICES® Dental Implant System is considered to

be substantially equivalent to its predicate devices and raises no new safety and/or effectiveness issues than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 21, 2014

A.B. Dental Devices, Limited
c/o Ms. Daniela Levy
Regulatory Consultant
Sterling Medical Registration
22817 Ventura Blvd. #161
Woodland Hills, CA 91364

Re: K132125
Trade/Device Name: A.B. DENTAL DEVICES® Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental IMPLANT
Regulatory Class: II
Product Code: DZE, NHA
Dated: December 11, 2013
Received: December 20, 2013

Dear Ms. Levy:

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 contact 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. 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,

Erin I. Keith

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 - Indication for Use Statement

510(k) Number (if known): K132125

Device Name:

A.B.DENTAL DEVICES® Dental Implants System

Indications for Use:

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Prescription Use _✓__ 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS MA

Mary S. Runner -S
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