November 23, 2018

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

Re: K181381
Trade/Device Name: A.B. Dental Devices® Dental Implants System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 25, 2018
Received: October 25, 2018

Dear John J. Smith, M.D., J.D.:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement on last page

510(k) Number *(if known)*

K181381

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.

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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K181381
510(k) SUMMARY
A.B. DENTAL DEVICES® Dental Implants System

Sponsor:

A.B. Dental Devices Ltd.
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Ashdod 7761117
Israel

Contact Person:

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Date Prepared: November 23, 2018

Name of Device: A.B. Dental Devices® Dental Implants System
Common or Usual Name: Abutment, implant, dental, endosseous
Classification Name: Endosseous dental implant abutment; 21 CFR §872.3630,
Product Code: NHA

Predicate Devices

K162482 A.B. DENTAL DEVICES® Dental Implants System (primary)
K132125 A.B. DENTAL DEVICES® Dental Implants System (reference)
K112440, DENTAL DEVICES® Dental Implants System (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.

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:

- P0-3 narrow platform healing caps, 4 and 7 mm length
- P0N-3.75 standard platform, narrow healing caps, 4 and 7 mm length

- P3-5 standard platform, straight abutment, 5 mm diameter, 5 mm length
- P3S-3 narrow platform, anatomic, straight abutment, 1, 2, 3 mm shoulder lengths
- P3SW-3.75 standard platform, anatomic, straight abutment, wide diameter, 1, 2, 3 mm shoulder lengths
- P3W-3 narrow platform, straight abutment, wide diameter, 9 mm length
- P5-3 narrow platform, ball attachment abutment, 4, 5, 6 mm height
- P5-3.75-20 standard platform, 20º ball attachment abutment, 4 and 6 mm height
- P9HG-3.75 standard platform, composed abutment, gold alloy
- P9R and P9HR -3.75 standard platform, composed abutment, CoCr alloy
- P25-3 narrow platform, A.B. LOC abutments, 0, 1, 2, 3, 4 5 mm height
- P25-3.75 standard platform, A.B. LOC abutments, 0, 1, 2 mm height
- P64-3.75 standard platform, straight adaptor abutment, 1, 2, 3, 4, 5 mm heights
- P64 plastic and Ti alloy sleeve
- P64 healing cap
- PK standard platform, anatomic anti-rotation abutment, 1, 2, 3, 4 mm height
- PK plastic sleeve
- PK healing cap

Technological Characteristics Comparison

The purpose of this 510(k) is to expand the current product line to include two new abutments listed above. No substantive changes are being made to the indications as compared to the most recent clearance, and the indications are provided below. Aside for K112440, the indications differ only in respect to indications related to the specific components contained within each submission. K112440 has the same intended use as it allows for implantation in the same anatomic location and, when appropriate, for immediate loading. Comparison tables for each modification are provided below.

K181381	K162482	K132125	K112440
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.	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.	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	The AB Dental Devices implants are intended for surgical' placement in the maxillary mandibular arch to support crowns, bridges, or overdentures in edentulous or partially and/or edentulous patients. I7 Integral implant, I5 Conical implant, P12-T,L Temporary flat connection abutment, connection abutment, and P16 Straight adaptor are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

		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.	

1. Healing Caps (P0)

	Subject P0-3,(4,7)	**Predicate P0-3**	**Predicate P0-3.75**
K-number	K181381	K132125	K132125
Material	Ti-6Al-4V ELI with gold colored anodization	Ti-6Al-4V ELI with gold colored anodization	Ti-6Al-4V ELI
Diameter, mm	4.0	4.0	4.5
Platform	Narrow	Narrow	Standard
Length, mm	4, 7	2, 3, 5, 6	0.5 - 7
Design	Standard	Standard	Standard
Allowed angulation	No correction allowed	No correction allowed	No correction allowed
Sterility	Non-Sterile	Non-Sterile	Non-Sterile

	Subject P0N-3.75,(4,7)	**Predicate P0N-3.75**	**Predicate P0-3.75**
K-number	K181381	K132125	K132125
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Diameter, mm	3.75	3.75	4.5
Platform	Standard	Standard	Standard
Length, mm	4, 7	3, 5, 6	0.5 - 7
Design	Standard	Standard	Standard
Allowed angulation	No correction allowed	No correction allowed	No correction allowed
Sterility	Non-Sterile	Non-Sterile	Non-Sterile

2. Cement Retained, Straight Abutments (P3)

	Subject P3-5,5	**Predicate P3-5,(7,9)**
K-number	K181381	K162482
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Diameter, mm	5.0	5.0
Platform	Standard	Standard
Length, mm	5	7, 9
Design	Anti –rotation	Anti-rotation
Allowed angulation	No correction allowed	No correction allowed

Sterility	Non-Sterile	Non-Sterile

	Subject P3S-3	**Predicate P3S-3.75**	**Predicate P3-3**
K-number	K181381	K112440	K112440
Material	Ti-6Al-4V ELI with gold colored anodization	Ti-6Al-4V ELI	Ti-6Al-4V ELI with gold colored anodization
Diameter	4.5	4.5	4.5
Platform	Narrow	Standard	Narrow
Shoulder Height	1, 2, 3	1, 2, 3	
Design	Anatomic Anti-rotation	Anatomic Anti-rotation	Anti-rotation
Allowed angulation	No correction allowed	No correction allowed	No correction allowed
Sterility	Non-Sterile	Non-Sterile	Non-Sterile

	Subject P3S-Peek-3	**Predicate P3S-Peek-3.75**
K-number	K181381	K132125
Material	PEEK	PEEK
Diameter	4.5	4.5
Platform	Narrow	Standard
Shoulder Height	1, 2, 3	1, 2, 3
Design	Anatomic Anti -rotation	Anatomic Anti -rotation
Allowed angulation	No correction allowed	No correction allowed
Sterility	Non-Sterile	Non-Sterile

	Subject P3SW-3.75	**Predicate P3S-3.75**	**Predicate P3W-3.75**
K-number	K181381	K112440	K112440
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Diameter	5.5	3.75	5.5
Platform	Standard	Standard	Standard
Shoulder Height	1, 2, 3	1, 2, 3	
Design	Anatomic Anti –rotation Wide	Anatomic, Anti-rotation	Anti-rotation
Allowed angulation	No correction allowed	No correction allowed	No correction allowed
Sterility	Non-Sterile	Non-Sterile	Non-Sterile

	Subject P3W-3	**Predicate P3-3**	**Predicate P3W-3.75**
K-number	K181381	K112440	K112440
Material	Ti-6Al-4V ELI with gold color anodization	Ti-6Al-4V ELI with gold color anodization	Ti-6Al-4V ELI
Diameter	5.5	3.75	5.5
Platform	Narrow	Narrow	Standard
Length	9	9, 12	9, 12
Design	Anti-rotation	Anti-rotation	Anti-rotation

Allowed angulation	No correction allowed	No correction allowed	No correction allowed
Sterility	Non-Sterile	Non-Sterile	Non-Sterile

3. Overdenture Ball Attachment Abutments (P5)

	Subject P5-3,(4,5,6)	**Predicate P5-3,(1,2,3)**	**Predicate P5-3.75**
K-number	K181381	K132125	K132125
Material	Ti-6Al-4V ELI with gold color anodization	Ti-6Al-4V ELI with gold color anodization	Ti-6Al-4V ELI
Platform	Narrow	Narrow	Standard
Length, mm	4, 5, 6	1, 2, 3	1, 2, 3, 4, 5, 6
Design	Ball Attachment	Ball Attachment	Ball Attachment
Allowed angulation	No correction allowed	No correction allowed	No correction allowed
Sterility	Non-Sterile	Non-Sterile	Non-sterile

	Subject P5-3.75,20-(4,6)	**Predicate P5-3.75,20-(1,2,3,5)**
K-number	K181381	K132125
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Platform	Standard	Standard
Length, mm	4, 6	1, 2, 3, 5
Angle, °	20	20
Design	Ball Attachment	Ball Attachment
Sterility	Non-Sterile	Non-Sterile

4. Composed (UCLA) Abutments

	Subject P9R-3.75,11, P9HR-3.75,11	**Predicate P9-3.75,11, P9H-3.75,11**
K-number	K181381	K132125
Material	FWM 1058 Cobalt Chrome Alloy per ASTM F1058	Ti-6Al-4V ELI
Connection Method/Platform	Standard	Standard
Diameter, mm	3.75	3.75
Allowed angulation	No correction allowed	No correction allowed
Length, mm	11	11
Design	Composed Abutment	Composed Abutment
Sterility	Non-Sterile	Non-Sterile

	Subject P9HG-3.75,11	**Predicate P9G-3.75,11**	**Predicate P9H-3.75,11**
K-number	K181381	K132125	K132125
Material	Gold Alloy 6019	Gold Alloy 6019	Ti-6Al-4V
\Platform	Standard	Standard	Standard
Diameter, mm	3.75	3.75	3.75
Allowed	No correction allowed	No correction allowed	No correction allowed

angulation			
Length, mm	11	11	11
Design	Composed Hex Abutment	Composed Free Rotating Abutment	Composed Hex Abutment
Sterility	Non-Sterile	Non-Sterile	Non-Sterile

5. A.B. LOC Abutments (P25)

	Subject P25-3.75,(0,1,2)	**Predicate P25-3.75,(3,4,5,6,7)**
K-number	K181381	K132125
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Platform	Standard	Standard
Diameter, mm	3.75	3.75
Allowed angulation	No correction allowed	No correction allowed
Length, mm	0, 1, 2	3, 4, 5, 6, 7
Design	Integrated screw, attachment	Integrated screw, attachment
Sterility	Non-Sterile	Non-Sterile

	Subject P25-3	**Predicate P25-3.75**
K-number	K181381	K132125
Material	Ti-6Al-4V ELI with gold color anodization	Ti-6Al-4V ELI
Platform	Narrow	Standard
Diameter, mm	3	3.75
Allowed angulation	No correction allowed	No correction allowed
Length, mm	0, 1, 2, 3, 4, 5	3,4,5,6,7
Design	Integrated screw, attachment	Integrated screw, attachment
Sterility	Non-Sterile	Non-Sterile

6. P64 Straight Adaptor

	Subject P64-3.75	**Predicate P16-3.75**
K-number	K181381	K112440
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Platform	Standard	Standard
Allowed angulation	No correction allowed	No correction allowed
Height	1, 2, 3, 4, 5	1, 2, 3, 4, 5
Design	Integrated screw, screw retained	Integrated screw, screw retained
Sterility	Non-Sterile	Non-Sterile

	Subject P64b	**Predicate P14b**
K-number	K181381	K112440
Material	Delrin	Delrin
Connection Method/ Platform	Taper fit+ screw / P64 platform	Taper fit+ screw / P16 platform
Allowed angulation	No correction allowed	No correction allowed
Length, mm	10	10

Design	Plastic Sleeve for Adaptor	Plastic Sleeve for Adaptor
Sterility	Non-Sterile	Non-Sterile

	Subject P64-bT	**Predicate P14-bT**
K-number	K181381	K132125
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Connection Method/ Platform	Taper fit+ screw / P64 platform	Taper fit+ screw / P16 platform
Allowed angulation	No correction allowed	No correction allowed
Length, mm	12	12
Design	Titanium Sleeve for Adaptor	Titanium Sleeve for Adaptor
Sterility	Non-Sterile	Non-Sterile

	Subject P0-P64,5	**Predicate P0-P14**
K-number	K181381	K132125
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Connection Method/Platform	P64	P14/P16
Allowed angulation	No correction allowed	No correction allowed
Height	5	2.5, 4, 5, 7
Design	Temporary healing cap	Temporary healing cap
Sterility	Non-Sterile	Non-Sterile

7. PK Abutment

	Subject PK-P3-3.75	**Predicate P3-3.75**	**Predicate P3S-3.75,(1,2,3)**
K-number	K181381	K112440	K112440
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Connection Method/Platform	Standard	Standard	Standard
Allowed angulation	No correction allowed	No correction allowed	No correction allowed
Height/Length, mm	1, 2, 3, 4	5, 7, 9	1, 2, 3
Design	Anti-Rotation Abutment	Anti Rotation Abutment	Anatomic Anti-Rotation Abutment
Sterility	Non-Sterile	Non-Sterile	Non-Sterile

	Subject PK-P0-3.75	**Predicate P0-P14**
K-number	K181381	K132125
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Connection Method/Platform	PK	P14/P16
Allowed angulation	No correction allowed	No correction allowed
Height	N/A	2.5, 4, 5, 7
Design	Temporary healing cap	Temporary healing cap
Sterility	Non-Sterile	Non-Sterile

	Subject PK-P2-3.75	**Predicate P14b**
K-number	K181381	K112440
Material	Delrin	Delrin
Connection Method/ Platform	Taper fit/ PK platform	Taper fit+ screw / P16 platform
Allowed angulation	No correction allowed	No correction allowed
Length, mm	10	10
Design	Plastic Sleeve for Straight Adaptor	Plastic Sleeve for Adaptor
Sterility	Non-Sterile	Non-Sterile

	Subject PK-P2H-3.75	**Predicate P14b**
K-number	K181381	K112440
Material	Delrin	Delrin
Connection Method/ Platform	Taper fit/ PK platform	Taper fit+ screw / P16 platform
Allowed angulation	No correction allowed	No correction allowed
Length, mm	10	10
Design	Plastic Sleeve with Hex for Straight Adaptor	Plastic Sleeve for Adaptor
Sterility	Non-Sterile	Non-Sterile

Performance Data

- Engineering analysis to determine if additional components constitute a new worst-case.
- Biocompatibility testing per ISO 10993-1 per ISO 10993 as originally presented in K162482
- Cytotoxicity testing per ISO 10993-5
- Sterilization validation as per ANSI/AAMI/ISO 17665-1: 2006 as originally presented in K162482
- Fatigue testing as per ISO 14801 as originally presented in K162482

Substantial Equivalence

The A.B. Dental Devices® Dental Implants System has the same indications and similar technological characteristics and principles of operation as its predicate device. Performance data demonstrate that the A.B. Dental Devices® Dental Implants System is substantially equivalent.

Conclusions

The A.B. Dental Devices® Dental Implants System is substantially equivalent to the predicate device.