Bio Concept Co., Ltd
% Diana Hong
General Managr
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

August 10, 2022

Re: K212364
Trade/Device Name: BTL Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 13, 2022
Received: July 11, 2022

Dear Diana Hong:

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)*
K212364

Device Name
BLT Dental Implant System

Indications for Use *(Describe)*
BLT Dental Implant Systems are intended to be placed in the upper and lower jaw to support prosthetic devices and to restore a patient's chewing function. BLT Dental Implant systems are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Tab # 6 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K212364

1. Date of Preparation: 08/09/2022

2. Sponsor Identification

BIO CONCEPT CO., LTD
Unit C, No.26, Huashan Middle Road, Xinbei Zone, Changzhou, Jiangsu 213022, China
Establishment Registration Number: 3012465917

Contact Person: Tianshui Li
Position: General Manager
Tel: +86-519-85172266
Fax: +86-519-85172299
Email: daixiaodong@bioconcept.cn

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: BLT Dental Implant System
Common Name: Endosseous dental implant

Regulatory Information
Classification Name: Endosseous implant
Classification: II
Regulation Number: 21 CFR 872.3640
Primary Product Code: DZE
Secondary Product Code: NHA
Review Panel: Dental

Indications for Use

BLT Dental Implant Systems are intended to be placed in the upper and lower jaw to support prosthetic devices and to restore a patient's chewing function. BLT Dental Implant systems are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.

Device Description

The proposed devices, BLT Dental Implant Systems, are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. The proposed devices can also be used for immediate or early implantation following extraction or loss of natural teeth.

The proposed device contains dental implant, healing cap and abutment. The dental implant system is available in two types, NC type and RC type.

Table 1. Body Size of Dental Implants (Unit: mm)

Ref	Name	Type	Diameter	Length
115010	Implant	NC	Φ3.38±0.1	8.1±0.2
115020	Implant	NC	Φ3.38±0.1	10.1±0.2
115030	Implant	NC	Φ3.38±0.1	12.1±0.2

115040	Implant	NC	Φ3.38±0.1	14.1±0.2
115050	Implant	NC	Φ3.38±0.1	16.1±0.2
115060	Implant	NC	Φ3.38±0.1	18.1±0.2
116010	Implant	RC	Φ4.15±0.1	8.2±0.2
116020	Implant	RC	Φ4.15±0.1	10.2±0.2
116030	Implant	RC	Φ4.15±0.1	12.2±0.2
116040	Implant	RC	Φ4.15±0.1	14.2±0.2
116050	Implant	RC	Φ4.15±0.1	16.2±0.2
116060	Implant	RC	Φ4.15±0.1	18.2±0.2
117010	Implant	RC	Φ4.8±0.1	8.2±0.2
117020	Implant	RC	Φ4.8±0.1	10.2±0.2
117030	Implant	RC	Φ4.8±0.1	12.2±0.2
117040	Implant	RC	Φ4.8±0.1	14.2±0.2
117050	Implant	RC	Φ4.8±0.1	16.2±0.2
117060	Implant	RC	Φ4.8±0.1	18.2±0.2

The healing cap can be divided into closure screw, healing abutment and protective Cap. Abutment can be divided into anatomic abutment, meso abutment, cementable abutment, equator abutment, Screw-retained abutment and coping. And it is available in NC, RC, crown, bridge, A Type and B Type.

5. Identification of Predicate Device

510(k) Number: K150388
Product Name: Dental Implant System
Manufacturer: BIO CONCEPT CO., LTD.

6. Identification of Reference Devices

Reference Device 1
510(k) Number: K153758
Device Name: Straumann Bone Level Tapered Implants
Manufacturer: INSTITUT STRAUMANN AG

Reference Device 2
510(k) Number: K072071
Device Name: STRAUMANN P.004 CEMENTABLE ABUTMENTS, TEMPORARY COPINGS AND PROTECTIVE CAPS
Manufacturer: Institut Straumann AG

Reference Device 3
510(k) Number: K080286
Device Name: CEMENTABLE ABUNTMENTS; TEMPORARY COPINGS; PROTECTIVE CAPS
Manufacturer: STRAUMANN USA

Reference Device 4
510(k) Number: K093027
Device Name: STRAUMANN RC TEMPORARY ABUTMENTS
Manufacturer: STRAUMANN USA

Reference Device 5
510(k) Number: K192401
Device Name: Straumann Screw-Retained Abutments
Manufacturer: Straumann USA, LLC

Reference Device 6
510(k) Number: K171757
Device Name: Straumann Screw Retained Abutments
Manufacturer: Straumann USA, LLC (On Behalf Of Institut Straumann AG)

Reference Device 7
510(k) Number: K182091
Device Name: Osstem Abutment System
Manufacturer: Osstem Implant Co., Ltd.

Reference Device 8
510(k) Number: K130808
Device Name: STRAUMANN HEALING ABUTMENTS, HEALING CAPS, CLOSURE SCREWS
Manufacturer: STRAUMANN USA

Reference Device 9
510(k) Number: K071585
Device Name: P.004 HEALING ABUTMENTS AND CLOSURE SCREWS
Manufacturer: STRAUMANN USA

Reference Device 10
510(k) Number: K133421
Device Name: STRAUMANN MAGELLAN(TM) ABUTMENT,PROTECTIVE CAP,TITANIUM COPINGS,GOLD CHOPINGS,BASAL SCREW
Manufacturer: STRAUMANN USA, LLC

Reference Device 11
510(k) Number: K171409
Device Name: OT EQUATOR
Manufacturer: Rhein'83 SRL

Reference Device 12
510(k) Number: K161689
Device Name: OSSTEM Implant System - Abutment
Manufacturer: OSSTEM IMPLANT Co., Ltd.

Reference Device 13
510(k) Number: K092814
Device Name: STRAUMANN DENTAL ABUTMENTS
Manufacturer: STRAUMANN MANUFACTURING, INC.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate device and reference devices.

Mechanical test was performed on both the proposed device and prediate device according to FDA guidance and ISO 14801. The test result does not show any significant difference.

The patient contact materials of the proposed device, BLT Dental Implant System, are identical to the material of BV Dental Implant System as it was cleared in K192274 in 06/18/2020. in formulation, processing and sterilization, and no other chemicals have been added. (e.g., plasticizers, filters, color additives, cleaning agents, mold release agents, etc.). Therefore, new biocompatibility test were not conducted on the proposed device.

The subject dental implant were sterilized by irradiation to achieve a SAL of 10^{-6} and the sterilization method was validated in accordance ISO 11137-2. Vacuum leak test and sterility test were provided to verify the package integrity.The package process for the proposed device is same as Dental Implant System as it was cleared in K150388 in 11/12/2015. Therefore, new package integrity test was not conducted on the proposed device. Besides, bacteria endotoxin limit were evaluated for the each lot device.

The modified surface for the proposed device is same as Dental Implant System as it was cleared in K150388 in 11/12/2015 which is also manufactured by the sponsor. Therefore, the chemical analysis of the surface will leverage on the test report performed on the device K150388 instead of performing a new test.

The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro Cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical Devices-Part 10: Test for irritation and skin sensitization
- ISO 10993-11:2017, Biological evaluation of medical Devices-Part 11: Test for systemic toxicity
- ISO 14801:2016 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants
- USP <85> Bacterial Endotoxin Test
- ASTM F136-13, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F67-13 (Reapproved 2017), Standard Specification for Unalloyed Titanium for Surgical Implant Applications
- ISO 11137-2:2013 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

- AAMI TIR 30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- USP <85> Bacterial Endotoxins Test
- ASTM F1980-07(2011) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D3078-02(2013) Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- ISO 11737-2: 2009 Sterilization of edical Devices-Microbiological Methods-Part 2: Tests of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process.
- ISO 11137-1:2006 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F2096-11 (Reapproved 2019) Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Summary of Technological characteristics

Table 2. Characteristic Comparison for Implant

ITEM	Proposed Device	Predicate Device K150388	Reference Device 1 K153758	Remark
Product Code	DZE	DZE	DZE	Same
Regulation No.	872.3640	872.3640	872.3640	Same
Classification	II	II	II	Same
Indication for use	BLT Dental Implant systems are intended to be placed in the upper and lower jaw to support prosthetic devices and to restore a patient's chewing function. BLT Dental Implant systems are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the	Dental implant systems are intended to be placed in the upper and lower jaw to support prosthetic devices and to restore a patient's chewing function. Dental implant systems are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components	Straumann® Bone Level Tapered Implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann Bone Level Tapered Implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial	Different

	corresponding components (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.	(abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.	or full dentures, which are connected to the implants by the corresponding elements (abutments).	
Surgery type	One or two stage Surgery	One or two stage Surgery	One or two stage Surgery	Same
Structure	- Internal Crossfit connected - Submerged Implant - Tapered body shape - 3 sided cutting edge with self-tapping	- Internal Crossfit connected - Submerged Implant - Straight body shape	- Internal Crossfit connected - Submerged Implant - Straight body shape	Same
Coronal Thread Form	Constant major and minor thread diameters (i.e., parallel wall) 0.8mm thread pitch	Constant major and minor thread diameters (i.e., parallel wall) 0.8mm thread pitch	Constant major and minor thread diameters (i.e., parallel wall) 0.8mm thread pitch	Same
Apical Thread Form	Angled major and minor thread diameters (i.e., tapered wall), with the major and minor diameters have differing angles such that the depth increases toward the apical end of the implant and the addition of cutting flutes. 0.8mm thread pitch	Constant major and minor thread diameters (i.e., parallel wall) 0.8mm thread pitch	Constant major and minor thread diameters (i.e., parallel wall) 0.8mm thread pitch	Different
Body Diameter (D)	Ø3.3mm, Ø4.1mm, Ø4.8mm	Ø3.3mm, Ø4.1mm, Ø4.8mm	Ø3.3mm, Ø4.1mm, Ø4.8mm	Same
Implant Length	8, 10, 12, 14, 16, 18mm	8, 10, 12, 14mm	18 mm	Different
Material of	Pure Titanium	Pure Titanium	Titanium zirconium alloy	Different

Fixture				
Surface	Sand blasted and acid etched	Sand blasted and acid etched	Sand blasted and acid etched	Same
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile	Same
Shelf life	5 years	5 years	/	Same

Different – Indication for Use

The indications for use for the proposed device is the same as that of the predicated device. In addition, although the description of indications for use for the proposed device is different from that of the reference device K153758, in fact their indications for use is the same. Therefore, this difference will not affect substantially equivalence on safety and effectiveness.

Different - Apical Thread Form

The difference in structure does not affect intended use, in addition, mechanical test has been conducted on the proposed device and predicate device and the test result does not show any significant difference. Therefore, this difference will not affect substantially equivalence on safety and effectiveness.

Different - Implant Length

The implant length range of the proposed device can be covered by the predicated device and reference device K153758. Therefore, this difference will not affect substantially equivalence on safety and effectiveness.

Different - Material of Fixture

The material of fixture of the proposed device is the same as that of the predicated device. Therefore, this difference will not affect substantially equivalence on safety and effectiveness.

Table 3. Characteristic Comparison of Abutment and healing cap

Anatomic Abutment				
ITEM	Proposed Device	Reference Device K072071	Reference Device K080286	Remark
Indications for Use	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.	Same
Principle of Operation	Using making for general cement-type prosthesis.	Using making for general cement-type prosthesis.	Using making for general cement-type prosthesis.	Same
Interface Type	Engaging	Engaging	Engaging	Same
Angle	0°, 15°	0°, 15°	0°, 15°	Same
Gingiva Height (mm)	2, 3.5	2, 3.5	2, 3.5	Same
Material	Titanium alloy	Titanium alloy	Titanium alloy	Same
Cementable Abutment				
ITEM	Proposed Device	Reference Device K072071	Reference Device K080286	Remark
Indications for Use	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.	Same
Principle of Operation	Using making for general cement-type prosthesis.	Using making for general cement-type prosthesis.	Using making for general cement-type prosthesis.	Same
Interface Type	Engaging	Engaging	Engaging	Same
Gingiva Height (mm)	1.3, 1.35, 2.3, 2.35, 3.3, 3.35	1, 2, 3, 4, 5, 6	1, 2, 3, 4, 5, 6	Different
Material	Titanium alloy	Titanium alloy	Titanium alloy	Same
Temporary Abutment				

ITEM	Proposed Device	Reference Device K093027	Reference Device K092814	Remark
Indications for Use	Temporary Abutments are intended for use in Bone Level Dental Implant for temporary restorations of single crowns and bridges for up to six months.	The Straumann RC Temporary Abutments are indicated for use in Straumann RC bone level implants for temporary restorations of single crowns and bridges for up to six months.	The Straumann NC Temporary Abutments are indicated for use in Straumann NC Bone Level Implants for temporary restorations of single crowns and bridges for up to six months.	Same
Principle of Operation	Cement retained restoration; using making temporary prosthesis to maintain aesthetic appearance until final prosthesis is made.	Cement retained restoration; using making temporary prosthesis to maintain aesthetic appearance until final prosthesis is made.	Cement retained restoration; using making temporary prosthesis to maintain aesthetic appearance until final prosthesis is made.	Same
Interface Type	Engaging/Non-engaging	Engaging/Non-engaging	Engaging/Non-engaging	Same
Angle	Straight	Straight	Straight	Same
Diameter (mm)	3.5, 4.5	4.5	3.5	Same
Height (mm)	11	11	11	Same
Material	Titanium alloy	Pure Titanium	Titanium alloy	Different
Screw-retained Abutment				
ITEM	Proposed Device	Reference Device K171757		Remark
Indications for Use	Screw Retained Abutments are indicated to be placed into the implants of the Dental Implant System to provide support for prosthetic reconstructions such as crowns, bridges and bars. The final processed devices have the purpose of restoring chewing	Screw Retained Abutments are indicated to be placed into the implants of the Dental Implant System to provide support for prosthetic reconstructions such as crowns, bridges and bars. The final processed devices have the purpose of restoring chewing function. Screw Retained Abutments are indicated for screw-retained restorations.		Same

	function. Screw Retained Abutments are indicated for screw-retained restorations.		
Principle of Operation	Using making for general screw-retained prosthesis.	Using making for general screw-retained prosthesis.	Same
Interface Type	Engaging	Engaging	Same
Angle	0°, 17°, 30°	0°, 17°, 30°	Same
Diameter (mm)	3.5, 4.6	3.5, 4.6	Same
Gingiva Height (mm)	1, 1.5, 2.5, 3.5, 4, 4.5, 5.5	1, 2.5, 4, 5.5	Different
Material	Titanium alloy	Titanium alloy	Same
Coping for screw-retained abutment			
ITEM	Proposed Device	Reference Device K192401	Remark
Indications for Use	Copings for screw-retained abutment are intended for use in screw-retained abutment for temporary restorations of single crowns and bridges for up to six months.	Straumann temporary copings are compatible with Straumann screw retained abutments and are used for temporary restorations of single crowns and bridges.	Same
Principle of Operation	Screw retained restoration; using making temporary prosthesis before loading final prosthesis by connected with screw-retained abutment,	Screw retained restoration; using making temporary prosthesis before loading final prosthesis by connected with screw-retained abutment,	Same
Interface Type	Engaging/Non-engaging	Engaging/Non-engaging	Same
Abutment Connection	Crown, Bridges	Crown, Bridges	Same
Diameter (mm)	3.5, 4.6	3.5, 4.6	Same
Material	Pure Titanium	Titanium alloy	Different

Equator Abutment				
ITEM	Proposed Device	Reference Device K182091		Remark
Indications for Use	Equator Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Equator Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.		Same
Principle of Operation	Using making implant retained overdenture at maxilla/mandible.	Using making implant retained overdenture at maxilla/mandible.		Same
Interface Type	Non-engaging	Non-engaging		Same
Diameter (mm)	3.7	3.5, 3.7, 4.1, 4.8, 5.1		Different
Length (mm)	1, 2, 3, 4, 5, 6	1, 2, 3, 4, 5, 6, 7		
Material	Titanium alloy	Titanium alloy		Same
Healing abutment				
ITEM	Proposed Device	Reference Device K130808	Reference Device K071585	Remark
Indications for Use	Healing abutments are intended for use with the Bone Level Implant system to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.	Healing abutments are intended for use with the Straumann Dental implant system (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.	Healing abutments are intended for use with the Straumann P.004 Bone Level Implant System to protect the inner configuration of the implant. Healing abutments have a secondary function to maintain, stabilize and form the soft tissue during the healing process.	Same
Principle of Operation	Used to make a soft tissue shape before setting up prosthetics.	Used to make a soft tissue shape before setting up prosthetics.	Used to make a soft tissue shape before setting up prosthetics.	Same
Interface Type	Non-engaging	Non-engaging	Non-engaging	Same

Diameter (mm)	3.3, 3.6, 4.5, 4.8, 5, 6, 6.5	3.3, 3.6, 4.8, 5	4.4, 4.5, 4.7, 5, 6, 6.5, 7	Different
Height (mm)	2, 3.5, 4, 5, 6	2, 3.5, 5, 7	2, 4, 6, 7	
Material	Titanium alloy	Titanium alloy	Titanium alloy	Same
Protective Cap				
ITEM	Proposed Device	Reference Device K133421		Remark
Indication for use	Protective Caps are intended to protect the outer configuration of the abutment and to maintain and condition the contours of the soft tissue during the healing phase for up to 6 months.	Protective Caps are intended to protect the outer configuration of the abutment and to maintain and condition the contours of the soft tissue during the healing phase for up to 6 months.		Same
Principle of Operation	Used to make a soft tissue shape and protect the outer configuration of the abutment before setting up prosthetics.	Used to make a soft tissue shape and protect the outer configuration of the abutment before setting up prosthetics.		Same
Interface Type	Non-engaging	Non-engaging		Same
Diameter (mm)	3.5, 4.6	3.5, 4.6		Same
Height (mm)	5, 6.5, 8	5, 6.5, 8		Same
Material	Titanium alloy	PEEK+ Titanium alloy		Different
Basal Screw				
ITEM	Proposed Device	Reference Device K161689		Remark
Diameter (mm)	2.1, 2.2	2.0, 2.05, 2.2, 2.3, 2.5		Different
Height (mm)	7.85, 7.9	3.35, 5.6, 7.5, 8.35, 9.6, 10.2		
Material	Titanium alloy	Titanium alloy		Same
Screw for screw-retained abutment				
ITEM	Proposed Device	Reference Device K161689		Remark
Diameter (mm)	2	2.0, 2.05, 2.2, 2.3, 2.5		Different

Height (mm)	7.2, 8.8, 10.3, 11.8	3.35, 5.6, 7.5, 8.35, 9.6, 10.2	Different
Material	Titanium alloy	Titanium alloy	Same
Occlusal Screw			
ITEM	Proposed Device	Reference Device K161689	Remark
Diameter (mm)	2.2	2.0, 2.05, 2.2, 2.3, 2.5	Different
Height (mm)	3.65	3.35, 5.6, 7.5, 8.35, 9.6, 10.2	
Material	Titanium alloy	Titanium alloy	Same

Different - Gingiva Height of Cementable Abutment

The gingiva heigh range of the proposed cementable abutment is different from reference device. However, the proposed specifications can be covered by the reference device K072071 and reference device K080286. Therefore, this difference will not affect substantially equivalence on safety and effectiveness.

Different - Material of Temporary Abutment

The material of proposed temporary abutment of the proposed device is the same as that of the reference K092814. Therefore, this difference will not affect substantially equivalence on safety and effectiveness.

Different-Gingiva Height of Screw-retained Abutment

The gingiva height for the proposed Screw-retained Abutment is different from reference device K171757. However, the proposed specifications can be covered by the reference device. Therefore, this difference will not affect substantially equivalence on safety and effectiveness.

Different - Material of Coping for screw-retained abutment

The material of the proposed coping for screw-retained abutment is different from the reference device K192401. However, the biocompatibility evaluation was performed on the proposed device and the result demonstrate that this material does not cause any adverse effects. Therefore, this difference will not affect substantially equivalence on safety and effectiveness.

Different - Diameter and Length of Equator Abutment

The diameter and length specification for the proposed equator abutment is different from reference device. However, the proposed specifications can be covered by the reference device K182091. Therefore, this difference will not affect substantially equivalence on safety and effectiveness.

Different - Diameter and Height of Healing abutment

The diameter and height of the proposed healing abutment is different from reference device. However, the proposed specifications can be covered by the reference device K130808 and K071585. Therefore, this difference will not affect substantially equivalence on safety and effectiveness.

Different - Material of Protective Cap

The material of the proposed protective cap is different from the reference device K133421. However, the biocompatibility evaluation was performed on the proposed device and the result demonstrate that this material does not cause any adverse effects. Therefore, this difference will not affect substantially equivalence on safety and effectiveness.

Different - Diameter and Height of Basal Screw

The diameter and height of the proposed Basal Screw is different from the reference device K161689. However, the proposed diameter and length can be covered in the range of reference device K161689. Therefore, this difference will not affect the safety and effectiveness.

Different - Diameter of Screw for screw-retained abutment

The diameter of the proposed Screw for screw-retained abutment is different from the reference device K161689. However, the proposed diameter can be covered in the range of reference device K161689. Therefore, this difference will not affect the safety and effectiveness.

Different - Height of Screw for screw-retained abutment

The height of the proposed Screw for screw-retained abutment is different from the reference device K161689. The height of the proposed device of 7.2mm, 8.8mm and 10.3mm can be covered in the range of reference device K161689. Besides, the proposed device provides an additional 11.8mm height which provide more options for physician to select an appropriate device per patients' condition. This difference will not affect intended use. Therefore, this difference will not affect the safety and effectiveness.

Different - Diameter and Height of Occlusal Screw

The diameter and height of the proposed Occlusal Screw is different from the reference device K161689. However, the proposed diameter and length can be covered in the range of reference device K161689. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Table 4. Biocompatibility Comparison

ITEM	Proposed Device	Predicate Device K150388	Remark
Material			
Dental Implant	Pure Titanium	Pure Titanium	Same
Abutment	Titanium Alloy	Titanium Alloy	Same
Healing Cap	Titanium Alloy	Titanium Alloy	Same
Surgical Instrument	Stainless Steel	Stainless Steel	Same
Sterilization			
Dental Implant	Gamma Irradiation	Gamma Irradiation	Same
Attachment	Non-sterile	Non-sterile	
Surgical Instrument	Non-sterile	Non-sterile	
Biocompatibility			
Dental Implant	Comply with ISO 10993 standards	Comply with ISO 10993 standards	Same
Instrument	Comply with ISO 10993 standards	Comply with ISO 10993 standards	Same

10. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K150388 and reference devices.