July 15, 2019

A.B. Dental Device Ltd.
% John Smith
Partner
Hogan Lovells US LLP
555 13th Street
Washington, District of Columbia 20004

Re: K182455
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: June 18, 2019
Received: June 18, 2019

Dear 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. 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,

for Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement on last page

510(k) Number *(if known)*
K182455

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.

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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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K182455
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: July 15, 2019

Trade Name:	A.B. DENTAL DEVICES® Dental Implants System
Common or Usual Name:	Abutment, implant, dental, endosseous
Classification:	21 CFR §872.3630 Endosseous dental implant abutment
Product Code:	NHA

Predicate Devices
K162482 A.B. DENTAL DEVICES® Dental Implants System (primary)
K131215 A.B. DENTAL DEVICES® Dental Implants System (reference)
K112440, DENTAL DEVICES® Dental Implants System (reference)
K111357 Straumann Crossfit SLA 3.3 mm (reference)

Device Description
A.B. DENTAL DEVICES® Dental Implants System consists of narrow (XXX-3 model number) and standard (XXX-3.75 model number) platform internal hex implants that are used with screw retained, cement retained, or overdenture abutments. This submission adds the following abutments:

- Expansion of the P4 angled abutments to include:
  - Narrow platform abutments (standard and long lengths, 15 and 25 degrees)
  - Narrow platform, anatomic abutments (15 degrees)
  - Additional standard platform abutments (15 and 25 degrees)
  - Additional standard platform, anatomic abutments (15 and 25 degrees)
- Expansion of the P5 ball attachments to include narrow platform, 20 degree abutments
- Expansion of the P14 multiunit, angled abutments to include:
  - Additional sleeve materials (Delrin and CoCr)
  - Narrow platform abutments (17 and 30 degrees)
  - P25 AB LOC for angular adaptor
- Addition of P64 multiunit, straight and angled product line (narrow and standard platform, 17 and 30 degrees, with Delrin and Ti alloy sleeves), including its healing cap.
- Modification to the P4a-S screw to improve its performance characteristics

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.

Technological Characteristics Comparison

K162482 Indications	K182455 Indications
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.

The indications for the subject device and the indications cleared in K162482 are provided above. The only difference is the highlighted text which details a subset of AB Dental implants that were the subject of K162482 and compatibility limitations for the angled P4 and P14 abutments. The reference device Indications for Use do not include any component-specific additional language which would apply to the subject devices and therefore are not included in this comparison. In comparison to K162482, the subject device only differs in respect to indications related to the specific components contained within each submission. As K162482 dealt with implants (I22, I5, I10) specific instruction related to these devices are contained in the indications but are omitted from this submission which does not modify these devices. The limitation to P4 and P14 abutments is also being removed, as this submission contains the required information to support use of angled abutments with narrow platform implants.

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. Cement Retained, Angled Abutments (P4)

	Subject P4-3,(15 and 25)	**Predicate P4L-3.75,25**
510(k) Number	Subject	K162482
Material	Ti-6Al-4V ELI with gold colored anodization	Ti-6Al-4V ELI
Diameter, mm	4.23, 4.21	5.43

Platform	Narrow	Standard
Angulation, º	15, 25	25
Length, mm	8.3, 8.7	13.08
Design	Anti–rotation	Anti-rotation, Long
Loading	Single unit	Single unit
Sterility	Non-Sterile	Non-Sterile

Both standard length and long length narrow platform P4 abutments are being added as part of this 510(k). As their geometry is identical aside for differences in length, the standard length abutments are less worst-case than the long. Material, manufacturing methods (aside from color anodization), and sterility are identical between the subject and predicate device. The same color anodization has been cleared on other abutments in K162482.

	Subject P4-3.75,(15 and 25)	**Predicate P4L-3.75,25**
510(k) Number	Subject	K162482
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Diameter, mm	4.59, 4.68	5.43
Platform	Standard	Standard
Angulation, º	15, 25	25
Length, mm	9.05, 8.95	13.08
Design	Anti–rotation	Anti-rotation, Long
Loading	Single unit	Single unit
Sterility	Non-Sterile	Non-Sterile

The two abutments have the same design, and differ only in length. As the subject abutments have a shorter length, they have a shorter moment arm and do not create a new worst-case. Material, manufacturing methods, and sterility are identical between the subject and predicate device.

	Subject P4-3.75,15st	**Predicate P4-3.75,25st**
510(k) Number	Subject	K162482
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Diameter, mm	4.7	4.2
Platform	Standard	Standard
Angulation, º	15	25
Length, mm	9.15	9.15
Design	Anti–rotation, Straight	Anti-rotation, Straight
Loading	Single unit	Single unit
Sterility	Non-Sterile	Non-Sterile

The geometries are identical except for the lower angulation, which does not present a new worst-case. Material, manufacturing methods, and sterility are identical between the subject and predicate device.

	Subject P4L-3,(15 and 25)	**Predicate P4L-3.75,25**
510(k) Number	Subject	K162482

Material	Ti-6Al-4V ELI with gold colored anodization	Ti-6Al-4V ELI
Diameter, mm	4.53	5.43
Platform	Narrow	Standard
Angulation, º	15, 25	25
Length, mm	13.35	13.08
Design	Anti–rotation, Long	Anti-rotation, Long
Loading	Single unit	Single unit
Sterility	Non-Sterile	Non-Sterile

The subject device is similar to the predicate; however, small geometric differences, including a narrower platform, is addressed through bench testing. Material, manufacturing methods (aside from color anodization), and sterility are identical between the subject and predicate device. The same color anodization has been cleared on other abutments in K162482.

	Subject P4S-3,15-(1,2,3)	**Predicate P4S-3.75,15-(1,3)**
510(k) Number	Subject	K162482
Material	Ti-6Al-4V ELI with gold colored anodization	Ti-6Al-4V ELI
Diameter, mm	4.1, 4.4, 4.4	4.3, 4.9
Platform	Narrow	Standard
Angulation, º	15	15
Length, mm	8.05, 9.2, 10.25	8.25, 9.8
Shoulder Height, mm	1, 2, 3	1, 3
Design	Anti–rotation, Anatomic	Anti-rotation, Anatomic
Loading	Single unit	Single unit
Sterility	Non-Sterile	Non-Sterile

The subject device is similar to the predicate; however, small geometric differences, including a narrower platform, is addressed through bench testing. Material, manufacturing methods (aside from color anodization), and sterility are identical between the subject and predicate device. The same color anodization has been cleared on other abutments in K162482.

	Subject P4S-3.75,15-2	**Predicate P4S-3.75,15-(1,3)**
510(k) Number	Subject	K162482
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Diameter, mm	4.5	4.3, 4.9
Platform	Standard	Standard
Angulation, º	15	15
Length, mm	9.4	8.25, 9.8
Shoulder Height, mm	2	1, 3
Design	Anti–rotation, Anatomic	Anti-rotation, Anatomic
Loading	Single unit	Single unit

Sterility	Non-Sterile	Non-Sterile

The addition of an intermediate shoulder length does not create a new worst-case. Material, manufacturing methods, and sterility are identical between the subject and predicate device.

	Subject P4S-3.75,25-(1,2,3)	**Predicate P4S-3.75,15-(1, 3)**	**Predicate P4L-3.75,25**
510(k) Number	Subject	K132125	K162482
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Diameter, mm	5, 4.92, 4.83	4.3, 4.9	5.43
Platform	Standard	Standard	Standard
Angulation, º	25	15	25
Length, mm	7.95, 9.1, 10.3	8.25, 9.8	13.08
Shoulder Height, mm	1, 2, 3	1, 3	N/A
Design	Anti–rotation, Anatomic	Anti–rotation, Anatomic	Anti-rotation, Long
Loading	Single unit	Single unit	Single unit
Sterility	Non-Sterile	Non-Sterile	Non-Sterile

These abutments are similar in design to the predicate P4S-3.75,15-(1,3) abutments and differ only in that they have a 25° angulation while the predicate abutments have 15° angulation. None-the-less, an engineering rationale shows that the new abutments do not create a new-worst as compared to the previously cleared P4L-3.75,25 abutment. Specifically, while the angulation between the P4S-3.75,25 and the P4L-3.75,25 abutments are the same, the subject P4S abutment is 2.5 mm shorter, and therefore has a shorter moment arm as compared to the predicate P4L-3.75,25 abutment. Material, manufacturing methods and sterility are identical between the subject and predicate device.

	Subject P4SW-3.75,3	**Predicate P4L-3.75,25**
510(k) Number	Subject	K162482
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Diameter, mm	5.3	5.43
Platform	Standard	Standard
Angulation, º	15	25
Length, mm	11.4	13.08
Shoulder Height, mm	3	N/A
Design	Anti–rotation, Anatomic, Wide	Anti-rotation, Long
Loading	Single unit	Single unit
Sterility	Non-Sterile	Non-Sterile

An engineering rationale shows that the angulation and length of the subject abutment is less than predicate, resulting in a shorter moment arm. Further, the wide diameter abutment has more material than a standard diameter abutment. Therefore, this abutment does not create a new, worst-case. Material, manufacturing methods, and sterility are identical between the subject and predicate device.

2. Overdenture Ball Attachment Abutments (P5)

	Subject P5-3,20-(1.5,3,4,5)	**Predicate P5-3.75,20-(1,2,3,5)**
510(k) Number	Subject	K132125
Material	Ti-6Al-4V ELI with gold colored anodization	Ti-6Al-4V ELI
Platform	Narrow	Standard
Length, mm	1.5, 3, 4, 5	1, 2, 3, 5
Angle, °	20	20
Design	Ball Attachment	Ball Attachment
Loading	Multi-unit	Multi-unit
Sterility	Non-Sterile	Non-Sterile

The subject device is similar to the predicate; however, small geometric differences, including a narrower platform, is addressed through bench testing. Material, manufacturing methods (aside from color anodization), and sterility are identical between the subject and predicate device. The same color anodization has been cleared on other abutments in K162482.

3. Multiunit Angular Adaptor (P14)

	Subject P14-3,17-(1 and 3) and **P14-3,30-(1 and 3)**	**Predicate P14-3.75,17-(1 and 3)** and **P14-3.75,30-(1 and 3)**	**Predicate Straumann Crossfit SLA 3.3 mm**
510(k) Number	Subject	K132125	K111357
Material	Ti-6Al-4V ELI with gold colored anodization	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Platform	Narrow	Standard	Narrow
Shoulder Height, mm	1, 3	1, 3	2.5, 4, 5.5
Angle, °	17, 30	17, 30	17, 30
Design	Multi-unit	Multi-unit	Multi-unit
Loading	Multi-unit	Multi-unit	Multi-unit
Sterility	Non-Sterile	Non-Sterile	Non-Sterile

Dynamic testing of the worst-case narrow platform construct shows the abutment is substantially equivalent to the Straumann Crossfit SLA 3.3 mm (K111357) which has similar dimensions and materials. Material, manufacturing methods and sterility (aside from color anodization) are identical between the subject and predicate device. The same color anodization has been cleared on other abutments in K162482.

	Subject P14b	**Predicate P14b**	**Predicate P14-bG**
510(k) Number	Subject	K112440	K132125
Material	Delrin	Delrin	6019 Gold Alloy + Delrin
Connection Method/ Platform	Taper fit+ screw / P14 platform	Taper fit+ screw / P16 platform	Taper fit+ screw / P14 platform
Angle, °	Mounts to 17^0, 30^0 or straight (0^0) P16	Mounts straight (0^0) P16	Mounts to 17^0, 30^0 or straight (0^0) P16
Length, mm	10	10	10
Design	Plastic Sleeve for Angled Adaptor	Plastic Sleeve for Straight Adaptor	Composed Sleeve for Angled Adaptor
Loading	Multi-unit	Multi-unit	Multi-unit
Sterility	Non-Sterile	Non-Sterile	Non-Sterile

This sleeve has been previously cleared for use with the P16 straight abutment (cleared in K112440) and this submission seeks to expand its use with the angled P14 abutment. These sleeves are comparable to the P14-bG composed sleeves cleared for use with the P14 in K132125, except that the entire sleeve is made from plastic that is replaced with metal. Material, manufacturing methods, and sterility are identical for the subject and predicate device.

	Subject P25-P14(1,2)	**Predicate P5-P14(1,2)**	**Predicate P25-3.75**
510(k) Number	Subject	K132125	K132125
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Connection Method/ Platform	Screws into P14 platform	Screws into P14 platform	Standard
Angle, °	Mounts to 17, 30	Mounts to 17, 30	0
Length, mm	1, 2	1, 2	3 - 7
Design	AB LOC for Angular Adaptor	Ball Attachment for Angular Adaptor	AB LOC Abutment
Loading	Multi-unit	Multi-unit	Multi-unit
Sterility	Non-Sterile	Non-Sterile	Non-Sterile

These abutments are similar in design to the predicate P5-P14 abutments in that both allow the P14 base to be used the proximal portion of another implant. For the predicate P5-P14 abutment, connection is made to a P5 abutment, while the subject device allows connection to a P25 abutment. The proximal geometry of the P25-P14 is identical to the proximal geometry of the P25 abutments cleared in K132125 and is compatible with the same class I exempt silicone caps. Material, manufacturing methods and sterility are identical between the subject and predicate device.

4. Single Unit Straight and Angled Adaptor (P64)

	Subject P64-3,(1,2,3)	**Predicate P16-3.75**

510(k) Number	Subject	K112440
Material	Ti-6Al-4V ELI with gold colored anodization	Ti-6Al-4V ELI
Platform	Narrow	Standard
Angle, °	N/A	N/A
Height	1, 2, 3	1, 2, 3, 4, 5
Design	Integrated screw, screw retained	Integrated screw, screw retained
Loading	Single unit	Single unit
Sterility	Non-Sterile	Non-Sterile

Both systems contain an integrated screw to connect to standard platform implants and are made from Ti-6Al-4V ELI. The subject and predicate P64 have heights that vary from 1 – 3 mm. The subject device is contained within the same height range as the predicate and does not create a new worst-case. Material (aside from color anodization), manufacturing methods, and sterility are identical for the subject and predicate device. The same color anodization has been cleared on other abutments in K162482.

	Subject P64-3,17-(0.5 and 2) and **P64-3,30-(0.5 and 2)**		**Predicate Straumann Crossfit SLA 3.3 mm**
510(k) Number	Subject		K111357
Material	Ti-6Al-4V ELI with gold colored anodization		Ti-6Al-4V ELI
Platform	Narrow		Narrow
Shoulder Height, mm	0.5, 2		2.5, 4, 5.5
Angle, °	17, 30		17, 30
Design	Single-unit		Multi-unit
Loading	Multi-unit		Multi-unit
Sterility	Non-Sterile		Non-Sterile

Dynamic testing of the worst-case narrow platform construct shows that the narrow platform abutment is substantially equivalent to the Straumann Crossfit SLA 3.3 mm (K111357) which has similar dimensions and materials. Material, manufacturing methods (aside from color anodization) and sterility are identical between the subject and predicate device. The same color anodization has been cleared on other abutments in K162482.

	Subject P64-3.75,17-(0.5, 2, and 3) and **P64-3.75,30-(0.5, 2, and 3)**	**Predicate P14-3.75,17-(1 and 3)** and **P14-3.75,30-(1 and 3)**
510(k) Number	Subject	K132125
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Platform	Standard	Standard
Shoulder Height, mm	0.5, 2, 3	1, 3
Angle, °	17, 30	17, 30

Design	Single-unit	Multi-unit
Loading	Multi-unit	Multi-unit
Sterility	Non-Sterile	Non-Sterile

These abutments are similar in design to the predicate P14 abutments except that they are monolithic single-units while the predicate P14 abutments are composed of two different parts. Both abutments are intended for multi-unit loading and have the same maximum shoulder height and angulations. Dynamic testing of the worst-case narrow platform construct shows the P64-3.75 to be equivalent to the standard platform P14 abutment. Material, manufacturing methods and sterility are identical between the subject and predicate device.

	Subject P64b	**Predicate P14b**
510(k) Number	Subject	K112440
Material	Delrin	Delrin
Connection Method/ Platform	Taper fit+ screw / P64 platform	Taper fit+ screw / P16 platform
Angle, °	Mounts to 17^0, 30^0 or straight (0^0)	Mounts to straight (0^0) P16
Length, mm	10	10
Design	Plastic Sleeve for Angled Adaptor	Plastic Sleeve for Straight Adaptor
Loading	Multi-unit	Multi-unit
Sterility	Non-Sterile	Non-Sterile

The two sleeves primarily differ in their distal geometry so that they fit their respective compatible abutments. Material, manufacturing methods and sterility are identical for the subject and predicate device.

	Subject P64-bT	**Predicate P14-bT**
510(k) Number	Subject	K132125
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Connection Method/ Platform	Taper fit+ screw / P64 platform	Taper fit+ screw / P14 platform
Angle, °	Mounts to 17^0, 30^0 or straight (0^0)	Mounts to 17^0, 30^0 or straight (0^0) P16
Length, mm	12	12
Design	Metal Sleeve for Angled Adaptor	Metal Sleeve for Angled Adaptor
Loading	Multi-unit	Multi-unit
Sterility	Non-Sterile	Non-Sterile

The two sleeves primarily differ in their distal geometry so that they fit their respective compatible abutments. Its addition is supported by the same information as the P64 abutment itself, as the two are evaluated together via dynamic testing. Material, manufacturing methods and sterility are identical for the subject and predicate device.

	Subject P0-P64,5	**Predicate P0-P14,(5 and 7)**
510(k) Number	Subject	K132125
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Connection Method/Platform	P64	P14/P16
Angle, °	N/A	N/A
Height	5	5, 7
Design	Temporary Healing Cap	Temporary Healing Cap
Sterility	Non-Sterile	Non-Sterile

The caps differ with respect to their abutment mating geometry to match their respective abutments. The subject cap is only available in 5 mm height, while the predicate is available in additional shorter and longer heights. Material, manufacturing methods, and sterility are identical for the subject and predicate device.

Performance Data

- Engineering analysis to determine if additional components constitute a new mechanical worst-case.
- Testing per ISO 14801 in air on the worst-case construct.
- Static torque to failure testing of modified P4a-S screw. In addition, static and dynamic testing per ISO 14801 in the same construct was conducted.
- Scientific rationale to determine if additional components constitute a new cleaning or sterility worst-case
- Application of ISO 10993-1 to justify that biocompatibility testing was not needed as materials and manufacturing methods are identical to the sponsor's own predicate
- Sterilization validation per ISO 17665

Substantial Equivalence

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

Conclusions

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