DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 15, 2017

A. B. Dental Device Ltd.
% John Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 13th St. NW
Washington, District of Columbia 20004

Re: K162482
Trade/Device Name: A.B. DENTAL DEVICES® Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 15, 2017
Received: August 15, 2017

Dear Dr. John Smith:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement on last page*

510(k) Number *(if known)*

K162482

Device Name

A.B. DENTAL DEVICES® Dental Implants System

Indications for Use *(Describe)*

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: I22, I5, I55, I10.

P4 and P14 angled abutments are to be used only with standard platform implants 3.5 mm in diameter or larger.

| Type of Use *(Select one or both, as applicable)* | |
|---|---|
| ☒ Prescription Use (Part 21 CFR 801 Subpart D) | ☐ Over-The-Counter Use (21 CFR 801 Subpart C) |

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**K162482**
**510(k) SUMMARY**
**A.B. Dental Devices Dental Implant System**

**Submitter:**

A.B. Dental Devices Ltd.
19 Hayalomim St.,
Ashdod 7761117
Israel

Phone: 972-8-8531388
Facsimile: 972-8-8522562
Contact Person: Gabi Krauss, RA Manager

**Date Prepared**: September 15, 2017

**Name of Device:** A.B. DENTAL DEVICES® Dental Implants System
**Common or Usual Name:** Root-form Endosseous Dental Implants & Abutments
**Classification Name:** Endosseous dental implant; 21 CFR §872.3640
**Product Code**: DZE, Additional Product Code NHA

**Predicate Device**

K132125 A.B. DENTAL DEVICES® Dental Implants System (primary)
K051719 A.B. DENTAL DEVICES® Dental Implants System (reference)
K112440 A.B. DENTAL DEVICES® Dental Implants System (reference)
K071370 Nobel Biocare AB NobelActive (reference)

**Indications 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: I22, I5, I55, I10.

P4 and P14 angled abutments are to be used only with standard platform implants 3.5 mm in diameter or larger.

**Device Description and Technological Characteristics**

A.B. DENTAL DEVICES® Dental Implants System consists of one and two stage endosseous form dental implants, internal hexagonal and one piece implants systems. Narrow platform implants are to be used with straight abutments only. The following components are being added:

| Implant | Platform | Diameter, mm | Length, mm |
|---|---|---|---|
| I22 | Standard | 3.75 | 8, 10, 11.5, 13, 16 |
| | | 4.2 | 8, 10, 11.5, 13, 16 |
| | | 4.5 | 8, 10, 11.5, 13, 16 |
| | | 5 | 8, 10, 11.5, 13, 16 |
| I5 | Narrow | 3.3 | 10, 11.5, 13, 16 |
| I55 | Narrow | 3.3 | 10, 11.5, 13, 16 |
| | | 3.5 | 8, 10, 11.5, 13, 16 |
| | Standard | 3.75 | 8, 10, 11.5, 13, 16 |
| | | 4.2 | 8, 10, 11.5, 13, 16 |
| | | 4.5 | 8, 10, 11.5, 13, 16 |
| | | 5 | 8, 10, 11.5, 13, 16 |
| | | 6 | 8, 10, 11.5, 13, 16 |
| I10 | Standard | 4.5 | 10, 11.5, 13, 16 |

Abutments:

- P0-14 Healing caps, 2.5 – 7 mm heights
- P3-5 straight abutments, 5 mm diameter, 7 – 9 mm length
- P4 angled abutments, 15 – 25 degree angulation, standard platform, standard and long lengths

**Technological Characteristics Comparison**

The purpose of this 510(k) is to expand the current product line to include two new endosseous implant product lines (I22 and I55). Minor additions to existing implant lines have also been added. Comparison tables for each modification are provided below.

| | Subject I5 | Predicate I5 | Predicate I6bi |
|---|---|---|---|
| **K-number** | K162482 | K132125, K112440 | K132125 |
| **Material** | Ti-6Al-4V | Ti-6Al-4V | Ti-6Al-4V |
| **Diameter, mm** | 3.3 | 3.5, 3.75, 4.2, 4.5, 5, 6 | 3 |
| **Platform** | Narrow | Standard | Narrow |
| **Length, mm** | 10, 11.5, 13, 16 | 8, 10, 11.5, 13, 16 | 10, 11.5, 13, 16 |
| **Profile** | Tapered | Tapered | Tapered |
| **Surface Treatment** | Sand blasted with CaP | Sand blasted with CaP | Sand blasted with CaP |
| **Sterility** | Sterile | Sterile | Sterile |

| | Subject I10 | Predicate I10 |
|---|---|---|
| **K-number** | K162482 | K112440 |
| **Material** | Ti-6Al-4V | Ti-6Al-4V |
| **Diameter, mm** | 4.5 | 3.75, 4.2, 5 |
| **Platform** | Standard | Standard |
| **Length, mm** | 10, 11.5, 13, 16 | 10, 11.5, 13, 16 |
| **Profile** | Tapered | Tapered |

| | | |
|---|---|---|
| **Surface Treatment** | Sand blasted with CaP | Sand blasted with CaP |
| **Sterility** | Sterile | Sterile |

| | **Subject I22** | **Predicate I2** |
|---|---|---|
| **K-number** | K162482 | K132125, K112440 |
| **Material** | Ti-6Al-4V | Ti-6Al-4V |
| **Diameter, mm** | 3.75, 4.2, 4.5, 5 | 3.5, 3.75, 4.2, 4.5, 5, 6 |
| **Platform** | Standard | Standard |
| **Length, mm** | 8, 10, 11.5, 13, 16 | 8, 10, 11.5, 13, 16, 18, 20 |
| **Profile** | Tapered | Tapered |
| **Surface Treatment** | Sand blasted with CaP | Sand blasted with CaP |
| **Sterility** | Sterile | Sterile |

| | **Subject I55** | **Predicate I5** | **Predicate I6bi** |
|---|---|---|---|
| **K-number** | K162482 | K132125, K112440 | K132125 |
| **Material** | Ti-6Al-4V | Ti-6Al-4V | Ti-6Al-4V |
| **Diameter, mm** | 3.3,3.5, 3.75, 4.2, 4.5, 5, 6 | 3.5, 3.75, 4.2, 4.5, 5, 6 | 3 |
| **Platform** | Narrow (≤3.5) and Standard (≥3.75) | Standard | Narrow |
| **Length, mm** | 8, 10, 11.5, 13, 16 | 8, 10, 11.5, 13, 16 | 10, 11.5, 13, 16 |
| **Profile** | Tapered | Tapered | Tapered |
| **Surface Treatment** | Sand blasted with CaP | Sand blasted with CaP | Sand blasted with CaP |
| **Sterility** | Sterile | Sterile | Sterile |

| | **Subject P0 Healing Caps** | **Predicate P0 Caps** |
|---|---|---|
| **K-number** | K162482 | K132125 |
| **Material** | Ti-6Al-4V | Ti-6Al-4V |
| **Connection Method** | Taper fit | Screw |
| **Platform** | P14 angled abutments | Narrow, Standard |
| **Length, mm** | 2.5, 4, 5, 7 | 0.5, 2, 3, 4, 5, 6, 7 |
| **Sterility** | Non-Sterile | Non-Sterile |

| | **Subject P3-5** | **Predicate P3** |
|---|---|---|
| **K-number** | K162482 | K132125, K112440 |
| **Material** | Ti-6Al-4V | Ti-6Al-4V |
| **Diameter, mm** | 5 | 3.75, 4.5, 5.5 |
| **Platform** | Standard | Narrow, Standard |
| **Length, mm** | 7, 9 | 5, 7, 9, 11,12, 15 |
| **Design** | Anti-rotation | Anti-rotation |
| **Sterility** | Non-Sterile | Non-Sterile |

| | **Subject P4** | **Predicate P4** |
|---|---|---|
| **K-number** | K162482 | K132125 |
| **Material** | Ti-6Al-4V | Ti-6Al-4V |
| **Diameter, mm** | 3.75, 5 | 3.75 |
| **Angle, °** | 15, 25 | 15 |
| **Platform** | Standard | Standard |

| | | |
|---|---|---|
| **Length, mm** | 8, 9, 15.5 | 15.7 |
| **Design** | Straight, Standard, Narrow, Long | Long, Anatomic (shoulder heights 1,3) |
| **Sterility** | Non-Sterile | Non-Sterile |

In addition, a comparison of the indications for use of the subject and primary predicate follows:

| | **Subject A.B. DENTAL DEVICES® Dental Implants System** | **Primary Predicate A.B. DENTAL DEVICES® Dental Implants System** |
|---|---|---|
| **K-number** | **K162482** | **K132125** |
| **Indications 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.<br><br>Two Stage Implants: I22, I5, I55, I10.<br><br>P4 and P14 angled abutments are to be used only with standard platform implants 3.5 mm in diameter or larger. | 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.<br>Two Stage Implants: I2, I5, I6BI.<br>One Stage: I6, I6b, I6B.<br>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.<br>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.<br>P14 Angulated Abutment Adapter is to be used with implant diameter 4.2mm and higher. |

With regard to differences in the indications for use between the subject and primary predicate:

- The list of two stage implants was updated to include the new endosseous implant product lines.
- Limitations for the 2.4 mm and 3.0 diameter implant bodies are not included because the subject devices do not contain any of that size.
- One stage indications were removed because the subject devices are only indicated for two stage.
- The indication for the P14 abutment was reduced to the standard platform implant diameter of 3.5 mm or larger based on the fatigue testing provided.

**Performance Data**

Fatigue testing per ISO 14801:2007 of the worst-case implant and abutment combination for the standard platform implants and abutments

Engineering analysis to determine if additional components constitute a new worst-case.

Cytotoxicity testing per ISO 10993-5 and biological risk assessment
Gamma sterilization validation per ISO 11137
Steam sterilization validation per ANSI/AAMI/ISO 17665-1:2006
Packaging validation and accelerated shelf-life testing
LAL testing in accordance with the FDA Guidance on Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile

**Substantial Equivalence**

The AB Dental Implant System has the same indications and similar technological characteristics and principles of operation as its predicate device. The minor technological differences between the AB Dental Implant Systems do not raise different issues. Performance data demonstrate that the AB Dental Implant System is substantially equivalent.

**Conclusions**

The AB Dental Implant System is substantially equivalent to the predicate device.