510(K) SUMMARY

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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:	Implance Dental Implant System, Implance Dental Abutment System - K160221

Reference Devices:	Straumann Dental Implant System - K150938
	LOCATOR RTx - K150295
	NobelActive Multi Unit Abutment - K072570

Device Description

The Implantswiss Dental Implant and Implantswiss Dental Abutment Systems are compatible titanium/titanium alloy dental 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 Implantswiss Bone Level Implants have diameters of 3.3mm, 3.7mm, 4.3mm and 4.8mm with lengths of 8mm, 10mm, 12mm and 14mm; and diameter of 5.5mm with lengths of 8mm, 10mm and 12mm. The 3.3mm and 3.7mm diameter Bone Level Implants are composed of Titanium Ti6Al4V ELI – ASTM F136-13. The 4.3mm, 4.8mm and 5.5mm diameter Bone Level Implants are composed of Titanium Grade 4 – ASTM F67-13.

The Implantswiss Tissue Level Implants have diameters of 3.7mm, 4.3mm and 4.8mm with lengths of 8mm, 10mm, 12mm and 14mm; and diameter of 5.5mm with lengths of 8mm, 10mm and 12mm. The Tissue Level Implants are composed of Titanium Grade 4 – ASTM F67-13.

The Implantswiss Dental Abutment System consists of Couple, Angled, Solid, O-ring, Multi, Octa, Synocta, Healing, Locator and Multi-Unit Abutments.

Bone Level Couple Abutments have diameters Ø 3.7mm and Ø 4.5mm. Tissue Level Couple Abutments have diameters Ø 5.2mm and Ø 6.4mm.

Bone Level Angled Abutments with 15° angles have diameters Ø 3.7mm and Ø 4.5mm. Bone Level Angled Abutments with 25° angles have a diameter of Ø 4.5mm. Tissue Level Angled Abutments have 15° angles with diameter Ø 3.5mm.

Bone Level Solid Abutments have diameters of Ø 3.7mm and Ø 4.5mm. Tissue Level Solid Abutments have diameters of Ø 3.5mm and Ø 4.3mm.

Bone Level O-ring Abutments have diameters of Ø 2.9mm and Ø 4.5mm.

Bone Level Multi Abutments have diameters of Ø 3.7mm and Ø 4.5mm. Tissue Level Multi Abutments have a diameter of Ø 5.2mm.

Bone Level Octa Abutments have diameter of Ø 4.8mm. Tissue Level Octa Abutments have a diameter of Ø 3.5mm.

Tissue Level Synocta Abutments have a diameter of Ø 3.5mm.

Bone Level Healing Abutments have diameters of Ø 3.7mm and Ø 4.5mm. Tissue Level Healing Abutments have a diameter of Ø 5.2mm.

Bone Level Locator Abutments have diameter of Ø 3.86mm. Tissue Level Healing Locator have diameter of Ø 3.86 mm.

Bone Level Multi-Unit Abutments with 17° angle have a diameter Ø 4.8mm.

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.

Substantial Equivalence Comparison

The Implantswiss Dental Implant System is comparable to the K160221- Implance Dental Implant System, Implance Dental Abutment System as the primary predicate and the reference predicate device Straumann Dental Implant System (K150938).

The Implantswiss Dental Abutment System is comparable to the primary predicate devices Implance Dental Abutment System (K160221) and reference predicate devices LOCATOR RTx (K150295) and NobelActive Multi Unit Abutment (K072570).

Implantswiss Dental Implant System Substantial Equivalence Comparison

	Implantswiss Dental Implant System, Implantswiss Dental Abutment System	**Primary Predicate Implance Dental Implant System, Implance Dental Abutment System**	**Reference Predicate Straumann Dental Implant System**
510k #	K181266	K160221	K150938
Manufacturer	Novodent SA	AGS Medikal Urunleri Ith. Ihr. Tic. Ltd. Sti.	Straumann USA, LLC
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.	Implance 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. Implance 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. Implance 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 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.	Straumann Dental 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 dental 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 appropriate occlusal loading, to store chewing function. The prosthetic restorations used are single crowns, bridge and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).

System Components	Dental implant and closing screw	Dental implant and closing screw	Dental implant and transfer piece
Design	Threaded root-form bone or tissue level implant with hybrid and straight designs and Morse taper internal hexagon or internal octagonal abutment interface Tissue Level Dental implant' machined length is 2.65 mm	Threaded root-form bone or tissue level implant with hybrid and straight designs and Morse taper internal hexagon or internal octagonal abutment interface	Implant-Abutment connection for Bone Level: -Narrow CrossFit (NC) -Regular CrossFit (RC) Implant-Abutment connection for Tissue Level: -Narrow Neck CrossFit (NNC) -Regular Neck (RN) -Wide Neck (WN) Tissue Level Dental implant' machined length is 1.8 and 2.8 mm respectively Narrow Neck CrossFit (NNC) and both Regular Neck (RN) and Wide Neck (WN)
Implant Sizes Bone Level	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	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	3.3x8, 3.3x10, 3.3x12, 3.3x14, 3.3x16 4.1x6, 4.1x8, 4.1x10, 4.1x12, 4.1x14, 4.1x16 4.8x6, 4.8x8, 4.8x10, 4.8x12, 4.8x14, 4.8x16
Implant Sizes Tissue Level	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	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	3.3x8, 3.3x10, 3.3x12, 3.3x14, 3.3x16 4.1x6, 4.1x8, 4.1x10, 4.1x12. 4.1x14, 4.1x16 4.8x6, 4.8x8, 4.8x10, 4.8x12, 4.8x14, 4.8x16
Materials	Commercially Pure Titanium Grade 4 & Titanium Ti6Al4V ELI	Titanium Grade 4 & Titanium Ti6Al4V	Commercially Pure Titanium Grade 4 Transfer piece-titanium-6aluminum-7niobium alloy (TAN)
Surface treatment	Sandblasted Rough Acid-etched (SRA) surface	Resorbable Blast Media (RBM) surface treatment	Sandblasting Large grit Acid etching (SLA) surface treatment
Sterilization	Gamma	Gamma	Gamma
Standards for Titanium	ASTM F-67 & ASTM F-136	ASTM F-67 & ASTM F-136-13	ASTM F-67

The Implantswiss Dental Implant System is the same or similar to the primary predicate Implance Dental Implant System with respect to indication for use, design, size and dimensions and material composition.

The Implantswiss Dental Implant System maximum implant diameter is the same as the primary predicate Implance Dental Implant System.

The Implantswiss Dental Implant System differs from the primary predicate with respect to the surface treatment.

The Implantswiss Dental Implant System is the same or similar to the reference predicate Straumann Dental Implant System with respect to indication for use, design, material composition and surface treatment. The Implantswiss Dental Implant System has the same surface modification which is sandblasted and following double acid-etching with reference predicate Straumann Dental Implant System (K150938). The Implantswiss Dental Implant System differs with respect to maximum implant diameter and minimum/maximum lengths. The Implantswiss Dental Implant has a maximum implant diameter of 5.5 mm while the reference predicate has a maximum implant diameter of 4.8 mm.

The Implantswiss Tissue Level Dental Implant's machined neck (cuff height) length is 2.65 mm while reference predicate Tissue Level Dental Implant's machined neck length is 1.8 and 2.8 mm respectively Narrow Neck CrossFit and both Regular Neck and Wide Neck. Minimum/maximum implant lengths for the Implantswiss Dental Implant System are 8 mm - 14 mm versus 6mm – 16mm for the reference predicate.

Implantswiss Dental Abutment System Substantial Equivalence Comparison

	Subject Device	Reference Predicate Device
Manufacturer	NOVODENT SA	AGS Medikal Urunleri Ith. Ihr. Tic. Ltd. Sti.
Trade Name	Implantswiss Dental Implant System	Implance Dental Implant System
510(k) No.	K181266	K160221
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	Implance 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. Implance 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. Implance 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 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.
Material	Bone Level: Titanium Ti6Al4V ELI ASTM F-136 Tissue Level: Commercially Pure Titanium Grade 4 ASTM F-67 Screw: Titanium Ti6Al4V ELI ASTM F136	Bone Level: Titanium Ti6Al4V ASTM F-136 Tissue Level: Titanium Grade 4 ASTM F-67 Screw: Titanium Ti6Al4V 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 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 (15º): Ø 3.7 mm, Bone Level Implant (25º): Ø 4.5 mm, Tissue Level Implant (15º): Ø 3.5 mm	Bone Level Implant (15º): Ø 3.7 mm, Bone Level Implant (15º, 25º): Ø 4.5 mm, Ø 5.5 mm, Ø 6.5 mm
Solid Abutment Design		
Solid Abutment Diameters (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		
Diameters (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		
Diameters (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
Octa Abutment Design		

Diameters (mm)	Bone Level Implant: Ø 4.8 mm Tissue Level Implant: Ø 3.5 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
Syoncta Abutment Design		
Diameters (mm)	Tissue Level Implant: Ø 3.5 mm	Tissue Level Implant: Ø 3.5 mm
Healing Abutment Design		
Diameters (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 subject device is similar in size and features as the predicate device (K160221).	

Implantswiss Locator abutment

	Subject Device	**Reference Predicate Device**
Manufacturer	NOVODENT SA	Zest Anchors, LLC
Trade Name	Implantswiss Dental Implant System	LOCATOR RTx
510(k) No.	K181266	K150295
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	The LOCATOR® RTx Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla. LOCATOR®RTx Attachment System is compatible with the following implant systems. Implant Manufacturer - System BioHorizons - Internal Hex (3.0, 3.5, 4.5, 5.7mm) External Hex (3.5, 4.0, 5.0mm) Biomet 3i – Certain Internal (3.4, 4.1, 5.0, 6.0 mm) External Hex (3.4, 4.1, 5.0, 6.0 mm)

	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.	Camlog – Camlog and Conelog (3.3, 3.8, 4.3, 5.0 mm) iSy (3.8, 4.4, 5.0 mm) Dentsply – Ankylos (3.5, 4.5, 5.5, 7.0 mm) XiVE/FRIALIT-2 (3.4, 3.8, 4.5, 5.5 mm) Astra Tech OsseoSpeed EV (3.6, 4.2, 4.8mm) MIS Implants – Internal Hex (3.75, 4.5 mm) Nobel Biocare – Replace: Internal (3.5, 4.3, 5.0, 6.0 mm) MobelActive: Internal Conical (3.0, 3.5, 4.3, 5.0 mm) Branemark: External Hex (3.3, 3.75, 4.0, 5.0 mm) Straumann – Tissue Level (3.5, 4.8, 6.5 mm) Bone Level (3.3, 4.1, 4.8 mm) Zimmer – Tapered Screw Vent: Internal Hex (3.5, 4.5, 5.7 mm) Spline (3.25, 4.0, 5.0 mm) Swiss Plus: Internal Octagon (3.8, 4.8 mm)
Material	Abutments- Titanium Ti6Al4V ELI ASTM F-136	Abutments- Titanium Ti6Al4V ELI ASTM F-136
Sterile	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Delivered non sterile)
Locator Abutment Design		
Diameters (mm)	Bone Level Implant: Ø 3.86 mm Tissue Level Implant: Ø 3.86 mm	Diameter: Ø 3.0 mm to Ø 7.0 mm Bone Level: Ø 3.3 mm, Ø 4.1 mm, Ø 4.8 mm Tissue Level: Ø 3.5 mm, Ø 4.8 mm, Ø 6.5 mm
Brief Comparison	The Implantswiss Locator abutment is different than the LOCATOR RTx, Reference Predicate Device (K150295) in the size of the abutment.	

Implantswiss Multi-Unit Abutment

	Subject Device	**Reference Predicate Device**
Manufacturer	NOVODENT SA	Nobel Biocare AB
Trade Name	Implantswiss Dental Implant System	NobelActive Multi Unit Abutment
510(k) No.	K181266	K072570
Indication	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. Implantswiss Multi-Unit Supports prosthetic restoration for bridge.	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.
Material	Abutments and screws: Titanium Ti6Al4V ELI ASTM F-136	Abutments and screws – Titanium vanadium alloy
Sterile	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Delivered non sterile)
Multi-Unit Abutment Design		
Diameters	Ø 4.8 (17^0) mm	Ø 4.8 (0°, 17°, 30^0) mm
Brief Comparison	The Implantswiss Multi-Unit abutment is different than the Reference Predicate Device (K072570) NobelActive Multi Unit Abutment, in the angulation of the abutment.	

The Implantswiss Dental Abutment System is the same or similar with respect to indication for use, material composition and basic design features as the predicate Implance Dental Abutments (K160221). The Implantswiss Locator abutment is different than the LOCATOR RTx, Reference Predicate Device (K150295) in the size of the abutment.

Multi-Unit abutments supports prosthetic restoration for bridge. Angular correction cannot be fabricated into the design of any of the Octa and Multi-Unit Abutment models when combined with casting plastic or cylinder during patient-specific customization. The Implantswiss Multi-Unit abutment is different than the Reference Predicate Device (K072570) NobelActive Multi Unit Abutment in the angulation of the abutment.

Summary of Non-clinical Testing

Performance testing of the Implantswiss Dental Implant and Implantswiss Dental Abutment followed the FDA guidance Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments.

Biocompatibility

Biocompatibility testing was conducted according to ISO 10993-1:2009"Biological evaluation of medical devices-Part 1: Evaluation and testing within risk management process" and the biocompatibility evaluation flow chart according to the FDA Guidance document "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016" for each of the subject devices Fixture has been conducted the following biocompatibility test:

- Cytotoxicity (in vitro) - ISO 10993-5:2009
- Sensitization- ISO 10993-10:2010
  - ISO 10993-12:2012
- Irritation/ Intracutaneous Toxicity - ISO 10993-10:2010
- Implantation test - ISO 10993-6:2016
  - ISO 10993-12:2012
- Chemical Analysis - IS0 10993-12
  - Semi volatile Organics (SVOC) Method:8270D
  - Volatile Organic Compounds (VOC) Method: 8260C

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>.

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.

Packaging testing of accelerated aged and real-time aged product demonstrated that the sterility of the Implantswiss Dental Implant System is maintained over the 2-year shelf life period. Below tests are performed:

-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 found that the worst case (bone level) dental implant/abutment combinations was consistent with FDA Class II Special Controls guidance and ISO 14801.

Fatigue testing, in accordance with ISO 14801 Dentistry- Implants-Dynamic fatigue test for Endosseous dental implants, referenced in K160221 was performed on the worst-case tissue level Implance Dental Implant (K160221) mated with the worst case Implance Dental Abutment (K160221). Results of the fatigue testing found that the worst case (tissue level) dental implant/abutment combinations was consistent with FDA Class II Special Controls guidance and ISO 14801.

Surface analysis of the implant body after the SRA process was conducted using Scanning Electron Microscopy (SEM) and Energy Dispersive X-ray Spectroscopy(EDS). SEM found that the implant surface had a homogeneous structure.

Non-clinical performance testing consistent with the FDA's Class II Special Controls guidance document and ISO 14801 support the 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 Implantswiss Dental Implant System is substantially equivalent to the identified predicate devices.