November 25, 2024

Dentsply Sirona Inc.
Laura Sobrin
Sr. Technical Regulatory Affairs Manager
221 West Philadelphia St., Suite 60W
York, Pennsylvania 17401

Re: K241692
Trade/Device Name: MIS LYNX Conical Connection Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 12, 2024
Received: October 23, 2024

Dear Laura Sobrin:

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.

Submission Number *(if known)*

K241692

Device Name

MIS LYNX Conical Connection Implant System

Indications for Use *(Describe)*

MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.

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
for
MIS LYNX Conical Connection Implant System (K241692)

1. Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401, USA

Contact Person: Laura Sobrin
Telephone Number: 717-849-4434
Email: laura.sobrin@dentsplysirona.com
Date Prepared: November 25, 2024

2. Device Name:
   - Proprietary Name: MIS LYNX Conical Connection Implant System
   - Classification Name: Implant, Endosseous, Root-Form
   - CFR Number: 872.3630
   - Device Class: Class II
   - Primary Product Code: DZE
   - Secondary Product Code: NHA

3. Predicate/Reference Devices:

Predicate Device Name	**510(k)**	**Company Name**
MIS C1 Conical Connection Dental Implant System (Narrow Platform)	K172505	MIS (part of Dentsply Sirona)
Reference Device Name	**510(k)**	**Company Name**
MIS C1 Conical Connection Dental Implant System (Standard and Wide Platform)	K112162	MIS (part of Dentsply Sirona)
MIS V3 Conical Connection Dental Implants System (reference device)	K163349	MIS (part of Dentsply Sirona)
MIS CLEAR Dental Implant System	K200102	MIS (part of Dentsply Sirona)
PrimeTaper EV Dental Implants Ø3.0	K220841	Dentsply Sirona
SEVEN Implants, BIOCOM Implants, LANCE Implants	K103089	MIS (part of Dentsply Sirona)
MIS Internal Hex Dental Implant System (SEVEN Implants)	K180282	MIS (part of Dentsply Sirona)
MIS Dental Implant System (Lance Implants)	K040807	MIS (part of Dentsply Sirona)
MIS Dental Implant System (Lance Implants)	K192149	MIS (part of Dentsply Sirona)

4. Description of Device:

The proposed MIS LYNX Conical Connection Dental Implants are intended for one- or two-stage dental implant procedures and are used in the upper or lower jaw for supporting tooth replacement to restore chewing function.

The proposed dental implants have an internal conical connection with an anti-rotation index of six positions for standard and wide platforms and four positions for narrow platform.

The proposed implants and cover screw are manufactured from titanium alloy (Ti-6Al-4V ELI complying with standard ASTM F136-13 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant).

The 3.3 mm diameter size implant is available in 10, 11.5, 13, and 16 mm lengths while the 3.75, 4.2, and 5.0 mm diameter size implants are available in 8, 10, 11.5, 13, and 16 mm lengths.

The proposed implants feature an outer profile which has a coronal half which is cylindrical and an apical half which is conical. The threads are designed so the implant has a self-drilling property. The geometric design also includes spiral channels (flutes) stemming from the apex. These spiral channels are designed to enable insertion torque reduction when applying reverse torque. The proposed implant design also includes circumferential grooves at the coronal area which are called "micro-rings". These horizontal micro-rings are designed to increase the BIC (Bone to Implant Contact) of the implant with the bone. The proposed implants also feature a triangular neck ("V-Cut"). The gaps around the sides of the implant neck are designed to result in an open, compression free zone.

The implant-abutment connection surface of the proposed MIS LYNX Conical Connection Implant is anodized for color coding to indicate the platform: yellow for narrow platform implants, purple for standard platform implants, and green for wide platform implants. The proposed implants are packaged in either a dry or wet package. Implants packaged in the wet packaging configuration are packaged in NaCl solution and are not anodized. The liquid environment is intended to maintain the super-hydrophilic (contact angle exhibited by water in contact with the surface is equal to zero degrees) property of the proposed dental implants until the implants are installed in the patients.

Cover screws are intended to be used in a two-stage surgical procedure as temporary components to the proposed endosseous implant to allow healing of the soft tissue. They are inserted into the implant and the gums are sutured over it. Their purpose is to let the osseointegration begin without any forces being applied to the implant. After a healing period, the cover screw is exposed and removed, and replaced by either a healing cap or an abutment. The cover screws are also anodized for color coding.

5. Intended Use and Indications for Use:

The proposed device and the predicate device, MIS C1 Conical Connection Dental Implant System (K172505), have the same intended use.

The Indications for Use of the proposed device are very similar to those of the predicate device. The only differences are that redundancy related to restoring patient chewing function was removed, and reference to a discontinued product was also removed. Otherwise, Indications for Use are the same.

Table 5.1 Comparison of Intended Use and Indications for Use of Proposed and Predicate Device

Item of Comparison	Proposed device MIS LYNX Conical Connection Implant System (K241692)	Predicate device MIC C1 Conical Connection Dental Implant System (Narrow Platform) (K172505)	Discussion
Intended Use	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.	Intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function.	Same
Indications for Use	MIS Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	MIS dental implant system is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	Very similar Indications for Use. The only differences are that the predicate device's indications include the words "& UNO" which is an implant system that is no longer marketed by the manufacturer. In addition, "in order to restore the patient chewing function" is removed from the proposed device indications as it is redundant with "in order to restore masticatory function".

6. Technological Comparison:

The proposed MIS LYNX Conical Connection Implants are bone level implants made of the same raw material (Ti-6Al-4V ELI per ASTM F136) that undergo the same manufacturing process as the predicate device (K172505).

The conical connection of the proposed implants has the same 12° cone angulation as the predicate device (K172505). The implant-abutment conical connection of the narrow platform implants is identical to that of the predicate device (K172505), the standard platform connection is identical to that of the reference device K163349 and the wide platform connection is similar to that of the reference device (K112162). The proposed implant diameters also correspond to the available diameters in the predicate (K172505) and reference (K112162) devices.

The overall tapered body design and apex, and profile of the circumferential grooves in the coronal area of the implant, called "Micro-Rings", of the proposed MIS LYNX Conical Connection implants are the same as those of the predicate device (K172505).

The proposed implants have gaps around the sides of the implant, creating a "V-Cut" triangular neck, similar to the reference device (K163349). The minor differences in the design of the outer thread of the proposed implants from the predicate device (K172505) do not raise new questions on safety and effectiveness as demonstrated with the results of fatigue testing.

The lengths of the narrow platform implants are identical to those of the predicate device (K172505). The lengths of the standard and wide platforms implants are identical to those of the reference device (K112162).

The predicate device (K172505) is available in two packaging configurations. A "Dry" packaging configuration in which the implant is placed in an inner tube in air, and a "Wet" packaging configuration in which the implant is placed in an inner tube in NaCl solution. The "Wet" packaging configuration of the predicate device (K172505) was cleared under K200102.

The proposed MIS LYNX Conical Connection implants and cover screws, in both "Dry" and "Wet" packaging configurations, are placed in the inner tube cleared under K200102 with the exception of an additional silicone O-ring that was added to the cap of the inner tube for the "Wet" packaging configuration. The secondary package of the proposed implants and cover screws is different from that of the predicate device (K172505, as modified in K200102): while the predicate device (K172505) inner tube is placed in an outer tube, that serves as the sterile barrier, the proposed implants inner tube is placed in a blister. The blister packaging was demonstrated to be substantially equivalent to the secondary package of the predicate device (K172505, as modified in K200102) via sterility and shelf-life testing.

Both the proposed device and the predicate device (K172505) are delivered sterile, for single use, sterilized by Gamma radiation.

An overall comparison of the technological characteristics of the proposed MIS LYNX Conical Connection Implants and cover screws to the predicate device (K172505, as modified in K200102) and reference devices (K112162, K163349, as modified in K200102) is provided in Table 6.1.

Table 6.1: Comparison of Technological Characteristics between the Proposed Device, the Predicate Device and the Reference Devices (Implants)

Item	Proposed Device MIS LYNX Conical Connection Dental Implant System K241692	Predicate Device MIS C1 Conical Connection Dental Implant System K172505 with wet packaging configuration cleared in K200102	Reference Device MIS C1 Conical Connection Dental Implant System K112162 with wet packaging configuration cleared in K200102	Reference Device MIS V3 Conical Connection Dental Implant System K163349 with wet packaging configuration cleared in K200102	Equivalence Comparison
Product code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	Same
Manufacturer	MIS Implants Technologies Ltd. (part of Dentsply Sirona)	MIS Implants Technologies Ltd. (part of Dentsply Sirona)	MIS Implants Technologies Ltd. (part of Dentsply Sirona)	MIS Implants Technologies Ltd. (part of Dentsply Sirona)	Same
Implant Material	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136	Same
Implant Surface Treatment	**For implants in "Dry" packaging configuration:** Anodized (internally), sand blasted and acid etched **For implants in "Wet" packaging configuration:** Sand blasted and acid etched	**For implants in "Dry" packaging configuration:** Anodized (internally), sand blasted and acid etched **For implants in "Wet" packaging configuration:** Sand blasted and acid etched	**For implants in "Dry" packaging configuration:** Anodized (internally), sand blasted and acid etched **For implants in "Wet" packaging configuration:** Sand blasted and acid etched	**For implants in "Dry" packaging configuration:** Anodized (internally), sand blasted and acid etched **For implants in "Wet" packaging configuration:** Sand blasted and acid etched	Same
Implant Connection Type	**For Narrow Platform:** Conical connection with four index slots with even width Cone angulation 12° **For Standard & Wide Platforms:** Conical connection with six index slots with alternating width Cone angulation 12°	**For Narrow Platform:** Conical connection with four index slots with even width Cone angulation 12°	**For Standard and Wide Platforms:** Conical connection with six index slots with even width Cone angulation 12°	**For Narrow Platform:** Conical connection with three index slots with even width Cone angulation 12° **For Standard Platforms:** Conical connection with six index slots with alternating width Cone angulation 12°	Similar The narrow platform connection of the proposed implants is identical to that of the predicate device (K172505). The standard platform connection of the proposed implants is identical to that of the reference device standard platform (K163349). The wide platform connection is similar to that of the reference device (K112162). The cone angulation of 12° is the same for the proposed, predicate and reference devices.
Implant Overall Body Design	Tapered. The implant body is half cylindrical (the coronal part of the implant) and half conical (the apical part of the implant). The implant is threaded.	Tapered. The implant body is half cylindrical (the coronal part of the implant) and half conical (the apical part of the implant). The implant is threaded.	Tapered, SP - the implant body is half cylindrical (the coronal part of the implant) and half conical (the apical part of the implant). The implant is threaded.	Tapered. The implant body with the "V-Cut" is cylindrical (the coronal part of the implant) and the body of the implant is conical (the apical part of the implant). The implant is threaded.	Same as predicate device (K172505).

Item	Proposed Device MIS LYNX Conical Connection Dental Implant System K241692	Predicate Device MIS C1 Conical Connection Dental Implant System K172505 with wet packaging configuration cleared in K200102	Reference Device MIS C1 Conical Connection Dental Implant System K112162 with wet packaging configuration cleared in K200102	Reference Device MIS V3 Conical Connection Dental Implant System K163349 with wet packaging configuration cleared in K200102	Equivalence Comparison
			WP - the implant body is partially cylindrical (the coronal part of the implant) and partially conical (the apical part of the implant). The implant is threaded.		
Implant Neck	"V-Cut" a back-tapered triangular neck	Round neck	Round neck	"V-Cut" a triangular neck	Similar The differences in the angulation and radius with reference device (K163349) do not affect the proposed implants' strength and stability as demonstrated in fatigue testing.
Implant Apex	Domed apex	Domed apex	Domed apex	Flat apex	Same The proposed device has the same apical design as the predicate (K172505) and reference (K112162) devices.
Implant Outer Thread	Dual thread The threads are thin at the apical portion, and thicker at the coronal portion of the implant's body.	Dual thread The threads are thin at the apical portion, and thicker at the coronal portion of the implant's body	Dual thread The threads are thin at the apical portion, and thicker at the coronal portion of the implant's body	Dual thread The threads are thin at the apical portion, and thicker at the coronal portion of the implant's body	Similar The minor differences in the lead of the outer thread and the pitch created by it, are due to the slight changes in the design of the body of the implant. The minor differences in the outer thread lead and pitch do not affect the proposed implants' strength and stability as demonstrated in fatigue testing.
Type of Implant	Bone level implant	Bone level implant	Bone level implant	Bone level implant	Same
Implant Platform	Narrow Platform (NP), Standard Platform (SP), Wide Platform (WP)	Narrow Platform (NP)	Standard Platform (SP), Wide Platform (WP)	Narrow Platform (NP), Standard Platform (SP)	Same No difference between the platforms of the proposed implants and the platforms available with the predicate (K172505) and reference (K112162) devices, combined.
Implant	NP: Ø 3.30 mm	NP: Ø 3.30 mm	SP: Ø 3.75 mm, 4.20 mm,	NP: Ø 3.30 mm	Same

Item	Proposed Device MIS LYNX Conical Connection Dental Implant System K241692	Predicate Device MIS C1 Conical Connection Dental Implant System K172505 with wet packaging configuration cleared in K200102	Reference Device MIS C1 Conical Connection Dental Implant System K112162 with wet packaging configuration cleared in K200102	Reference Device MIS V3 Conical Connection Dental Implant System K163349 with wet packaging configuration cleared in K200102	Equivalence Comparison
Diameters	SP: Ø 3.75 mm, 4.20 mm, WP: Ø 5.00 mm		WP: Ø 5.00 mm	SP: Ø 3.90 mm, 4.30 mm, 5.00 mm	No difference between the diameters of the proposed implants and the diameters available with the predicate (K172505) and reference (K112162) devices, combined.
Implant Lengths	**For Ø 3.30 implants:** 10, 11.5, 13, 16 mm **For Ø 3.75, Ø 4.20 & Ø 5.00 implants:** 8, 10, 11.5, 13, 16 mm	**For Ø 3.30 implants:** 10, 11.5, 13, 16 mm	**For Ø 3.75, Ø 4.20 & Ø 5.00 implants:** 8, 10, 11.5, 13, 16 mm	**For Ø 3.30 implants:** 10, 11.5, 13, 16 mm **For Ø 3.90, Ø 4.30 & Ø 5.00 implants:** 8, 10, 11.5, 13, 16 mm	Same For Ø 3.30 implants: There is no difference between the lengths of the proposed implants and the length of the predicate device (K172505). For Ø 3.75, Ø 4.20 & Ø 5.00 implants: There is no difference between the lengths of the proposed implants and the length of the reference device (K112162).
Cover Screw Material	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136	Same
Cover Screw Surface Treatment	Polished and anodized after machined	Polished and anodized after machined	Polished and anodized after machined	Polished and anodized after machined	Same
Cover Screw Connection Type	**For Narrow Platform, Standard & Wide Platforms:** Conical connection. Cone angulation 14°	**For Narrow Platform:** Conical connection. Cone angulation 12°	**For Standard and Wide Platforms:** Conical connection. Cone angulation 12°	**For Narrow & Standard Platforms:** Conical connection. Cone angulation 12°	Similar The connection of the proposed cover screws is similar in design to the reference device (K163349). .
Cover Screw Diameters	NP: Ø 2.77 to 2.79 mm SP: Ø 3.15 to 3.17 mm WP: Ø 4.00 to 4.02 mm	NP: Ø 3.30 mm	SP: Ø 3.75 mm WP: Ø 5.00 mm	NP: Ø 2.77 to 2.79 mm SP: Ø 3.15 to 3.17 mm	Similar There is no difference between the diameters of the proposed NP and SP cover screws compared to those of the reference device (K163349). These diameters correspond to

Item	Proposed Device MIS LYNX Conical Connection Dental Implant System K241692	Predicate Device MIS C1 Conical Connection Dental Implant System K172505 with wet packaging configuration cleared in K200102	Reference Device MIS C1 Conical Connection Dental Implant System K112162 with wet packaging configuration cleared in K200102	Reference Device MIS V3 Conical Connection Dental Implant System K163349 with wet packaging configuration cleared in K200102	Equivalence Comparison
					the diameters of the implants' inner connection. Similarly, the diameter of the proposed WP cover screw corresponds to the diameter of the proposed device WP implant inner connection.
Packaging of Implant and Cover Screw	Inner tube/Outer blister packaging	Double tube packaging	Double tube packaging	Double tube packaging	Different. Performance and safety of modified packaging and materials were verified via packaging validation, shelf-life testing, sterility testing, and bench testing.
Sterilization Method of Implant and Cover Screw	Delivered sterile, for single use Sterilization by Gamma Radiation SAL 10^{-6}	Delivered sterile, for single use Sterilization by Gamma Radiation SAL 10^{-6}	Delivered sterile, for single use Sterilization by Gamma Radiation SAL 10^{-6}	Delivered sterile, for single use Sterilization by Gamma Radiation SAL 10^{-6}	Same

7. Non-Clinical Tests Summary and Conclusion:

Fatigue testing was performed according to ISO 14801:2016, Dentistry – Implants – Dynamic fatigue test for endosseous dental implants, and FDA guidance document "Root-form endosseous dental implants and endosseous dental abutments", and confirms that the proposed device is similar or exceeds performance when compared to the predicate device (K172505) and reference (K112162) devices.

Biocompatibility assessment was performed to evaluate the biocompatibility profile of the implants and screws packaged in modified inner tube packaging according to the following standards:

- Cytotoxicity testing was performed according to ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Irritation testing was performed according to ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- Sensitization testing was performed according to ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- Material mediated pyrogenicity testing was assessed per recommendations of FDA's 2023 Biocompatibility Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'"
- Acute systemic toxicity was performed according to ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Genotoxicity was performed according to ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- Analytical chemistry testing and chemical characterization was performed according to ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
- Toxicological risk assessment was performed according to ISO/TS 21726:2019, Biological evaluation of medical devices – Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents and ISO 10993-17: 2023 Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents

Dose mapping was performed to ensure that each routine Gamma irradiation will result in a minimum of 20kGy. The dose mapping was performed according to:

- ISO 11137-1:2006, Sterilization of health care products — Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-3:2017, Sterilization of health care products — Radiation Part 3: Guidance on dosimetric aspects of development, validation and routine control, and
- ISO/ASTM 52303:2015 - Guide for absorbed-dose mapping in radiation processing facilities,

Bioburden testing was performed on the proposed final, finished packaging configuration according to:

- AAMI TIR35:2016 - Sterilization of Health Care Products - Radiation Sterilization - Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits, and
- BS EN ISO 11137-2:2015- Sterilization of Health Care Products - Radiation - Part 2: Establishing the sterilization dose.

Based on the results, the proposed device was included into the existing sterilization validation.

Sterility testing was performed according to the following standard to ensure that the packaging maintains the sterility of the device after simulated distribution:

- ISO 11737-2:2019(E) - Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenances of a sterilization process

To confirm the acceptability of the shelf-life, prior to accelerated aging, representative implants underwent simulated distribution and transportation testing according to:

- ASTM D4169-22 - Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D4332-22 - Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

After one year accelerated aging, visual inspection, packaging integrity testing, seal strength testing, "wet" packaging weight loss testing, and hydrophilicity testing were performed on representative implants and the subject device according to the following standards and methods:

- ASTM F1980-21 - Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
- ASTM F1929-15 - Standard test method for detecting seal leaks in porous medical packaging by dye penetration
- ASTM F2096-11: 2019 - Standard Test for detecting gross leaks in packaging by internal pressurization (Bubble test)
- ASTM F88/F88M-23 - Standard Test Method for Seal Strength of Flexible Barrier Materials
- BS EN 868-5:2018 - Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous materials and plastic film construction. Requirements and test methods
- Hydrophilicity testing according to internal test method

Test results met acceptance criteria.

The following testing or analysis was performed on the worst-case implant combination for Dentsply Sirona implant products, which consider the proposed implants:

- Magnetically induced displacement force, according to ASTM F2052-21, Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment
- Magnetically induced torque, according to ASTM F2213-17, Standard test method

for measurement of magnetically induced torque on medical devices in magnetic resonance environment

- Image Artifact, according to ASTM F2119-07 (2013), Standard test method for evaluation of MR image artifacts from passive implants
- RF Induced Heating Simulation using Computational modeling and simulation (CM&S)

Based on the test or analysis results, device labeling for the proposed implants will indicate MRI Conditional.

8. Clinical Tests Summary and Conclusion:
   Not applicable. There are no clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

9. Conclusion Regarding Substantial Equivalence:
   The proposed implants and abutments (cover screws) are made of the same material as the predicate device (K172505) and reference devices (K112162, K163349), which is Ti 6Al-4V ELI. The proposed implants undergo the same manufacturing process and surface treatment, and are provided sterilized by gamma irradiation. In addition, the proposed devices connect directly to the implant in the same conical connection, and share similarities in design characteristics. Differences in implant design were confirmed via fatigue testing where the proposed device was shown to perform as well or better than the predicate (K172505) and reference (K112162) devices.

   Changes in packaging materials, components, and configuration mainly by adding an additional component to the inner packaging and changes to the secondary packaging from an outer tube to a blister package, were assessed via sterilization, packaging integrity, and shelf-life testing to confirm that the changes do not raise new questions regarding safety and effectiveness of the final finished device. In addition, biocompatibility testing was performed to confirm the biological safety of the proposed implants.

   The differences in design and packaging between the proposed device, the predicate device, and reference devices do not raise new concerns regarding safety or performance. The performance and safety data included in this premarket notification support a conclusion of substantial equivalence.