November 18, 2025

Prismatik Dentalcraft, Inc.
So Hyun Park
Sr. Manager - Regulatory Affairs
2144 Michelson Drive
Irvine, California 92612

Re: K252582
Trade/Device Name: Inclusive® Titanium Abutments compatible with: Camlog® CONELOG® Implant System, Dentium® NR Line Implant Systems
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 14, 2025
Received: October 27, 2025

Dear So Hyun Park:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252582

Please provide the device trade name(s).

Inclusive® Titanium Abutments compatible with: Camlog® CONELOG® Implant System, Dentium® NR Line Implant Systems

Please provide your Indications for Use below.

Inclusive® Titanium Abutments are premanufactured prosthetic components connected to endosseous dental implants in edentulous or partially edentulous maxilla or mandible to provide support for cement-retained or screw-retained prosthetic restorations. All digitally designed abutments for use with Inclusive® Titanium Abutments for CAD/CAM are intended to be sent to a Prismatik Dentalcraft validated milling center for manufacture.
Compatible Implant Systems: Camlog® CONELOG®, Dentium® NR Line

Compatible Implant Fixtures	Implant Body Diameter Implant	Platform Diameter
Camlog® CONELOG®	3.3 mm	3.3 mm
	3.8 mm	3.8 mm
	4.3 mm	4.3 mm
	5.0 mm	5.0 mm
Dentium® NR Line	3.1 mm	3.2 mm
		3.6 mm

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PRISMATIK DENTALCRAFT, INC.

510(k) Summary – K252582

I. SUBMITTER

Prismatik Dentalcraft, Inc.
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Irvine, CA 92612, USA

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Date Prepared: November 17, 2025

II. DEVICE

Name of Device: Inclusive® Titanium Abutments compatible with: Camlog® CONELOG® Implant System, Dentium® NR Line Implant System
Common Name or Usual Name: Dental Implant Abutment
Classification Name: Endosseous Dental Implant Abutment (21 CFR 872.3630)
Regulatory Class: Class II
Product Code: NHA

III. PREDICATE DEVICE

Primary Predicate

Inclusive® Titanium Abutments compatible with: Dentsply Implants Astra Tech Implant System® EV (K191222)

Reference Devices

Inclusive® Titanium Abutment Blanks (K083192)
Inclusive® Abutments (K160979)
CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants (K193401)
CONELOG® Implant System (K113779)
NR Line Implant System (K153268)

CAMLOG® and CONELOG® Abutments For Screw-retained Restorations (ASR) (K152509)

IV. DEVICE DESCRIPTION

Inclusive® Titanium Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. Inclusive® Titanium Abutments are designed and fabricated to be compatible with Camlog® CONELOG® and Dentium® NR Line Implant Systems. The products are made from titanium alloy Ti-6Al-4V ELI, which meets ASTM F136-13(2021), *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*. They include Inclusive® Titanium Abutment Blanks intended to be used to fabricate one-piece, all-titanium, patient-specific abutments using CAD/CAM technology and Inclusive® Titanium Abutments 4.5mmH and 6mmH intended to be used for support of fabricated crowns/bridges or a zirconia coping to complete the two-piece abutment. The zirconium coping intended for use with the Inclusive® Titanium Abutments 4.5mmH and 6mmH devices are made from zirconium oxide ceramic, conforming to ISO 13356 *Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP).* Inclusive® Titanium Abutments 4.5mmH and 6mmH devices are a two-piece abutment with a titanium base and a ceramic top-half which when cemented together (Shofu MonoCem K020481) constitutes the final finished abutment. Each patient-specific abutment is prescribed by a clinician and manufactured by an authorized milling center validated by Prismatik Dentalcraft Inc. Inclusive® Titanium Abutments are provided non-sterile and intended for single use and prescription use.

Inclusive® Multi-Unit Coping is manufactured from titanium alloy, Ti-6Al-4V ELI conforming to ASTM F136-13(2021) and used in conjunction with the Camlog® CONELOG® and Dentium® NR Line multi-unit abutments. Inclusive® Multi-Unit Coping is bonded with the dental restoration prior to being seated on the multi-unit abutment via a multi-unit prosthetic screw. The non-engaging configuration of the multi-unit coping does not have an internal connection feature and seats onto the flat mating surface of the multi-unit abutment. The multi-unit coping is used in combination with screw-retained multi-unit dental prosthetics, e.g. bridges and bars, which are used to reconstruct the function and aesthetics of lost teeth. The multi-unit coping is straight with no angle correction and provided non-sterile. The device is intended for singe use and prescription use.

The design parameters for the Titanium Abutment Blanks are:

- the minimum wall thickness is no less than 0.5 mm.
- the gingival margin diameter is no less than 0.5 mm wider than implant.
- maximum angle correction is no greater than 30°. *
- minimum margin height is no less than 0.5 mm.
- maximum gingival height is no greater than 6 mm, and
- minimum post height above the gingival collar is no less than 4.0 mm.

NOTE:

*Angulation up to 30° for Titanium Abutment Blanks only allowed for compatible implant bodies of Camlog® CONELOG® Ø3.3mm Implants and Dentium® NR Line Ø3.1mm Implants for anterior use in the mouth under single-unit loading.

Inclusive® Titanium Abutments Blanks compatible with Camlog® CONELOG® Ø3.8mm, Ø4.3mm, and Ø5.0mm Implants are not to be used as angled abutments in the posterior region.

The design parameters for the zirconia coping for the Titanium Abutment 4.5mmH and 6mmH are:

- the minimum wall thickness is no less than 0.5mm.
- the gingival margin diameter is no less than 0.5 mm wider than implant.
- no angulation correction, straight (0°) only.
- minimum margin height is no less than 0.5 mm.
- maximum gingival height is no greater than 6 mm, and
- minimum post height above the gingival collar is no less than 4.0 mm.

V. INDICATIONS FOR USE

Inclusive® Titanium Abutments are premanufactured prosthetic components connected to endosseous dental implants in edentulous or partially edentulous maxilla or mandible to provide support for cement-retained or screw-retained prosthetic restorations. All digitally designed abutments for use with Inclusive® Titanium Abutments for CAD/CAM are intended to be sent to a Prismatik Dentalcraft validated milling center for manufacture.

Compatible Implant System: Camlog® CONELOG®, Dentium® NR Line

Compatible Implant Fixtures	Implant Body Diameter	Implant Platform Diameter
Camlog® CONELOG®	3.3 mm	3.3 mm
	3.8 mm	3.8 mm
	4.3 mm	4.3 mm
	5.0 mm	5.0 mm
Dentiumt® NR Line	3.1 mm	3.2 mm
		3.6 mm

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

<table>
<tr><th>Technological Characteristics</th><th>Subject Device (K252582)</th><th>Predicate Device (K191222)</th><th>Comparison</th></tr>
<tr><td>Device Name</td><td>Inclusive® Titanium Abutments compatible with: Camlog® CONELOG®, Dentium® NR Line Implant Systems</td><td>Inclusive® Titanium Abutments compatible with: Dentsply Implants Astra Tech Implant System® EV</td><td>N/A</td></tr>
<tr><td>Manufacturer</td><td>Prismatik Dentalcraft, Inc.</td><td>Prismatik Dentalcraft, Inc.</td><td>Identical</td></tr>
<tr><td>Product Code</td><td>NHA</td><td>NHA</td><td>Identical</td></tr>
<tr><td>Prescription Device</td><td>Yes</td><td>Yes</td><td>Identical</td></tr>
<tr><td>Intended Use</td><td>Inclusive® Abutments are intended for use as an aid in prosthetic rehabilitation.</td><td>Inclusive® Abutments are intended for use as an aid in prosthetic rehabilitation.</td><td>Identical</td></tr>
<tr><td>Indications for Use</td><td>Inclusive® Titanium Abutments are premanufactured prosthetic components connected to endosseous dental implants in edentulous or partially edentulous maxilla or mandible to provide support for cement-retained or screw-retained prosthetic restorations.

All digitally designed abutments for use with Inclusive® Titanium Abutments for CAD/CAM are intended to be sent to a Prismatik Dentalcraft validated milling center for manufacture.

Compatible Implant Systems: Camlog® CONELOG®, Dentium® NR Line
<table>
<tr><th>Compatible Implant Fixtures</th><th>Implant Body Diameter</th><th>Implant Platform Diameter</th></tr>
<tr><td rowspan="4">Camlog® CONELOG®</td><td>3.3 mm</td><td>3.3 mm</td></tr>
<tr><td>3.8 mm</td><td>3.8 mm</td></tr>
<tr><td>4.3 mm</td><td>4.3 mm</td></tr>
<tr><td>5.0 mm</td><td>5.0 mm</td></tr>
<tr><td rowspan="2">Dentium® NR Line</td><td rowspan="2">3.1 mm</td><td>3.2 mm</td></tr>
<tr><td>3.6 mm</td></tr>
</table></td><td>Inclusive® Titanium Abutments are premanufactured prosthetic components connected to endosseous dental implants in edentulous or partially edentulous maxilla or mandible to provide support for cement-retained or screw-retained prosthetic restorations.

All digitally designed abutments for use with Inclusive® Titanium Abutments for CAD/CAM are intended to be sent to a Prismatik Dentalcraft validated milling center for manufacture.

Compatible Implant System: Dentsply Implants Astra Tech Implant System® EV
<table>
<tr><th>Compatible Implant Fixtures</th><th>Implant Body Diameter</th><th>Implant Platform Diameter</th></tr>
<tr><td>OsseoSpeed® EV 3.0S</td><td>3.0 mm</td><td>3.0 mm</td></tr>
<tr><td>OsseoSpeed® EV 3.6S</td><td>3.6 mm</td><td>3.6 mm</td></tr>
</table></td><td>Identical except for compatible platforms</td></tr>
</table>

<table>
<tr><th colspan="3">Technological Characteristics</th><th>Subject Device (K252582)</th><th>Predicate Device (K191222)</th><th>Comparison</th></tr>
<tr><td colspan="3"></td><td></td><td><table>
<tr><td>OsseoSpeed® EV 4.2S</td><td>4.2 mm</td><td>4.2 mm</td></tr>
<tr><td>OsseoSpeed® EV 4.2C</td><td>3.6 mm</td><td>4.2 mm</td></tr>
<tr><td>OsseoSpeed® EV 4.8S</td><td>4.8 mm</td><td>4.8 mm</td></tr>
<tr><td>OsseoSpeed® EV 4.8C</td><td>4.2 mm</td><td>4.8 mm</td></tr>
<tr><td>OsseoSpeed® EV 5.4S</td><td>5.4 mm</td><td>5.4 mm</td></tr>
</table></td><td></td></tr>
<tr><td rowspan="8">Design Characteristics</td><td rowspan="4">Material</td><td>Abutment &Screw</td><td>Ti-6Al-4V ELI</td><td>Ti-6Al-4V ELI</td><td>Identical</td></tr>
<tr><td>Multi-Unit Coping & Screw</td><td>Ti-6Al-4V ELI</td><td>Ti-6Al-4V ELI</td><td>Identical</td></tr>
<tr><td>Coping/ Superstructure</td><td>Y-TZP (ISO 13356)</td><td>Y-TZP (ISO 13356)</td><td>Identical</td></tr>
<tr><td>Cement</td><td>Shofu MonoCem resin cement (K020481)</td><td>Shofu MonoCem resin cement (K020481)</td><td>Identical</td></tr>
<tr><td colspan="2">Connection</td><td><table>
<tr><th>Implant</th><th>Connection Design</th></tr>
<tr><td>Camlog® CONELOG®</td><td>Tri-key connection</td></tr>
<tr><td>Dentium® NR Line</td><td>Square connection</td></tr>
</table></td><td>Taper followed with a six-position indexing connection feature</td><td>Different connection design</td></tr>
<tr><td colspan="2">Titanium Abutment Blank</td><td>Provided in 9.4mm diameter; To machine a patient-specific, engaging, one-piece abutment</td><td>Provided in 9.4mm diameter; To machine a patient-specific, engaging, one-piece abutment</td><td>Identical</td></tr>
<tr><td colspan="2">Prosthetic Post Height</td><td>4.0 mm minimum</td><td>4.0 mm minimum</td><td>Identical</td></tr>
<tr><td colspan="2" rowspan="2">Gingival Height</td><td>0.5 mm minimum</td><td>0.5 mm minimum</td><td>Identical</td></tr>
<tr><td>6.0 mm maximum</td><td>6.0 mm maximum</td><td>Identical</td></tr>
<tr><td colspan="2">Angulation</td><td>0º – 30º</td><td>0º – 20º</td><td>Increased angulation range, supported by fatigue testing</td></tr>
</table>

Technological Characteristics		Subject Device (K252582)	Predicate Device (K191222)	Comparison
	Prosthetic Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained	Identical
	Restoration Types	Single-unit, Multi-unit	Single-unit, Multi-unit	Identical
	Titanium Abutment 4.5mmH and 6mmH	Engaging/Non-Engaging two-piece abutment	Engaging/Non-Engaging two-piece abutment	Identical
	Prosthetic Post Height	4.0 mm minimum	4.0 mm minimum	Identical
	Margin Height	0.5 mm minimum	0.5 mm minimum	Identical
	Gingival Height	6.0 mm maximum	6.0 mm maximum	Identical
	Angulation	0º	0º	Identical
	Prosthesis Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained	Identical
	Restoration Type	Single-unit, Multi-unit	Single-unit, Multi-unit	Identical
Design Characteristics	**Multi-Unit Coping**	Prefabricated coping to be used in conjunction with the OEM multi-unit abutment.	N/A	The predicate device does not have multi-unit coping.
	Angulation	0º	N/A	The predicate device does not have multi-unit coping. The functionality of the subject device is supported by dimensional analysis and reverse engineering analysis.
	Prosthetic Attachment	Screw-retained multi-unit dental prosthesis, e.g. bridges and bars	N/A	The predicate device does not have multi-unit

Technological Characteristics		Subject Device (K252582)	Predicate Device (K191222)	Comparison
				coping. The functionality of the subject device is supported by dimensional analysis and reverse engineering analysis.
	Restoration Type	Multi-unit	N/A	The predicate device does not have multi-unit coping. The functionality of the subject device is supported by dimensional analysis and reverse engineering analysis.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The subject device is substantially equivalent to the primary predicate device (K191222) listed above in intended use, material, design principles and technological characteristics. The subject device and the primary predicate device (K191222) include prefabricated, precision interface (implant/abutment connection) abutments that are manufactured from titanium alloy conforming to ASTM F136-13(2021). The subject device and the primary predicate device (K191222) include Inclusive® Titanium Abutment Blanks intended to be used to fabricate one-piece, all-titanium, patient-specific abutments using CAD/CAM technology and Inclusive® Titanium Abutments 4.5mmH and 6mmH intended to be used for support of fabricated crowns/bridges or zirconia copings. Inclusive® Titanium Abutments 4.5mmH and 6mmH are two-piece abutment with a titanium base and a ceramic top half. Each patient-specific abutment is individually prescribed by the clinician and manufactured by Prismatik Dentalcraft, Inc. or a qualified validated milling center.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate device (K191222) except the compatible implant system due to different implant connection. Both devices have the same intended use as endosseous dental implant abutments for the support of a prosthesis to restore chewing function.

The subject device designs are substantially equivalent to the corresponding design of the primary predicate device (K191222), including titanium blank abutments and titanium base abutments (engaging and non-engaging). The subject device and the primary predicate device (K191222) are for single-unit or multiple-unit restorations and for cement-retained or screw-retained prostheses. Both devices have internal implant interface connections and are made of titanium alloy Ti-6Al-4V ELI conforming to ASTM F136-13(2021) (abutments and abutment screws), and the titanium base abutments are to be used with zirconia superstructures.

The subject device includes designs for abutment angulation up to 30°; this angulation range is similar to the primary predicate device (K191222), but increased angulation range from 20° to 30°. The subject device is compatible with the following OEM implant systems, Camlog® CONELOG® (K113779, K193401) and Dentium® NR Line (K153268), and the compatibility of the subject device and the OEM implants was established by dimensional analysis and reverse engineering analysis regarding specific critical dimensions. When the subject device is used according to its labeling, this difference does not impact safety or effectiveness. Furthermore, mechanical performance testing was performed according to ISO 14801:2016, *Dentistry – Implants – Dynamic loading test for endosseous dental implants* and demonstrated that the subject device has sufficient strength for its intended use.

The subject device also includes Inclusive® Multi-Unit Coping, which is used in conjunction with the OEM Camlog® CONELOG® (K113779, K193401) and Dentium® NR Line (K153268) multi-unit abutments. The Multi-Unit Coping has not been subjected to static load and fatigue testing since it is provided straight with no angle correction. The

intended use of the Multi-Unit Coping is to support a multi-unit restoration that will have other implant anchors. Therefore, the Multi-Unit Coping is always used in splinted applications reducing the effect of compressive and shear forces. The compatibility of the subject device and the OEM multi-unit abutments was established by dimensional analysis and reverse engineering analysis regarding specific critical dimensions. When the subject device is used according to its labeling, there is no concern of safety and effectiveness of the device.

The subject device is provided non-sterile and to be steam sterilized by the end-user, the same as the primary predicate device (K191222). The validated moist heat sterilization method according to ISO 17665-1:2006, *Sterilization of health care products – Moist heat – Requirements for the development, validation and routine control of a sterilization process for medical devices* and ISO/TS 17665-2:2009, *Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1* is the same as the primary predicate device (K191222), and the reference devices K083192 and K160979. Substantial equivalence of the subject device components in terms of biocompatibility is supported by the fact that materials are identical in formulation, processing, component interactions, and storage conditions to the primary predicate device (K191222) and the reference device (K160979). The biological evaluation was also performed on the subject device and concluded that there is no biocompatibility concern.

VII. PERFORMANCE DATA

Non-clinical testing data are submitted to demonstrate substantial equivalence. No clinical data was included in this submission.

Biocompatibility Evaluation

Biocompatibility evaluation was conducted by following 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* and concluded that there is no biocompatibility concern. The subject device has the same material and manufacturing process at the same manufacturing facility as the primary predicate device (K191222) and the reference device (K169079); therefore, additional biocompatibility testing was not conducted. Cytotoxicity testing according to ISO 10993-5:2009, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity* was referenced from K169079 to demonstrate the biocompatibility of the final finished device consisting of the titanium abutment, zirconia coping and cement. Biological evaluation was used to address questions related to substantial equivalence between the subject device and the primary predicate device (K191222) in terms of biocompatibility.

Mechanical Properties

Static load and fatigue testing of the implant/abutment assembly was considered according to the FDA Guidance Document, *Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous*

Dental Implant Abutments and ISO 14801:2016 standard with the worst-case scenario. The fatigue limit data demonstrated that the subject device has sufficient strength for its intended use. Reverse engineering of OEM implant bodies, OEM abutments, and OEM abutment screws was conducted to confirm compatibility. The results of the mechanical testing were used to address questions related to substantial equivalence based on the differences in technical specifications between the subject device and the primary predicate device (K191222).

Sterilization Validation

The subject device is provided non-sterile intended to be steam sterilized by the end user with the same parameters as the primary predicate device (K191222) as validated by ISO 17665-1:2006 and ISO/TS 17665-2:2009. The subject device has the same material and manufacturing process at the same manufacturing facility as the primary predicate device (K191222) and the reference device (K160979); therefore, additional sterilization validation was not conducted. Sterilization validation according to ISO 17665-1:2006 and ISO/TS 17665-2:2009 were referenced from K083192 and K160979. The results of the previous testing were used to address questions related to substantial equivalence based on the differences in technical specifications between the subject device and the primary predicate device (K191222).

Shelf Life and Packaging Validation

The subject device performance is not adversely affected by aging because the subject device is made from titanium alloy conforming to ASTM F136-13(2021); this material is known to be stable in air at room temperature for an indefinite period. Shelf-life is not applicable because of the low likelihood of time-dependent product degradation. Packaging validation according to ASTM D4169-22, *Standard Practice for Performance Testing of Shipping Containers and Systems* was conducted to ensure that the packaging configurations for the subject device are suitable to withstand the distribution environment. It was determined that the packaging for the subject device is suitable for use. The results of the testing were used to address questions related to substantial equivalence based on differences in product packaging between the subject device and the primary predicate device (K191222).

Use in MR Environment

Non-clinical MR review was performed to evaluate the metallic devices in the MR environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the subject device components and material composition. Rationale addressed parameters per the FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment”.

VIII. CONCLUSION

Based on the technological characteristics and non-clinical test data included in this submission, the subject device has been shown to be substantially equivalent to the predicate device (K191222).