April 28, 2020

Novodent SA
% H. Oktay
President
CardioMed Device Consultants, LLC
1783 Forest Drive #254
Annapolis, Maryland 21401

Re: K200867
Trade/Device Name: Implantswiss Dental Implant System and Implantswiss Dental Abutment System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: March 31, 2020
Received: April 1, 2020

Dear H. Oktay:

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.
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 below.

510(k) Number *(if known)*
K200867

Device Name
Implantswiss Dental Implant System and Implantswiss Dental Abutment System

Indications for Use *(Describe)*
Implantswiss Dental Implant System is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single and multiple units' prosthetic appliance attachment to restore a patient's chewing function. Implantswiss Dental Implant can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible based on four splinted-interforminal placed implants.

Implantswiss Dental Abutment System is used with a dental implant to provide support to prosthetic restorations such as crown, bridge and overdentures in partially or fully edentulous patients. Octa and Multi-Unit Abutment models that contain an abutment post height less than 4 mm are indicated only for multi-unit loading, such as a bridge or overdenture. All digitally designed Premill abutments for use with the Implantswiss Dental Abutment System are intended to be sent to a Novodent 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

(as required by 21 CFR 807.92)

Implantswiss Dental Implant System
Implantswiss Dental Abutment System

510(k) K200867

SUBMITTER

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Date of Summary: 28 April 2020

DEVICE

Proprietary name	Implantswiss Dental Implant System Implantswiss Dental Abutment System
Common name	Implant, Endosseous, Root-Form
Classification name	Endosseous Dental Implant
Regulatory Class	II
Primary Product Code	DZE
Subsequent Product Code	NHA
Regulation Number	21 CFR 872.3640

PREDICATE DEVICE

Primary Predicate Device:	K181266 - Implantswiss Dental Implant System Implantswiss Dental Abutment System
Reference Devices:	K160221 - Implance Dental Implant System Implance Dental Abutment System K161416 - Multi-unit Abutment Plus K150295 - LOCATOR RTx K181037 - DIO CAD/CAM Abutment

Device Description

The Implantswiss Dental Implant and Implantswiss Dental Abutment Systems are compatible titanium/titanium alloy dental implants and abutments. This submission provides additional models to the existing family of implants and abutments.

The Implantswiss Dental Implants are provided as bone level or tissue level type implants and their surface is modified by a Sandblasted Rough Acid-etched (SRA) process. The additional devices added in this

submission are all bone level implants, manufactured of pure titanium. The subject implant bodies have the same surface modification as the existing/cleared devices.

The Implantswiss Bone Level Implants have diameters of 3.3 mm, 3.7 mm, 4.3 mm 4.8 mm, and 5.5mm with lengths of 8 mm, 10 mm, 12 mm and 14 mm. Additional implant models are 3.3 mm diameter implants with straight design and 3.7 mm diameter implants with hybrid design (tapered apex).

The Implantswiss Dental Abutment System is used in combination with Implantswiss dental implants to provide support to prosthetic restorations such as crown, bridge and overdentures in partially or fully edentulous patients. The Implantswiss Dental Abutment System consists of provisional (temporary) and final type abutments, abutment screws, and the Healing Cap, a protective cover. The dental abutment provides the link between the dental implant and the prosthetic restoration that restores the chewing function.

The Implantswiss Dental Abutment System consists of Healing, Solid, Couple, Angled, Multi, O-ring, Multi-Unit, Premill, and Locator abutments. Couple abutments with diameters Ø 5.5 mm, Ø 6.5 mm have lengths of 8.9 mm, 9.9 mm, 10.9 mm, 11.9 mm, 12.9 mm and 10.4 mm, 11.4 mm, 12.4 mm, 13.4 mm, 14.4 mm. Non-hex Couple abutments with diameters Ø 5.5 mm, Ø 6.5 mm have lengths of 8.7 mm, 9.7 mm, 10.7 mm, 11.7 mm and 12.7 mm.

Bone Level Angled Abutments with 15° angles have diameters Ø 5.5 mm, Ø 6.5 mm with lengths varying from 10.57 mm to 12.57 mm. Bone Level Angled Abutments with 25° angles have diameters Ø 5.5 mm, Ø 6.5 mm with lengths varying from 11.06 mm to 13.13 mm. Non-hex Bone Level Angled Abutments with 15° angles have diameters Ø 5.5 mm, Ø 6.5 mm with lengths varying from 10.37 mm to 12.38 mm. Non-hex Bone Level Angled Abutments with 25° angles have diameters Ø 5.5 mm, Ø 6.5 mm with lengths varying from 10.86 mm to 12.93 mm. Tissue Level Angled Abutments have 15° angles with diameter Ø 3.5 mm with length 9.8 mm.

Bone Level Solid Abutments have diameters of Ø 5.5 mm and Ø 6.5 mm with lengths between 12.4 mm to 16.4 mm.

Bone Level O-ring Abutments have diameters of Ø 3.42 mm and Ø 3.7 mm with lengths between 10.1 mm to 13.1 mm. Tissue Level O-ring Abutments have a diameter of 3.5 mm with lengths 9.1 mm, 11.1mm and 13.1 mm.

Bone Level Multi Abutments have diameter of Ø 5.5 mm with length 15.63 mm. Non-Hex Bone Level Multi Abutments have a diameter of Ø 5.5 mm with length 15.63 mm.

Bone Level Healing Abutments have diameters of Ø 5.5 mm and Ø 6.5 mm with lengths 9.5 to 13.5 mm. Tissue Level Healing Abutments have diameter of Ø 6.4 mm with lengths 7.4 mm, 8.4 mm and 9.9 mm.

Bone Level Locator Abutments have diameter of Ø3.86 mm with length 13.95 mm.

Bone Level Multi-Unit Abutments have a diameter Ø 4.8 mm with lengths 8.45 mm and 12.65 mm. Bone Level Multi-Unit Abutments with 17° angle have a diameter Ø 4.8 mm with length 7.2 mm. Bone Level Multi-Unit Abutments with 25° angle have a diameter Ø 4.8 mm with lengths 7.5 mm, 8.5 mm and 9.5 mm.

Bone Level Premill Abutments have pre-mill diameters of Ø 10 mm, Ø 14 mm and Ø 16 mm with length 33.75 mm. Tissue Level Premill Abutments have pre-mill diameters of Ø 10 mm, Ø 14 mm and Ø 16 mm with length 30.08 mm. The finished premill custom abutment diameter is Ø 4.0 mm to Ø 6.0 mm.

Indication for Use

Implantswiss Dental Implant System is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single and multiple units' prosthetic appliance attachment to

restore a patient's chewing function. Implantswiss Dental Implant can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible based on four splinted-interforminal placed implants.

Implantswiss Dental Abutment System is used with a dental implant to provide support to prosthetic restorations such as crown, bridge and overdentures in partially or fully edentulous patients. Octa and Multi-Unit Abutment models that contain an abutment post height less than 4 mm are indicated only for multi-unit loading, such as a bridge or overdenture. All digitally designed Premill abutments for use with the Implantswiss Dental Abutment System are intended to be sent to a Novodent validated milling center for manufacture.

Substantial Equivalence Comparison

The additional models of the Implantswiss Dental Implant System are equivalent to the primary predicate implants cleared in K181266.

The additional models of the Implantswiss Dental Abutment System are comparable to the predicate and reference devices cleared in K181266, K160221, K150295, K161416, and K181037.

Implantswiss Dental Implant System and Implantswiss Dental Abutment System Substantial Equivalence

	Implantswiss Dental Implant System, Implantswiss Dental Abutment System	**Implantswiss Dental Implant System, Implantswiss Dental Abutment System**
	Subject	**Predicate**
510k #	This submission	K181266
Manufacturer	Novodent SA	Novodent SA
Indication	Implantswiss Dental Implant System is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single and multiple units' prosthetic appliance attachment to restore a patient's chewing function. Implantswiss Dental Implant can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible based on four splinted-interforminal placed implants. Implantswiss Dental Abutment System is used with a dental implant to provide support to prosthetic restorations such as crown, bridge and overdentures in partially or fully edentulous patients. Octa and Multi-Unit Abutment models that contain an abutment post height less than 4 mm are indicated only for multi-unit loading, such as a bridge or overdenture. All digitally designed Premill abutments for use with the Implantswiss Dental Abutment System are intended to be sent to a Novodent validated milling center for manufacture.	Implantswiss Dental Implant System is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single and multiple units' prosthetic appliance attachment to restore a patient's chewing function. Implantswiss Dental Implant can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible based on four splinted-interforminal placed implants. Implantswiss Dental Abutment System is used with a dental implant to provide support to prosthetic restorations such as crown, bridge and overdentures in partially or fully edentulous patients. Octa and Multi-Unit Abutment models that contain an abutment post height less than 4 mm are indicated only for multi-unit loading, such as a bridge or overdenture.
Design	Threaded root-form bone level implants with hybrid designs and Morse taper internal hexagon or internal octagonal abutment interface	Threaded root-form bone or tissue level implant with hybrid and straight designs and Morse taper internal hexagon or internal octagonal abutment interface.
Implant Sizes Bone Level	3.3x8, 3.3x10, 3.3x12, 3.3x14 3.7x8, 3.7x10, 3.7x12, 3.7x14	3.3x8, 3.3x10, 3.3x12, 3.3x14 3.7x8, 3.7x10, 3.7x12, 3.7x14 4.3x8, 4.3x10, 4.3x12, 4.3x14 4.8x8, 4.8x10, 4.8x12, 4.8x14 5.5x8, 5.5x10, 5.5x12
Implant Sizes Tissue Level	Not applicable	3.7x8, 3.7x10, 3.7x12, 3.7x14 4.3x8, 4.3x10, 4.3x12, 4.3x14 4.8x8, 4.8x10, 4.8x12, 4.8x14 5.5x8, 5.5x10, 5.5x12

	Implantswiss Dental Implant System, Implantswiss Dental Abutment System	**Implantswiss Dental Implant System, Implantswiss Dental Abutment System**
	Subject	**Predicate**
510k #	This submission	K181266
Materials	Commercially Pure Titanium Grade 4	Commercially Pure Titanium Grade 4: Ø4.3, 4.8, 5.5 BL, all TL Titanium Ti6Al4V ELI: Ø3.3, 3.7 BL implants
Surface treatment	Sandblasted Rough Acid-etched (SRA) surface	
Sterilization	Gamma	
Standards for Titanium	ASTM F-67	ASTM F-67 & ASTM F-136

Implantswiss Dental Implant System Substantial Equivalence Comparison

The additional models of the Implantswiss Dental Implants are the same or similar to the primary predicate Implantswiss Dental Implant System (K181266) with respect to indication for use, design, size and dimensions and material composition.

- The new implant models have the same intended use. The only difference for the subject and primary predicate Indications for Use is in reference to milling a new abutment type and this difference is acceptable as discussed in the applicable abutment section
- The new implant models in the Implantswiss Dental Implant System have the same maximum implant diameter. Bench testing on the worst-case dental implant of the subject devices found acceptable fatigue resistance properties. The primary predicate fatigue testing addresses the worst-case assembly of subject devices.
- The minimum/maximum implant lengths for the additional models of the Implantswiss Dental Implant System are 8 mm - 14 mm, the same as for the predicate.
- The additional models, diameter 3.3 mm – 3.7 mm and length 8 -14 mm implant, have the same surface treatment as the predicate device Implantswiss Dental Implant System and Implantswiss Dental Abutment System (K181266) in the surface treatment.
- The additional implant models in the Implantswiss Dental Implant System are all bone level implants, whereas the original had both bone level and tissue level designs.
- The additional models are manufactured from Commercially Pure Titanium Grade 4, whereas the predicate models were available in both pure titanium and titanium alloy.

Implantswiss Dental Abutment System Substantial Equivalence Comparison

	Subject Device	Predicate Device	Reference Device
Trade Name	Implantswiss Dental Implant System, Implantswiss Dental Abutment System	Implantswiss Dental Implant System, Implantswiss Dental Abutment System	Implance Dental Implant Implance Dental Abutment System
Manufacturer	NOVODENT SA	NOVODENT SA	AGS Medikal İth. İhr. Tic. Ltd. Şti.
510(k) No.	This submission	K181266	K160221
Material	Bone Level: Titanium Ti6Al4V ASTM F-136 Tissue Level: Titanium Grade 4 ASTM F-67 Screw: Titanium Ti6Al4V ELI ASTM F136		Bone Level: Titanium Ti6Al4V ELI ASTM F-136 Tissue Level: Commercially Pure Titanium Grade 4 ASTM F-67 Screw: Titanium Ti6Al4V ELI ASTM F136
Surface Treatment	Machine Surface		Machine Surface
Sterile	Steam Sterilization by user (Delivered non sterile)		Steam Sterilization by user (Delivered non sterile)
Couple Abutment Design			
Couple Abutment Diameters (mm)	Bone Level Implant: Ø 5.5 mm, Ø 6.5 mm	Bone Level Implant: Ø 3.7 mm, Ø 4.5 mm Tissue Level Implant: Ø 5.2 mm, Ø 6.4 mm	Bone Level Implant: Ø 3.7 mm, Ø 4.5 mm, Ø 5.5 mm, Ø 6.5 mm Tissue Level Implant: Ø 5.2 mm, Ø 6.4 mm
Angled Abutment Design			
Angled Abutment Diameters (mm)	Bone Level Implant (15°, 25°): Ø 5.5 mm, Ø 6.5 mm Tissue Level Implant (25°): Ø 3.5 mm	Bone Level Implant (15º): Ø 3.7 mm, Bone Level Implant (25º): Ø 4.5 mm, Tissue Level Implant (15º): Ø 3.5 mm	Bone Level Implant (15°): Ø 3.7 mm, Bone Level Implant (15°, 25°): Ø 4.5 mm, Ø 5.5 mm, Ø 6.5 mm Tissue Level Implant (25°): Ø 3.5 mm

	Subject Device	Predicate Device	Reference Device
Trade Name	Implantswiss Dental Implant System, Implantswiss Dental Abutment System	Implantswiss Dental Implant System, Implantswiss Dental Abutment System	Implance Dental Implant Implance Dental Abutment System
Manufacturer	NOVODENT SA	NOVODENT SA	AGS Medikal İth. İhr. Tic. Ltd. Şti.
Solid Abutment Design			
Solid Abutment Diameters (mm)	Bone Level Implant: Ø 5.5 mm, Ø 6.5 mm	Bone Level Implant: Ø 3.7 mm, Ø 4.5 mm Tissue Level Implant: Ø 3.5 mm, Ø 4.3 mm	Bone Level Implant: Ø 3.7 mm, Ø 4.5 mm, Ø 5.5 mm, Ø 6.5 mm Tissue Level Implant: Ø 3.5 mm, Ø 4.3 mm
O-ring Abutment Design			
O-ring Abutment Diameters (mm)	Bone Level Implant: Ø 3.42 mm, Ø 3.7 mm Tissue Level Implant: Ø 3.5 mm	Bone Level Implant: Ø 2.9 mm, Ø 4.5 mm,	Bone Level Implant: Ø 2.9 mm, Ø 3.42 mm, Ø 3.5 mm, Ø 4.5 mm, Tissue Level Implant: Ø 3.5 mm
Multi Abutment Design			
Multi Abutment Diameters (mm)	Bone Level Implant: Ø 5.5 mm	Bone Level Implant: Ø 3.7 mm, Ø 4.5mm Tissue Level Implant: Ø 5.2 mm	Bone Level Implant: Ø 3.7 mm, Ø 4.5 mm, Ø 5.5 mm Tissue Level Implant: Ø 5.2 mm

	Subject Device	Predicate Device	Reference Device
Trade Name	Implantswiss Dental Implant System, Implantswiss Dental Abutment System	Implantswiss Dental Implant System, Implantswiss Dental Abutment System	Implance Dental Implant Implance Dental Abutment System
Manufacturer	NOVODENT SA	NOVODENT SA	AGS Medikal İth. İhr. Tic. Ltd. Şti.
Healing Abutment Design			
Healing Abutment Diameters (mm)	Bone Level Implant: Ø 5.5 mm, Ø 6.5 mm Tissue Level Implant: Ø 6.4 mm	Bone Level Implant: Ø 3.7 mm, Ø 4.5 mm Tissue Level Implant: Ø 5.2 mm	Bone Level Implant: Ø 3.7 mm, Ø 4.5 mm, Ø 5.5 mm, Ø 6.5 mm Tissue Level Implant: Ø 3.7 mm, Ø 6.4 mm
Brief Comparison	The additional models of the subject device have the same basic design with additional diameters as compared to the predicate device (K181266). Additional dimensional features not addressed by the primary predicate are addressed by the reference device, K160221, by identical dimensions or a range which encompasses the subject dimensions.		

Implantswiss Locator abutment

	Subject Device	Predicate Device	Reference Device
Trade Name	Implantswiss Dental Implant System Implantswiss Dental Abutment System	Implantswiss Dental Implant System Implantswiss Dental Abutment System	LOCATOR RTx
Manufacturer	NOVODENT SA	NOVODENT SA	Zest Anchors, LLC
510(k) No.	This submission	K181266	K150295
Material	Abutments- Titanium Ti6Al4V ELI ASTM F-136		Titanium
Sterile	Steam Sterilization by user (Delivered non sterile)		Steam Sterilization by user (Delivered non sterile)
Locator Abutment Design			
Diameters (mm)	Ø 3.86 mm	Ø 3.86 mm	Ø 3 - 7 mm
Cuff Height (mm)	6mm (for 3.3 mm diameter implant)	1-2-3-4-5 mm (for 3.3 diameter implant) 1-2-3-4-5-6 mm (for 3.7 mm, 4.3 mm, 4.8 mm and 5.5 mm diameter implant)	1, 2, 3, 4, 5, and 6 mm (for 3.0 mm – 7.0 mm diameter implant)
Brief Comparison	The primary predicate and reference device Indications for Use do not include any device-specific language for the Locator abutment that would need to be included in the subject Indications for Use. The Implantswiss Locator abutment is same design as the predicate (K181266) and proposes an additional cuff height option for the 3.3mm diameter implant compatible locator abutment. The abutment gingival height and abutment post height are within the range of the reference device (K150295).		

Implantswiss Multi-Unit Abutment

	Subject Device	**Predicate Device**	**Reference Device**
Trade Name	Implantswiss Dental Implant System Implantswiss Dental Abutment System	Implantswiss Dental Implant Implantswiss Dental Abutment System	Multi-unit Abutments Plus
Manufacturer	NOVODENT SA	NOVODENT SA	Nobel Biocare AB
510(k) No.	This submission	K181266	K161416
Material	Abutments and screws: Titanium Ti6Al4V ELI ASTM F-136		Abutments and screws – Titanium vanadium alloy
Sterile	Steam Sterilization by user (Delivered non sterile)		Radiation sterilization
Multi-Unit Abutment Design			
Diameters	Ø 4.8 (0°, 17°, 25°) mm	Ø 4.8 (17°) mm	Ø 4.8 (0°, 17°, 30°) mm
Brief Comparison	The primary predicate and reference device Indications for Use do not include any device-specific language for the Multi-Unit abutment that would need to be included in the subject Indications for Use. The additional models of the Implantswiss Multi-Unit Abutment have the same diameter and material as the predicate models, with two new angulations. The angulation of the subject device is within the range of angulation of the reference device, Multi-unit Abutment Plus (K161416).		

Implantswiss Premill Abutment

	Subject Device	Reference Device
Trade Name	Implantswiss Dental Implant System Implantswiss Dental Abutment System	DIO CAD/CAM Abutment
Manufacturer	NOVODENT SA	DIO Corporation
510(k) No.	This submission	K181037
Material	Titanium Ti6Al4V ELI ASTM F-136	Titanium Ti6Al4V ELI ASTM F-136
Sterile	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Delivered non sterile)
Premill Abutment		
Diameters	Prior to milling: Ø 10mm, Ø 14 mm, Ø 16 mm Post milling: min Ø 4.0mm, max Ø 6.5 mm	Ø 3.0mm, Ø 3.3mm, Ø 3.8mm, Ø 4.0mm, Ø 4.5mm, Ø 5.0mm, Ø 5.5mm, Ø 6.0mm, Ø 6.5mm, Ø 7.0mm
Maximum Allowable Angulation	25°	29.8° or 29.3°
Connection	Internal Hex	Hex / Non Hex
Brief Comparison	The size of the finished Implantswiss Premill abutment is within the range of the Reference Device K181037 DIO CAD/CAM Abutment. The subject device Indications for Use includes component- specific language regarding location of milling, the same as the reference device. Both Implantswiss Premill abutment and Reference device are being used in conjunction with dental implants for the purpose of supporting dental prostheses and are CAD/CAM custom abutments intended for fabrication at a validated milling center.	

The additional models of the Implantswiss Dental Abutment System are the same or similar with respect to indication for use, material composition and basic design features as the predicate Implantswiss Dental Abutment System (K181266), and reference devices: Implance Dental Implant and Dental Abutment System (K160221), DIO CAD/CAM Abutment (K181037), Multi-unit Abutment Plus (K161416) and LOCATOR RTx (K150295). The diameter size ranges have been broadened.

- The new abutment models in the Implantswiss Dental Implant System have larger abutment diameters compared to the predicate. Bench testing on the worst-case dental implant - abutment found acceptable fatigue resistance properties.
- The subject device is similar in size and technological features as the reference device (K160221).
- The Implantswiss Locator abutment is same as the predicate (K181266) with respect to diameter and cuff height. This submission proposes an additional cuff height option for the 3.3mm diameter implant compatible locator abutment. The abutment gingival height and abutment post height are within the range of the reference device, LOCATOR RTx (K150295).
- The Implantswiss Premill abutment is within the range of sizes of the Reference Device K181037 DIO CAD/CAM Abutment. Both Implantswiss Premill abutment and Reference device are being used in conjunction with dental implants for the purpose of supporting dental prostheses and are CAD/CAM custom abutments fabricated at a validated milling center.
- The additional models of the Implantswiss Multi-Unit Abutment have the same diameter and material as the predicate models. The angulation of the subject device is within the range of angulation of the reference device, Multi-unit Abutment Plus (K161416).
- The additional models and predicate models are manufactured from both pure titanium and titanium alloy.
- All digitally designed abutments for use with Implantswiss Premill abutments for CAD/CAM are intended to be sent to a Novodent validated milling center for manufacture.

Summary of Non-clinical Testing
Non-clinical testing was conducted on the primary predicate device (K181266) and determined to be applicable to the subject device, based on rationale provided below.

Biocompatibility
The additional models of Implantswiss Dental Implants and Implantswiss Dental Abutments were compared to the predicate devices. Biocompatibility testing was conducted on the predicate Implantswiss Dental Implant and Implantswiss Dental Abutment Systems per the ISO 10993 series of standards and was leveraged for the subject devices due to identical materials and manufacturing as the predicate.

Sterilization and Shelf Life
Implantswiss Dental Implants are sterilized using a gamma ray sterilization process ISO 11137-1 and ISO 11737-2 that has been validated to ensure a SAL of 10^{-6}. LAL testing was conducted in accordance with USP <85>. No additional sterilization validation was required as the validation from the primary predicate may be appropriately leveraged, based on identical materials and manufacturing and worst-case analysis conducted.

The Implantswiss Dental Abutment System is provided non-sterile. The recommended end-user steam gravity sterilization method and sterilization parameters have been validated to achieve an SAL of 10^{-6} according to ISO 17665-1, ISO 17665-2, and ISO 11737-2. No additional sterilization validation was required as the validation from the primary predicate may be appropriately leveraged, based on identical materials and manufacturing and worst-case analysis conducted.

Pyrogenicity information from the predicate is applicable to the subject devices, based on worst-case analysis conducted.

Shelf life of the Implantswiss Dental Implant System remains at 2-years. Packaging testing of accelerated aged and real-time aged product previously demonstrated that the sterility of the Implantswiss Dental Implant System is maintained over the 2-year shelf life period. Below tests were performed on the predicate devices and leveraged for the subject, based on worst-case analysis conducted:

-Visual Inspection ASTM F1886
-Dye Penetration ASTM F1929-15
-Seal Peel Strength Test BS EN 868-5:2009
-Sterility test

Mechanical Testing
Fatigue testing, in accordance with ISO 14801 Dentistry- Implants-Dynamic fatigue test for Endosseous Dental Implants, was performed on the worst-case bone level Implantswiss Dental Implant mated with the worst case Implantswiss Dental Abutment. Results of the fatigue testing presented in the predicate submission found that the worst case (bone level) dental implant/abutment combinations was consistent with FDA Class II Special Controls guidance and ISO 14801. The additional models of the Implantswiss Dental Implants and Implantswiss Dental Abutments are covered by this testing and do not introduce a new worst-case.

Non-clinical testing has demonstrated substantial equivalence of the Implantswiss Dental Implant System and the Implantswiss Dental Abutment System.

Conclusion

Based on the similar designs, materials and applicable performance data, the modified Implantswiss Dental Implant System and Implantswiss Dental Abutment System is substantially equivalent to the identified predicate devices.