A.B. Dental Device Ltd.
% Nissim Shaked
RA Specialist
Nissim Shaked RA Specialist
17th Tel-Hay St.
Raanana, 4340525
ISRAEL

September 23, 2022

Re: K202144
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: August 1, 2022
Received: August 23, 2022

Dear Nissim Shaked:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202144

Device Name
A.B. Dental Devices® Dental Implants System

Indications for Use *(Describe)*
AB Dental CAD/CAM Base Abutments and Adhesive Sleeves are dental prosthetics placed onto a dental implant or screw retained abutment, to provide support for dental prosthetic restorations. The Base Abutments and Adhesive Sleeves include: Titanium bases/sleeves with a pre-machined implant connection or screw retained abutment connection on which the CAD/CAM designed upper structure may be fitted to complete a two-piece dental abutment. The Base Abutments and Adhesive Sleeves include an abutment/sleeve screw for fixation to the underlying implant/screw retained abutment.
These dental prosthetics may be used for single-unit (single-tooth) or multiple-unit (bridges and bars) restorations and are compatible for use with AB Dental Implants with internal connection and screw retained connections for standard and narrow platforms.
All digitally designed abutments and/or copings for use with AB Dental CAD/CAM Base Abutments and Adhesive Sleeves are intended to be sent to AB Dental validated milling center for manufacture.

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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510(K) SUMMARY
A.B. Dental Devices® CADCAM Products

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

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

Date Prepared: September 22, 2022

Name of Device: A.B. Dental Devices® Dental Implants System
Common or Usual Name: Base Abutment/ Adhesive sleeve
Classification Name: Endosseous dental implant abutment; 21 CFR §872.3630,
Product Code: NHA
Regulatory Class: Class II

Predicate Devices:

K181580 Cortex CAD/CAM Abutments

Device Description

A.B. Dental Devices® CADCAM Products consists of; Base Abutments and Adhesive Sleeves which are used with Standard Platform (Internal Hex connection) implants, Narrow Platform implants and Screw retained (P64 and P14/P16 MultiUnit) abutments.
Base Abutments (standard or narrow platform) and Adhesive Sleeves (screw retained abutment platform) are prefabricated abutments/sleeves made to be used as final abutments/ sleeves that will be used as adhesive connection (cement retained) of the prosthetic restoration on implant platform or on Multiunit platforms.
The design and manufacturing of the patient-specific abutments take into consideration the shape of the final prosthesis based on the patient's intra-oral scanning using CAD/CAM system during the manufacturing. All digitally designed abutments and/or copings for use with AB Dental CAD/CAM Base Abutments and Adhesive Sleeves are intended to be sent to AB Dental validated milling center for manufacture.
This submission adds the following Base Abutments and Adhesive sleeves:

Device	Description
Ti Base Anti-Rotational Abutments (Standard or Narrow platforms)	Base Abutment
Ti Base Rotational Abutments (Standard or Narrow platforms)	Base Abutment
P64 Ti Conical Adhesive Sleeve	Adhesive Sleeve
Ti Straight Adhesive Sleeves	Adhesive Sleeve

Base Abutments;

The titanium bases are used as part of a two-piece abutment, where the base is premanufactured from titanium alloy (Ti-6Al-4V ELI) and the top half is a CAD/CAM zirconia superstructure, milled at a validated milling center. These pieces are cemented together to form the final abutment.

- Raw material Zirconium blanks

  Dental Direkt Zirconia Blanks by Dental Direkt GmbH, cleared under K183569

- Dental Cement

  PANAVIA SA Cement Universal by Kuraray Noritake Dental Inc., cleared under K183537

Zirconia structure Details

Spec.	Zirconium Blank
Trade name	Dental Direkt Zirconia Blanks
Common name	Dental zirconia blanks/blocks
Manufacturer	Dental Direkt GmbH
510K number	K183569
Product code	EIH
Regulatory class	Class II
Intended use	DD cube ONE ML dental zirconia blanks are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both, anterior and posterior bridges.

Adhesive Sleeves

The adhesive sleeves are all Rotational (non-engage) for bridges restoration.
The adhesive sleeves are made of Titanium alloy (Ti-6Al-4V ELI) and will be installed on straight or angular screw-retained abutments.
The Multiunit (screw retained abutments already cleared devices) are P14/P16 platform and P64 platform:
The below listed devices are previously cleared items that the sleeves are intended to be used with:

Ref No.
P14-3,17-1
P14-3,17-3
P14-3,30-1
P14-3,30-3
P14-3.75,17-1
P14-3.75,17-3
P14-3.75,30-1
P14-3.75,30-3
P16-3.75,1
P16-3.75,2
P16-3.75,3
P16-3.75,4
P16-3.75,5
P64-3,1
P64-3,17-0.5
P64-3,17-2
P64-3,2
P64-3,3
P64-3,30-0.5
P64-3,30-2
P64-3.75,1
P64-3.75,2
P64-3.75,3
P64-3.75,4
P64-3.75,5
P64-3.75,17-0.5
P64-3.75,17-2
P64-3.75,17-3
P64-3.75,30-0.5
P64-3.75,30-2
P64-3.75,30-3

Indications for Use

AB Dental CAD/CAM Base Abutments and Adhesive Sleeves are dental prosthetics placed onto a dental implant or screw retained abutment, to provide support for dental prosthetic restorations. The Base Abutments and Adhesive Sleeves include: Titanium bases/sleeves with a pre-machined implant connection or screw retained abutment connection on which the CAD/CAM designed upper structure may be fitted to complete a two-piece dental abutment. The Base Abutments and Adhesive Sleeves include an abutment/sleeve screw for fixation to the underlying implant/screw retained abutment.

These dental prosthetics may be used for single-unit (single-tooth) or multiple-unit (bridges and bars) restorations and are compatible for use with AB Dental Implants with internal connection and screw retained connections for standard and narrow platforms.
All digitally designed abutments and/or copings for use with AB Dental CAD/CAM Base Abutments and Adhesive Sleeves are intended to be sent to AB Dental validated milling center for manufacture.

Technological Characteristics Comparison

	Subject Device	**Predicate**
Device Name	Base Abutment/ Adhesive Sleeves	Ti-Base Abutment 2-CONnect Abutment
510(k) number	K202144	K181580
Manufacture	A.B. Dental Devices Ltd.	Cortex Dental Implants Industries Ltd.
Classification	872.3630	872.3630
Indications for Use	AB Dental CAD/CAM Base Abutments and Adhesive Sleeves are dental prosthetics placed onto a dental implant or screw retained abutment, to provide support for dental prosthetic restorations. The Base Abutments and Adhesive Sleeves include: Titanium bases/sleeves with a pre-machined implant connection or screw retained abutment connection on which the CAD/CAM designed upper structure may be fitted to complete a two-piece dental abutment. The Base Abutments and Adhesive Sleeves include an abutment/sleeve screw for fixation to the underlying implant/screw retained abutment. These dental prosthetics may be used for single-unit (single-tooth) or multiple-unit (bridges and bars) restorations and are compatible for use with AB Dental Implants with internal connection and screw retained connections for standard and narrow platforms. All digitally designed abutments and/or copings for use with AB Dental CAD/CAM Base Abutments and Adhesive Sleeves are intended to be sent to AB Dental validated milling center for manufacture.	Cortex CAD/CAM Abutments are dental abutments placed onto a dental implant to provide support for dental prosthetic restorations. The abutments include: 1) Titanium abutment blanks with a pre-machined implant connection where the upper portion may be custom- milled in accordance with a patient-specific design using CAD/CAM techniques; and 2) Titanium bases with a pre-machined implant connection upon which a CAD/CAM designed superstructure may be fitted to complete a two-piece dental abutment. The abutments include an abutment screw for fixation to the underlying implant. The abutments may be used for single-unit (single-tooth) or multiple-unit (bridges and bars) restorations and are compatible for use with Cortex Dental Implants with internal hex-connection mating platform and conical connection platform diameters. All digitally designed abutments and/or copings for use with Cortex CAD/CAM Abutments are intended to be sent to a Cortex-validated milling center for manufacture. Cortex abutments designed using CAD/CAM techniques must fulfill the Cortex allowable range of design parameters.

The indications for the subject device and the indications cleared in K181580 are provided above.
The difference between the subject device and the predicate is that the highlighted sections were removed as this submission doesn't include the Titanium abutment blanks.
In addition, in the predicate devices the description of the Ti-Base refers also to screw retained sleeves (they refer to them as abutment or 2-component abutment).
The language was also adjusted to match AB Dental products throughout the text.

The sleeves are intended to be used with devices that are angled at 0°, 17°, and 30°.
No additional angulation provided by these sleeves or the CAD/CAM ceramic restorations.

The purpose of this traditional 510(k) is to expand the current product line to include the new abutments listed below. No substantive changes are being made to the indications.
Comparison tables for each modification are provided below.

1. Anti-Rotational Base Abutments (P3,TI)

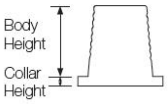
Spec.	**Subject P3-X,TI,XX ; P3H-X,TIT; (X=3.75 or 3) (XX=Different Lengths)**	**Predicate CORTEX**
510k number	K202144	K181580

Spec.	**Subject P3-X,TI,XX ; P3H-X,TIT; (X=3.75 or 3) (XX=Different Lengths)**	**Predicate CORTEX**
Diagram		
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Platform (Internal implant connection)	Standard Platform, Narrow platform	Internal Hex, Conical Connection
Diameter, mm	4.3, 5.2 4.3, 5.2	5.2
Overall Length, mm	6.45 ,7.85 ,8.85, 7.05 6.8, 8.0, 9.0, 7.3	Internal Hex Collar Height:1, 3 Body Height: 4 Conical Connection Collar Height:1, 2, 3 Body Height: 4
Angulation	Minimum and Maximum abutment angle (°): Straight structure with 0° angle	Minimum and Maximum abutment angle (°): Straight structure with 0° angle
Design	Anti–rotation	Anti–rotation
Zirconia	FDA Cleared Zirconia To be manufactured by validated milling center	FDA Cleared Zirconia To be manufactured by validated milling center
Sterility	End user sterilized	End user sterilized

2. Rotational Base Abutment (P3, TIT)

Spec.	**Subject P3N-X,TIT,XX ; P3-X,TIT; (X=3.75 or 3) (XX=Different Lengths)**	**Predicate CORTEX**
Picture		
510k number	Subject	K181580
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Platform (Internal implant connection)	Standard Platform, Narrow platform	Internal Hex, Conical Connection
Diameter, mm	4.3, 5.2 4.1, 5.2	4.6
Overall Length, mm	6.85 ,7.29 ,8.29, 6.85	Internal Hex Collar Height:1, 3 Body Height: 4 Conical Connection Collar Height:1, 2, 3 Body Height: 4
Angulation	Minimum and Maximum abutment angle (°): Straight structure with 0° angle	Minimum and Maximum abutment angle (°): Straight structure with 0° angle
Design	Rotational (Non engaging)	Rotational (Non engaging)
Zirconia	FDA Cleared Zirconia To be manufactured by validated milling center	FDA Cleared Zirconia To be manufactured by validated milling center
Sterility	End user sterilized	End user sterilized

3. Adhesive Sleeves - Cement Retained, Non-Angled Sleeves (P64, P14)

Spec.	Subject: P64 and P14 Adhesive Sleeves	Predicate CORTEX (refer Multi Unit Ti-Base)
Diagram	 (P14-bTs)  (P64-bTs-C)	 
510k number	Subject	K181580
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Platform (screw retained connection)	P64 P14	Multiunit 2-CONnect
Diameter, mm	4.9 4.4	5
Length, mm	5.5	Collar Height:0.3, 0.7 Body Height: 4
Design	Sleeve	Sleeve
Sterility	End user sterilized	End user sterilized

Performance Data

Non-clinical data submitted to demonstrate substantial equivalence included:

- Engineering analysis to determine if additional components constitute a new mechanical worst-case.
- Cytotoxicity testing per ISO 10993-5 (Nelson Lab. Study Number 1502319-S01).
- Fatigue testing at 40° per ISO 14801 on the two worst case constructs of the subject submission.
- Sterilization validation according to ANSI/AAMI/ISO 17665 (Sterilization of health care products- Moist heat- Part 1 and 2, ISO 11138- Sterilization of health care products- Biological indicators – Part 1, 3 and 7)
- The conducted MRI testing conducted per standards listed hereunder demonstrates that the claimed products are MR Conditional:
  - ASTM F2052-21 (Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment)
  - ASTM F2213-17 (Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment)
  - ASTM F2182-19 (Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging)
  - ASTM F2119-2013 (Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants)

  A patient with this device can be scanned safely in an MR system under the conditions as stated in the labeling (Recommended MRI labeling based on the document; American Society of Testing and Materials, International, ASTM F2503-20. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, Guidance for Industry and Food and Drug Administration Staff, Document issued on May 20, 2021.)

No clinical data were included in this submission.

Conclusions

Based on the data included in this submission, A.B. Dental Implants System is substantially equivalent in indication and design principles to the predicate device indicated above.