



July 24, 2025

Dentsply Sirona Inc.  
Jesus Valencia  
Regulatory Affairs Manager  
221 West Philadelphia St., Suite 60W  
York, Pennsylvania 17401

Re: K251297

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: April 24, 2025  
Received: April 28, 2025

Dear Jesus Valencia:

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](mailto: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

510(k) Number (if known)  
K251297

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. MIS LYNX short implants are indicated for delayed loading only.

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."*

**510(k) SUMMARY**  
**for**  
**MIS LYNX Conical Connection Implant System**

**1. Submitter Information:**

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

Contact Person: Jesus Valencia  
Telephone Number: (520) 409-9093  
Email: [jesus.valencia@dentsplysirona.com](mailto:jesus.valencia@dentsplysirona.com)  
Date Prepared: July 24, 2025

**2. Device Name:**

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

**3. Predicate/Reference Devices:**

<b>Predicate Device Name</b>	<b>510(k)</b>	<b>Company Name</b>
MIS LYNX Conical Connection Implant System	K241692	MIS (part of Dentsply Sirona)
<b>Reference Device Name</b>	<b>510(k)</b>	<b>Company Name</b>
MIS SEVEN Internal Hex Dental Implant System	K180282	MIS (part of Dentsply Sirona)

**4. Description of Device:**

The two additional implant size offerings which are being added to the predicate MIS LYNX Conical Connection Dental Implant System (K241692), and are the subject of this submission, consist of a standard platform, 4.20 mm diameter implant and a wide platform, 5.00 mm diameter implant, each available in a 6 mm length.

The proposed implant offerings, as their predicate K241692, are root-form, bone-level, self-tapping, two-piece, screw-type implants which 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.

Each implant offering is provided with a compatible cover screw based on the implant platform (standard and wide). The cover screws are identical to those cleared in K241692 and 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. The cover screw is screwed into the implant's internal thread and the gums are sutured over the cover screw. The cover screw's

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 is then removed and replaced by either a healing cap or an abutment.

The implants and cover screws 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 proposed implants feature an outer profile which has a coronal section which is cylindrical and an apical section which is conical. The outer threads are designed so the implant has a self-drilling property. The implant's geometric design includes a dual thread feature and 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 feature a round (cylindrical) neck.

The proposed MIS LYNX Conical Connection Implants have a conical connection with an anti-rotation index of six positions and an internal thread for cover screws, screw-retained abutments and screwed healing caps. The implant-abutment connection surface of the proposed implants is anodized for color coding purposes to indicate the platform: purple for standard platform implants, and green for wide platform implants. The cover screws are also anodized for platform color coding.

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 patients.

## **5. Intended Use and Indications for Use:**

The intended use of the proposed and predicate (K241692) devices are identical.

*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.*

The indications for use of the proposed and predicate (K241692) devices are similar with additions from K180282:

*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 LYNX short implants are indicated for delayed loading only.*

## **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) and undergo the same manufacturing, surface treatment, packaging and sterilization process as the predicate device (K241692).

The proposed implants are available in diameters and platforms (4.20 mm diameter for standard, 5.00 mm diameter for wide) which are identical to those available in the previously cleared predicate (K241692) and reference (K180282) devices. The two additional proposed device offerings are available in a single length, 6mm, which is identical to the implant length previously cleared for the same 4.20 mm and 5.00 mm implant diameters of the reference device (K180282).

The conical connection of the proposed implants has the same 12° cone angulation as the predicate device (K241692). The implant-abutment conical connection of the proposed implants is identical to that of the standard and wide platforms of the predicate device (K241692). The proposed implants are provided with cover screws which are identical to those previously cleared for use with the standard and wide platforms of the predicate device (K241692).

As with the predicate device (K241692), the overall implant body design of the proposed implants is tapered and dual-threaded with a domed apex and circumferential grooves in the coronal area of the implant, called “Micro-Rings”. The implant body is partially cylindrical (the coronal part of the implant) and partially conical (the apical part of the implant).

The coronal area of the proposed implants consists of a round (cylindrical) neck and a bevel which slightly elevates the implant-abutment connection above bone level and is very similar to the coronal area design of the reference device (K180282).

The proposed device is available in the same two packaging configurations which are also available with the predicate device (K241692); 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.

Both the proposed device and the predicate device (K241692) are delivered sterile, for single use, and are sterilized by Gamma radiation.

An overall comparison of the technological characteristics between the proposed, predicate (K241692) and reference (K180282) devices is provided in Table 6.1.

**Table 6.1: Comparison of Technological Characteristics between the Proposed, Predicate and Reference Devices**

Item	Proposed Device MIS LYNX Conical Connection Dental Implant System	Predicate Device MIS LYNX Conical Connection Dental Implant System (K241692)	Reference Device MIS SEVEN Internal Hex Dental Implant System (K180282)	Equivalence Comparison
<b>Manufacturer</b>	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
<b>FDA Product Code(s)</b>	DZE, NHA	DZE, NHA	DZE, NHA	Same
<b>Implant Platforms</b>	Standard Platform (SP) Wide Platform (WP)	Narrow Platform (NP) Standard Platform (SP) Wide Platform (WP)	Narrow Platform (NP) Standard Platform (SP) Wide Platform (WP)	Same The standard and wide implant platforms available for the proposed device are the same as those available for the predicate (K241692) and reference (K180282) devices.
<b>Implant Diameters</b>	SP: Ø 4.20 mm WP: Ø 5.00 mm	NP: Ø 3.30 mm SP: Ø 3.75, 4.20 mm WP: Ø 5.00 mm	NP: Ø3.30 mm SP: Ø3.75, 4.20 mm WP: Ø5.00, 6.00 mm	Same The proposed device is available in the same implant diameters which are also available with the predicate (K241692) and reference (K180282) devices.
<b>Implant Lengths</b>	<b>For Ø 4.20 &amp; Ø 5.00 implants:</b> 6 mm	<b>For Ø 3.30 implants:</b> 10, 11.5, 13, 16 mm  <b>For Ø 3.75, Ø 4.20 &amp; Ø 5.00 implants:</b> 8, 10, 11.5, 13, 16 mm	<b>For Ø 3.30 implants:</b> 10, 11.5, 13, 16 mm  <b>For Ø 3.75 implants:</b> 8, 10, 11.5, 13, 16, 18, 20 mm  <b>For Ø 4.20 implants:</b> 6, 8, 10, 11.5, 13, 16, 18, 20 mm  <b>For Ø 5.00 implants:</b> 6, 8, 10, 11.5, 13, 16 mm  <b>For Ø 6.00 implants:</b> 6, 8, 10, 11.5, 13 mm	Same The proposed and reference (K180282) devices are available in the same 6 mm length for the 4.20 mm and 5.00 mm implant diameters.
<b>Type of Implant</b>	Bone level implant	Bone level implant	Bone level implant	Same
<b>Overall Body Design</b>	The implant is tapered and threaded. The implant body is partially cylindrical (the coronal part of the implant) and partially conical (the apical part of the implant).	The implant is tapered and threaded. The implant body is half cylindrical (the coronal part of the implant) and half conical (the apical part of the implant).	The implant is tapered and threaded. The implant body is partially cylindrical (the coronal part of the implant) and partially conical (the apical part of the implant).	Same No difference between the overall design of the proposed implants and the overall design of the predicate (K241692) and reference (K180282) devices, combined.
<b>Bevel (Coronal Area)</b>	Ø 4.20, 5.00 mm: Yes	Ø 3.30, 3.75, 4.20, 5.00 mm: No	Ø 3.30, 3.75 mm: No Ø 4.20, 5.00, 6.00 mm: Yes	Same The proposed device includes a bevel in the coronal area of the implant which is also available in the 4.20 mm and 5.00 mm diameter implants of the reference

Item	Proposed Device MIS LYNX Conical Connection Dental Implant System	Predicate Device MIS LYNX Conical Connection Dental Implant System (K241692)	Reference Device MIS SEVEN Internal Hex Dental Implant System (K180282)	Equivalence Comparison
				device (K180282). For both the proposed and reference (K180282) devices, the bevel slightly elevates the implant-abutment connection above the bone level.
<b>Implant Material</b>	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136	Same
<b>Implant Surface Treatment</b>	<p><b>For implants in “Dry” packaging configuration:</b> Anodized (internally), sand blasted and acid etched</p> <p><b>For implants in “Wet” packaging configuration:</b> Sand blasted and acid etched</p> <p>Bevel in the neck area of the implant does not undergo anodization, sand blasting or acid etching.</p>	<p><b>For implants in “Dry” packaging configuration:</b> Anodized (internally), sand blasted and acid etched</p> <p><b>For implants in “Wet” packaging configuration:</b> Sand blasted and acid etched</p>	<p><b>For implants in “Dry” packaging configuration:</b> Anodized (internally), sand blasted and acid etched</p> <p><b>For implants in “Wet” packaging configuration (cleared in K200102):</b> Sand blasted and acid etched</p> <p>Bevel in the neck area of the implant does not undergo anodization, sand blasting or acid etching.</p>	Same The proposed device undergoes the same surface treatment as predicate device (K241692). For both the proposed and reference (K180282) devices, the bevel in the neck area of the implant does not undergo anodization, sand blasting or acid etching.
<b>Apex</b>	Domed	Domed	Domed	Same
<b>Outer Thread</b>	<p>Dual thread with 1.6-1.65 mm lead, creating a 0.8-0.825 mm pitch between the threads.</p> <p>The threads are thin at the apical portion, and thicker at the coronal portion of the implant’s body.</p> <p>The implants are designed with 3 long spiral flutes.</p>	<p>Dual thread with 1.6-1.65 mm lead, creating a 0.8-0.825 mm pitch between the threads.</p> <p>The threads are thin at the apical portion, and thicker at the coronal portion of the implant’s body.</p> <p>The implants are designed with 3 long spiral flutes.</p>	<p>Dual thread with 2 mm lead, creating a 1 mm pitch between the threads.</p> <p>The threads are thin at the apical portion, and thicker at the coronal portion of the implant’s body.</p> <p>The implants are designed with 3 short spiral flutes.</p>	Same The proposed device incorporates the same outer thread design as the predicate device (K241692).
<b>Connection Type</b>	<p><b>For Standard &amp; Wide Platforms:</b> Conical connection with six index slots with alternating width Cone angulation 12°</p>	<p><b>For Standard &amp; Wide Platforms:</b> Conical connection with six index slots with alternating width Cone angulation 12°</p> <p><b>For Narrow Platform:</b> Conical connection with four index slots with even width Cone angulation 12°</p>	<p><b>For Narrow, Standard &amp; Wide Platforms:</b> Internal hexagon</p>	Same The implant-abutment connection type and geometric profile of the proposed implants is identical to that of the standard and wide platforms of the predicate implants (K241692).
<b>Neck</b>	Round (cylindrical) neck	“V-Cut” a back-tapered triangular neck	Round (cylindrical) neck	Same The proposed and reference (K180282) devices incorporate a cylindrical neck profile.

Item	Proposed Device MIS LYNX Conical Connection Dental Implant System	Predicate Device MIS LYNX Conical Connection Dental Implant System (K241692)	Reference Device MIS SEVEN Internal Hex Dental Implant System (K180282)	Equivalence Comparison
<b>Coronal Area</b>	Circumferential grooves called “Micro-Rings” 6 mm length implants have 3 micro rings.	Circumferential grooves called “Micro-Rings” 8 mm, 10 mm and 11.5 mm length implants have 4 micro rings. 13 mm and 16 mm length implants have 6 micro rings.	Circumferential grooves called “Micro-Rings” All implants have 7 micro rings.	Similar The proposed device incorporates a “Micro-Ring” profile which is identical to the individual “Micro-Ring” profile of the predicate (K241692) and reference (K180282) devices.  The purpose of the “Micro-Rings” on the proposed implants is the same to that of the “Micro-Rings” on the predicate device (K241692); to enable retention of the bone in the implant’s neck area.  The difference in the number of “Micro-Rings” does not affect the proposed implants’ strength and stability as demonstrated by the fatigue and pull-out testing.
<b>Primary Packaging</b>	<b>For implants in “Dry” packaging configuration:</b> Implant inside inner tube with air  <b>For implants in “Wet” packaging configuration:</b> Implant inside inner tube with NaCl solution	<b>For implants in “Dry” packaging configuration:</b> Implant inside inner tube with air  <b>For implants in “Wet” packaging configuration:</b> Implant inside inner tube with NaCl solution	<b>For implants in “Dry” packaging configuration:</b> Implant inside inner tube with air  <b>For implants in “Wet” packaging configuration (cleared in K200102):</b> Implant inside inner tube with NaCl solution	Same The primary packaging configuration of the proposed device is identical to that of the predicate device (K241692).
<b>Secondary Packaging</b>	<b>For both “Dry” and “Wet” packaging configurations:</b> Blister is made of PET-G, blue tinted and is sealed with heat-seal coated Tyvek foil	<b>For both “Dry” and “Wet” packaging configurations:</b> Blister is made of PET-G, blue tinted and is sealed with heat-seal coated Tyvek foil	<b>For both “Dry” and “Wet” packaging configurations:</b> Outer tube	Same The secondary packaging configuration of the proposed device is identical to that of the predicate device (K241692).
<b>Tertiary packaging</b>	Cardboard box	Cardboard box	Cardboard box	Same
<b>Sterilization Method</b>	Delivered sterile, for single use Sterilization by Gamma Radiation SAL 10 <sup>-6</sup>	Delivered sterile, for single use Sterilization by Gamma Radiation SAL 10 <sup>-6</sup>	Delivered sterile, for single use Sterilization by Gamma Radiation SAL 10 <sup>-6</sup>	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 in or exceeds performance when compared to the predicate (K241692) and reference (K180282) devices.

Pull-out testing was performed to help support substantial equivalence and to ensure that the bone-to-implant strength of the proposed implants is appropriate for their intended use. Testing was performed based on Annex 3 of ASTM F543-23, Standard Specification and Test Methods for Metallic Medical Bone Screws. In both soft and hard bone replicas, the proposed device exhibited average pull-out forces which were larger than those of the reference device (K180282).

A surface area analysis using CAD software was performed with the smallest implant length (6 mm) and diameter (4.20 mm) available for both the proposed and reference (K180282) devices to demonstrate that the endosseous area that contacts bone of both implants is equivalent between the two devices. In summary, the implant surface area and initial bone-to-implant contact area calculations, simulating the recommended surgical drilling protocol in a CAD model, is equivalent between proposed and reference (K180282) implants of the same length and diameter.

The following testing and analysis were leveraged from the predicate (K241692):

- 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 and analysis results included by reference, the proposed implants, as their predicate K241692, are labeled as MR Conditional.

The proposed and predicate (K241692) devices are manufactured from identical materials and undergo the same machining, degreasing, anodization, sand-blasting, pre-etching and acid-etching processes. In addition, the packaging materials, packaging configurations, packaging process and sterilization process of the proposed device are identical to those of the predicate device (K241692). Therefore, additional biocompatibility, sterilization, package and shelf life testing was not necessary to demonstrate substantial equivalence of the proposed device.

**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 device is made of the same material as the predicate device (K241692), which is Ti 6Al-4V ELI, and is subjected to the same manufacturing, surface treatment, packaging and sterilization processes as the predicate device (K241692). The proposed device is provided with identical cover screws and incorporates an identical implant-abutment connection geometry as that of the standard and wide implant platforms of the predicate device (K241692). The predicate device (K241692) is currently available in the same diameters and platforms as those of the proposed device. In addition, the proposed device is also available in the same length, diameter and platform combinations as the similar legally marketed reference device (K180282).

The minor differences in design of the proposed, predicate (K241692) and reference (K180282) devices do not raise new concerns regarding safety or performance, and the performance and safety data included or referenced in this premarket notification support a conclusion of substantial equivalence.