9/26/23

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

Re: K223496
Trade/Device Name: Inclusive®Titanium Abutments compatible with: Straumann® Bone Level SC, BioHorizons® Tapered Internal, MIS® C1 Implant Systems
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 26, 2023
Received: September 26, 2023

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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.

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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223496

Device Name
Inclusive® Titanium Abutments compatible with: Straumann® Bone Level SC, BioHorizons® Tapered Internal, MIS® C1 Implant Systems

Indications for Use *(Describe)*

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: Straumann® Bone Level SC, BioHorizons® Tapered Internal, MIS® C1

Compatible Implant Fixtures	Implant Body Diameter	Implant Platform Diameter
Straumann® Bone Level SC	2.9mm	2.9mm
BioHorizons® Tapered Internal	3.0mm	3.0mm
	3.4mm	3.0mm
	3.8mm	3.5mm
	4.6mm	4.5mm
	5.8mm	5.7mm
MIS® C1	3.3mm	NP (2.75mm)
	3.75/4.2mm	SP (3.15mm)
	5.0mm	WP (4.0mm)

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PRISMATIK DENTALCRAFT, INC.

K223496

510(k) Summary

I. SUBMITTER

Prismatik Dentalcraft, Inc.
2144 Michelson Drive,
Irvine, CA 92612, USA

Primary Contact Person: So Hyun Park, Regulatory Affairs Manager, MS
Email: so.park@glidewelldental.com
Phone: (949) 863-5479

Secondary Contact Person: Herbert Crane, VP RA/QA
Email: Herbert.crane@glidewelldental.com
Phone: (949) 222-3531

Date Prepared: September 26, 2023

II. DEVICE

Name of Device: Inclusive® Titanium Abutments compatible with: Straumann® Bone Level SC, BioHorizons® Tapered Internal, MIS® C1 Implant Systems
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 Device

Inclusive® Titanium Abutment Blanks (K083192)
Inclusive® Abutments (K160979)
Straumann Ø2.9 mm Bone Level Tapered Implants (K162890)
BioHorizons Tapered Internal Implant System (K071638)
BioHorizons Laser-Lok 3.0 Implant System (K093321)
BioHorizons Tapered Internal Implants (K143022)
Conical Connection Implants (K112162)
MIS C1 Narrow Platform Conical Connection Implant System (K172505)

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 Straumann® Bone Level SC Implant System, BioHorizons® Tapered Internal Implant System and MIS® C1 Implant System. The products are made from titanium alloy Ti-6Al-4V ELI, which meets ASTM standard F136. 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 zirconia copings. Inclusive® Titanium Abutments are a two-piece abutment with a titanium base and a ceramic top half. Each patient-specific abutment is prescribed by a clinician and manufactured by Prismatik Dentalcraft, Inc. or a qualified validated milling center. 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 and used in conjunction with the OEM BioHorizons® Tapered Internal and OEM MIS® C1 multi-unit abutment. 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.

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 Systems: Straumann® Bone Level SC, BioHorizons® Tapered Internal, MIS® C1

Compatible Implant Fixtures	Implant Body Diameter	Implant Platform Diameter
Straumann® Bone Level SC	2.9mm	2.9mm
BioHorizons® Tapered Internal	3.0mm	3.0mm
	3.4mm	3.0mm
	3.8mm	3.5mm
	4.6mm	4.5mm
	5.8mm	5.7mm
MIS® C1	3.3mm	NP (2.75mm)
	3.75/4.2mm	SP (3.15mm)
	5.0mm	WP (4.0mm)

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

<table>
<tr><th>Technological Characteristics</th><th>Subject Device (K223496)</th><th>Predicate Device (K191222)</th><th>Comparison</th></tr>
<tr><td>Device Name</td><td>Inclusive® Titanium Abutments compatible with: Straumann® Bone Level SC, BioHorizons® Tapered Internal, MIS® C1 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>Same</td></tr>
<tr><td>Product Code</td><td>NHA</td><td>NHA</td><td>Same</td></tr>
<tr><td>Prescription Device</td><td>Yes</td><td>Yes</td><td>Same</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>Same</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: Straumann® Bone Level SC, BioHorizons® Tapered Internal, MIS® C1
<table>
<tr><th>Compatible Implant Fixtures</th><th>Implant Body Diameter</th><th>Implant Platform Diameter</th></tr>
<tr><td>Straumann® Bone Level SC</td><td>2.9mm</td><td>2.9mm</td></tr>
<tr><td>BioHorizons® Tapered Internal</td><td>3.0mm</td><td>3.0mm</td></tr>
<tr><td></td><td>3.4mm</td><td>3.0mm</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>3.0mm</td><td>3.0mm</td></tr>
<tr><td>OsseoSpeed® EV 3.6S</td><td>3.6mm</td><td>3.6mm</td></tr>
</table></td><td>Same except for compatible platforms</td></tr>
</table>

<table>
<tr><th colspan="3">Technological Characteristics</th><th>Subject Device (K223496)</th><th>Predicate Device (K191222)</th><th>Comparison</th></tr>
<tr><td colspan="3"></td><td><table>
<tr><td></td><td>3.8mm</td><td>3.5mm</td></tr>
<tr><td></td><td>4.6mm</td><td>4.5mm</td></tr>
<tr><td></td><td>5.8mm</td><td>5.7mm</td></tr>
<tr><td>MIS® C1</td><td>3.3mm</td><td>NP (2.75mm)</td></tr>
<tr><td></td><td>3.75/4.2mm</td><td>SP (3.15mm)</td></tr>
<tr><td></td><td>5.0mm</td><td>WP (4.0mm)</td></tr>
</table></td><td><table>
<tr><td>OsseoSpeed® EV 4.2S</td><td>4.2mm</td><td>4.2mm</td></tr>
<tr><td>OsseoSpeed® EV 4.2C</td><td>3.6mm</td><td>4.2mm</td></tr>
<tr><td>OsseoSpeed® EV 4.8S</td><td>4.8mm</td><td>4.8mm</td></tr>
<tr><td>OsseoSpeed® EV 4.8C</td><td>4.2mm</td><td>4.8mm</td></tr>
<tr><td>OsseoSpeed® EV 5.4S</td><td>5.4mm</td><td>5.4mm</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 (ASTM F136)</td><td>Ti-6Al-4V ELI (ASTM F136)</td><td>Same</td></tr>
<tr><td>Multi-Unit Coping & Screw</td><td>Ti-6Al-4V ELI (ASTM F136)</td><td>Ti-6Al-4V ELI (ASTM F136)</td><td>Same</td></tr>
<tr><td>Coping/ Superstructure</td><td>Y-TZP (ISO 13356)</td><td>Y-TZP (ISO 13356)</td><td>Same</td></tr>
<tr><td>Cement</td><td>Shofu MonoCem resin cement (K020481)</td><td>Shofu MonoCem resin cement (K020481)</td><td>Same</td></tr>
<tr><td colspan="2">Connection</td><td><table>
<tr><th>Implant</th><th>Connection Design</th></tr>
<tr><td>Straumann® Bone Level SC</td><td rowspan="2">Taper followed by four connection features</td></tr>
<tr><td>MIS® C1</td></tr>
<tr><td>BioHorizons® Tapered Internal</td><td>Taper followed with a hexagonal connection feature</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>Same</td></tr>
<tr><td colspan="2">Prosthetic Post Height</td><td>4.0 mm minimum</td><td>4.0 mm minimum</td><td>Same</td></tr>
<tr><td colspan="2">Margin Height</td><td>0.5 mm minimum</td><td>0.5 mm minimum</td><td>Same</td></tr>
<tr><td colspan="2">Gingival Height</td><td>6.0 mm maximum</td><td>6.0 mm maximum</td><td>Same</td></tr>
</table>

Technological Characteristics		Subject Device (K223496)	Predicate Device (K191222)	Comparison
	Angulation	0º – 30º	0º – 20º	Increased angulation range
	Prosthetic Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained	Same
	Restoration Types	Single-unit, Multi-unit	Single-unit, Multi-unit	Same
	Titanium Abutment	Engaging/Non-Engaging two-piece abutment	Engaging/Non-Engaging two-piece abutment	Same
	Prosthetic Post Height	4.0 mm minimum	4.0 mm minimum	Same
	Margin Height	0.5 mm minimum	0.5 mm minimum	Same
	Gingival Height	6.0 mm maximum	6.0 mm maximum	Same
	Angulation	0º	0º	Same
	Prosthesis Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained	Same
	Restoration Type	Single-unit, Multi-unit	Single-unit, Multi-unit	Same

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. 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 are a 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 conforming to ASTM F136 (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, Straumann® Bone Level SC, BioHorizons® Tapered Internal, MIS® C1, 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 is provided non-sterile and to be steam sterilized by the end-user. The validated moist heat sterilization method according to ISO 17665-1:2006 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 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). 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 was 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; this material is known to be stable in air at room temperature for an indefinite period of time. Shelf-life is not applicable because of low likelihood of time-dependent product degradation. A packaging validation according to ASTM D4169-16 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).