January 17, 2025

Smart Denture Conversions, LLC
% Azary Joseph
Regulatory Consultant
Aztech Regulatory & Quality LLC
543 Long Hill Avenue
Shelton, Connecticut 06484

Re: K242064
Trade/Device Name: Omni-Directional Multi-unit Abutment System (Trade Name: Omnibut™)
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 12, 2024
Received: December 19, 2024

Dear Azary Joseph:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242064

Device Name
Omni-Directional Multi-unit Abutment System (Trade Name: Omnibut™)

Indications for Use *(Describe)*
The Omnibut is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Table 1 – Compatible Implant Systems

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform, mm
Neodent Helix (Morse taper GM)	3.5,3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM (3.0)
NobelActive® (Conical Connection)	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
Straumann BLX (TorcFit™ Internal Hexalobular)	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Tapered Screw-Vent ® (Zimmer Internal Hex)	3.7, 4.1	3.5
	4.7	4.5
	6	5.7

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

K242064

Smart Denture Conversions, LLC

Omni-Directional Multi-Unit Abutment System

January 14, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name	Smart Denture Conversions, LLC 1800 N. Salem St., Suite 104 Apex, NC 27523
FDA Registration	3015527825
Telephone	(855) 550-0707
Representative/Consultant	Joseph Azary Aztech Regulatory & Quality LLC 543 Long Hill Ave Shelton, CT 06484 Telephone (203) 242-6670 Email jazary@rcn.com

DEVICE NAME AND CLASSIFICATION

Proprietary Name:	Omni-Directional Multi-unit Abutment System (Trade Name: Omnibut™)
Common/Usual Name:	Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Regulation Name:	Endosseous dental implant abutment
Regulatory Class:	Class II
Product code:	NHA
Classification Panel:	Dental
Reviewing Office:	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices
Reviewing Division:	Division of Dental and ENT Devices

PREDICATE AND REFERENCE DEVICE INFORMATION

Primary Predicate:
K161416, NobelActive Multi Unit Plus Abutment, Nobel Biocare AB

Reference Devices:
K192614, Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment, MegaGen Implant CO., Ltd.
K240208, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices for OEM Implant Body Clearances
K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários SA
K180536, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A.
K201225, Neodent Implant System – GM Helix Implants 7.0, JJGC Indústria e Comércio de Materiais Dentários S.A.
K071370, Nobelactive Internal Connection Implant, Nobel Biocare AB
K083205, Nobelactive 8.5 Mm & 18.0 Mm, Nobel Biocare AB
K142260, NobelActive®, Nobel Biocare AB
K173961, Straumann® BLX Implant System, Institut Straumann AG

K181703, Straumann® BLX Line Extension – Implants, SRAs and Anatomic Abutments, Institut Straumann AG
K191256, Straumann BLX Ø3.5 mm Implants, Institut Straumann AG
K210855, Straumann BLX Implant System, Institut Straumann AG
K212533, BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants, Institut Straumann AG
K072589, Tapered Screw-Vent Implant, 4.1mmD, Zimmer Dental, Inc.
K061410, Screw-Vent Implant System, SV, Tapered Screw-Vent Implant System TSV. Advent Implant System AV, Zimmer One Piece Implant, Zimmer Dental (includes 3.7, 4.7 and 6.0mm diameters)

INTENDED USE/INDICATIONS FOR USE STATEMENT

Indications for Use:
The Omnibut is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Table 1 – Compatible Implant Systems

Compatible Implant System (Connection)	**Implant Body Diameter, mm**	**Implant Platform, mm**
Neodent Helix (Morse taper GM)	3.5,3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM (3.0)
NobelActive® (Conical Connection)	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
Straumann BLX (TorcFit™ Internal Hexalobular)	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Tapered Screw-Vent ® (Zimmer Internal Hex)	3.7, 4.1	3.5
	4.7	4.5
	6	5.7

Intended Use:
Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Omnibuts, in combination with four or more endosseous implants, are indicated for multiple unit reconstructions when screw-retained prosthetics are preferred.

SUBJECT DEVICE DESCRIPTION

The Omnibut™ is a transmucosal abutment used to support screw-retained prostheses on four or more implants. The subject device has a premanufactured connection for the platforms listed in **Table 1** ***Compatible Implant Systems***.

The system involves a ball abutment attached to an implant. A retention attachment allows for angle corrections of up to 30° off the implant axis. The ball abutment is inserted into the implant, then, the attachment is adjusted to the desired angle using an orientation screw. The abutment supports prostheses that connect via titanium cylinders, which are incorporated into resin or ceramic prostheses. Finally, the prostheses are retained to the abutment by prosthetic screws.

The subject device abutments and system components are manufactured from Ti-6Al-4V alloy conforming to ASTM F136. The subject device is a single use device. The device is provided nonsterile and intended to be sterilized by the user prior to placement in the patient.

PERFORMANCE DATA

Non-clinical testing performed on the subject device to demonstrate substantial equivalence included:

- provided in this submission is reverse engineering dimensional analysis (of OEM implant bodies, OEM abutments, and OEM abutment screws) to demonstrate the subject device abutments are compatible with the Neodent GM Helix (Morse Taper GM connection) implants, the Nobel Internal (Conical Connection) implants, Straumann BLX (TorcFit™ Internal Hexalobular connection) implants, and Zimmer Internal (Internal Hex connection) implants;
- provided in this submission is dynamic load testing conducted according to ISO 14801:2016 to support the performance of the subject device abutments with the Neodent GM Helix (Morse Taper GM connection) implants, the Nobel Internal (Conical Connection) implants, Straumann BLX (TorcFit™ Internal Hexalobular connection) implants, and Zimmer Internal (Internal Hex connection) implants;
- provided in this submission was non-clinical analysis to evaluate the subject device in the MR environment using scientific rationale and published literature (TO Woods, JG Delfino, and S Rajan, "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices," Journal of Testing and Evaluation, Volume 49, No. 2, 2021, pp. 783-795); the analysis addressed parameters per the FDA guidance Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment (issued May 2021) including magnetically induced displacement force and torque;
- provided in this submission is moist heat sterilization for subject devices provided non-sterile to the end user, validated to a sterility assurance level of 10^{-6} by the overkill method according to ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO TIR 17665-2;
- Verification of biocompatibility of the final device in accordance with ISO 10993-1 and ISO 10993-5;
- Bench testing included Retention Force Testing and Simulated Use Testing.
- Simulated cleaning testing to show the cleanability of the Omnibut vs a predicate device.

Table 2 – Summary of Performance Data

Standard	Description of Test	Results
Biological Risk Assessment ISO 10993-1:2018 FDA Guidance on the Use of ISO 10993-1, 2023	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process	All biological endpoint testing performed on the device, along with the analysis on the physical and chemical information, returned passing results. All biological endpoint testing suggests that the Omnibut is biocompatible and does not present a foreseen biological risk to those patient populations it is intended for.
Cytotoxicity ISO 10993-5 (2009)	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity	The test article showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was grade 0 (no reactivity).
Sterilization Validation Testing per standards: • AAMI TIR12:2020 • ANSI/AAMI/ISO 17665-1:2026/(R)2013 • ANSI/AAMI ST79:2017	AAMI TIR12:2020 Designing, Testing, And Labeling Medical Devices Intended For Processing By Health Care Facilities: A Guide For Device Manufacturers, Overkill method according to Section 5.7	PASS – Results from testing have demonstrated that the Omnibut was able to achieve a 10^{-6} SAL when using the recommended parameters in the Instructions for Use (IFU).

Dynamic Fatigue Testing Testing per ISO 14801:2016 FDA Guidance Document, ***"Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments"*** (May 12, 2004)	Dynamic Fatigue testing per: ISO 14801:2016: Dentistry — Implants — Dynamic loading test for endosseous dental implants Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Class II Special Controls Guidance Document for Industry and FDA Staff Section 8	PASS – The results conclude that when evaluated in a manner consistent with ISO 14801:2016, the Omnibut met all predetermined acceptance criteria.
Compatibility FDA Guidance Document, ***"Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments"*** (May 12, 2004)	Reverse engineering dimensional analysis of OEM implant bodies, OEM abutments, and OEM abutment screws were performed to demonstrate that the Omnibut abutments are compatible with the noted implant systems.	PASS – The engineering and dimensional analysis concluded that each Omnibut design is compatible with the applicable implant connection.
	Compatibility must be demonstrated to ensure proper device functionality.	PASS – Omnibut prosthetic side components were demonstrated to be compatible.
Retention Force Testing No standard	The Omnibut has a retention attachment. Retention Force testing was performed via tensile push-out to ensure that the attachment will not detach during clinical use.	PASS – The Omnibut retention attachment did not detach at a predetermined acceptable force.
Simulated-Use Testing No standard	Simulated Use of four Omnibuts with components connected to a Titanium Bar under a clinically relevant cyclic load.	PASS – The Omnibut and components did not yield, deform, or fracture after fatigue testing.
Simulated Cleaning Testing No standard	Simulated cleaning of Omnibuts in a fixture with a clinically worst case cleansibility construction. Cleaning performed six times.	PASS – All parts of the Omnibuts were clean of soil indicators after six soilage and cleaning cycles.

Clinical performance data is not required to establish substantial equivalence for the subject devices.

EQUIVALENCE TO MARKETED DEVICES

The subject device abutments are substantially equivalent in intended use to the primary predicate device K161416, and the reference devices K192614 and K240208. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible.

The primary predicate device K161416 and the reference devices K192614 and K240208 are in support of the substantial equivalence of the subject device designs, material, manufacturing, and biocompatibility.

All subject device abutments have identical materials as the predicate device. The subject device is different in technology compared to the predicate, as it has a variable angulation and differently designed components. The device has many common characteristics with the predicate and reference devices as found in 510(k)sK161416, K192614, and K240208. The subject submission, K161416, K192614, and K240208 all include abutments manufactured from Ti-6Al-4V alloy conforming to ASTM F136. The scientific data described above demonstrates that the subject device has equivalent performance compared to the predicate device.

The subject device abutments have similar or identical ranges of abutment-implant platform diameter, prosthetic platform diameter, and angulation as the components cleared in K161416, K192614, and K240208.

The subject device abutments and the reference device K240208 include abutments compatible with the Reference Devices for OEM Implant Body Clearances above.

The subject device abutments and the reference device K240208 include non-sterile provided devices.

The risks associated with the use of the subject device abutment angulation in combination with the compatible implants are mitigated by the mechanical testing as described in the performance testing section of this summary.

CONCLUSION

Any differences in the technological characteristics between the subject device, the predicate device, and reference devices do not raise different questions of safety or effectiveness. The data included in this submission demonstrate substantial equivalence to the predicate and reference devices listed above.

Overall, the subject devices have the following similarities to the primary predicate and reference devices:

- Have similar intended use,
- Use similar operating principles,
- Incorporate identical materials,
- Are sterilized using similar materials and processes,
- And have similar packaging

The basis for the belief of Smart Denture Conversions, LLC that the subject device is substantially equivalent to the predicate devices is summarized in the following Table 3, *Substantial Equivalence*.

Table 3 – Substantial Equivalence

Descriptive Information	Subject Device	Primary Predicate	Reference Device #1	Reference Device #2	Comparison
	Omni-Directional Multi-Unit Abutment System Smart Denture Conversions	K161416 Multi-unit Abutment Plus Nobel Biocare AB	K192614 Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment MegaGen Implant CO., Ltd.	K240208 DESS Dental Smart Solutions Terrats Medical SL	N/A
Regulatory Classification					
Registration #	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Identical
Registration Title	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Identical
Regulation Class	II	II	II	II	Identical
Product Code	NHA	NHA	NHA	NHA	Identical
Reason for predicate or reference	N/A	Indications, function, system compatibility, retention testing, general technological characteristics	Technological comparison	Implant System Compatibility	N/A

	Subject Device	Primary Predicate	Reference Device #1	Reference Device #2	Comparison
510(k) Number	N/A	K161416	K192614	K240208	N/A
Device Name	**Omni-Directional Multi-Unit Abutment** For Omni-Directional Multi-Unit Abutment System	**Multi-unit Abutment Plus** For NobelActive	**Meg-Ball Abutment** For Meg-Ball Attachment System	**Multi-Unit Abutment** For DESS Dental Smart Solutions	N/A
Intended Use Statement	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Omnibuts, in combination with four or more endosseous implants, are indicated for multiple unit reconstructions when screw-retained prosthetics are preferred.	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Multi-unit Abutment in combination with endosseous implants are indicated for multiple unit reconstructions when screw retained prosthetics is preferred.	Meg-Ball Attachment System is a superstructure of a dental implant system to provide support for prosthetic restorations. It is intended to be used in implant-retained and removable overdenture restorations where the patient is fully edentulous.	Functional and esthetic rehabilitation of the edentulous mandible or maxilla.	Similar Intended Use expressed through a similar choice of words.
Indications for Use	The Omnibut is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. [Table of Compatible Implant]	The Multi-unit Abutment Plus is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	The Meg-Ball Attachment System is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. [Table of Compatible Implant]	Similar Indications for Use expressed through a similar choice of words. Subject, Predicate and Reference Device #2 used for multi-unit fixed restorations.
Design					N/A
Compatibility	Neodent Grand Morse, NobelActive®, Straumann BLX TorcFit™, Zimmer Tapered Screw-Vent®	NobelActive, NobelParallel and NobelReplace Conical Connection	MegaGen AnyRidge Internal Fixture, AnyRidge Octa 1 Fixture, ExFeel Internal Fixture	Astra Tech EV, Astra Tech OsseoSpeed, BioHorizons Internal, Biomet 3i OSSEOTITE®, Dentium Superline, DESS Active, PrimaConnex, Genesis, Molaris, Paltop, MIS Seven, MIS M4, MegaGen AnyRidge, Neodent Grand Morse, NobelActive®, NobelParallel Conical,	Similar connections as Predicate and Reference Device #2.

				NobelReplace Conical, NobelReplace® Trilobe, Nobel Brånemark System®, Osstem TS, Hiossen ET, Straumann TorcFit™, Straumann® Bone Level, Straumann® Tissue Level, Zimmer Screw Vent®/Tapered Screw-Vent®, TSX™ Implant System	
Prosthesis Attachment	Screw Retained	Screw Retained	Snap Retained	Screw Retained	Similar to Primary Predicate
Restoration	Multi-Unit	Multi-Unit	Multi-unit	Single and Multi-Unit	Similar to Primary Predicate
Abutment Collar Height	2.3 mm	1.5, 2.5, 3.5, 4.5 mm	0-6.0mm	1.0mm-5.5mm	Similar. Height is within cleared range of Primary Predicate and Reference Devices.
Platform Diameter	4.8mm	4.8mm	5mm	4.8mm	Identical to Primary Predicate
Abutment Angle	Straight to 30°	Straight to 30°	0°, 5°, 10°, 15°	Straight to 30°	Similar to Primary Predicate
Abutment Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Identical to Primary Predicate
Abutment Fixation	Abutment fixation with an integral screw	Abutment fixation with an integral screw or retaining screw	Abutment fixation with an integral screw	Abutment fixation with integral screw or retaining screw	Identical to Primary Predicate
Abutment/ Implant Interface	Internal	Internal	Internal	Internal, External	Identical to Primary Predicate
Sterility	Non-sterile	Sterile	Non-sterile	Non-sterile	Identical to Reference Devices #1 and #2
Usage	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Identical to Primary Predicate
Performance Testing					
Fatigue Testing	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Not performed per OEM 510(k)	Fatigue testing according to ISO 14801	Identical to Primary Predicate
Biocompatibility	Evaluated according to ISO 10993-1: 2018	Evaluated according to ISO 10993-1: 2018 as the materials were identical to the predicate device in 510(k) K072570.	Evaluated according to ISO 10993-1: 2018	Evaluated according to ISO 10993-1: 2018	Identical to reference devices and similar to Primary Predicate