August 21, 2025

Dentsply Sirona Inc.
Melanie Avila
Regulatory Affairs Director
221 West Philadelphia St.
Suite 60W
York, Pennsylvania 17401

Re: K251647
Trade/Device Name: MIS C1 Implant System, MIS Seven Implant System, MIS M4 Implant System, MIS Lance+ Implant System, MIS Lance+ Conical Connection System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 29, 2025
Received: May 29, 2025

Dear Melanie Avila:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251647 ?

Please provide the device trade name(s). ?

- MIS C1 Implant System
- MIS Seven Implant System
- MIS M4 Implant System
- MIS Lance+ Implant System
- MIS Lance+ Conical Connection System

Please provide your Indications for Use below. ?

MIS Dental Implants Systems

- MIS C1 Implant System
- MIS SEVEN Implant System

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 (Ø3.30mm) 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 SEVEN short implants are to be used only with straight abutments.

- MIS Lance+ Implant System
- MIS Lance+ Conical Connection System

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 (Ø3.30mm) 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 M4 Implant System

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 (Ø3.30 mm) 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 short implants are to be used only with straight abutments.
M4 short implants are indicated for delayed loading only.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

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

K251647

510(k) SUMMARY

1. Submitter Information:

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

Contact Person: Melanie Avila
Telephone Number: 210-262-7724
Email address: melanie.avila@dentsplysirona.com

Date Prepared: August 7, 2025

2. Device Name:

Device Trade Name	MIS C1 Implant System, MIS Seven Implant System, MIS M4 Implant System, MIS Lance+ Implant System, MIS Lance+ Conical Connection System
Classification Name:	Endosseous Dental Implant
Regulation Number	872.3640
Device Class:	Class II
Product Code:	DZE (Primary Product Code) NHA (Secondary Product Code)

3. Predicate Device:

Primary Predicate Device	510(k)	Company Name
MIS LYNX Conical Connection Implant System	K241692	MIS (part of Dentsply Sirona Inc)

Reference Devices	510(k)	Company Name
MIS C1 Implant System	K172505 (Dry configuration), K200102 (CLEAR configuration)	MIS (part of Dentsply Sirona Inc)
MIS Seven Implant System	K180282 (Dry configuration), K200102 (CLEAR configuration)	MIS (part of Dentsply Sirona Inc)
MIS M4 Implant System	K180282	MIS (part of Dentsply Sirona Inc)
MIS Lance+ Implant System	K192149 (Dry configuration), K200102 (CLEAR configuration)	MIS (part of Dentsply Sirona Inc)
MIS Lance+ Conical Connection	K210886 (Dry and CLEAR configuration)	MIS (part of Dentsply Sirona Inc)

4. Description of Device:

The subject devices, MIS Implants, are supplied sterile and packaged together with a cover screw which can be connected to the implant during the initial healing period after implant placement.

The implants and cover screws are made of 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 design and material of the implants and cover screws remain unchanged since most recently cleared 510(k).

The implants are also used with a wide range of previously cleared abutments which are sold separately.

Implant	**Connection type**	**Diameter (mm)**	**Length (mm)**	**Anodize color**
MIS C1/C1 CLEAR NP	Conical, Cone angulation 12°	3.30	10, 11.5, 13, 16	Yellow / None (“wet”)
MIS C1/C1 CLEAR SP	Conical, Cone angulation 12°	3.75, 4.20	8, 10, 11.5, 13, 16	Purple / None (“wet”)
MIS C1/C1 CLEAR WP	Conical, Cone angulation 12°	5.0	8, 10, 11.5, 13, 16	Green / None (“wet”)
MIS SEVEN/SEVEN CLEAR NP	Internal hex	3.30	10, 11.5, 13, 16	Yellow / None (“wet”)
MIS SEVEN/SEVEN CLEAR SP	Internal hex	3.75	8, 10, 11.5, 13, 16	Purple / None (“wet”)
MIS SEVEN/SEVEN CLEAR SP	Internal hex	4.20	6, 8, 10, 11.5, 13, 16	Purple / None (“wet”)
MIS SEVEN/SEVEN CLEAR WP	Internal hex	5.0	6, 8, 10, 11.5, 13, 16	Green / None (“wet”)
MIS SEVEN/SEVEN CLEAR WP	Internal hex	6.0	6, 8, 10, 11.5, 13	Green / None (“wet”)
MIS M4 NP	Internal hex	3.30	10, 11.5, 13, 16	None
MIS M4 SP	Internal hex	3.75	8, 10, 11.5, 13, 16	None
MIS M4 SP	Internal hex	4.20	6, 8, 10, 11.5, 13, 16	None
MIS M4 WP	Internal hex	5.0	6, 8, 10, 11.5, 13, 16	None
MIS M4 WP	Internal hex	6.0	6, 8, 10, 11.5, 13	None
MIS Lance+/Lance+ Clear NP	Internal hex / Conical connection, Cone angulation 12°	3.30	10, 11.5, 13, 16	Yellow / None (“wet”)
MIS Lance+/Lance+ Clear SP	Internal hex / Conical connection, Cone angulation 12°	3.75, 4.20	8, 10, 11.5, 13, 16	Purple / None (“wet”)
MIS Lance+/Lance+ Clear WP	Internal hex / Conical connection, Cone angulation 12°	5.0	8, 10, 11.5, 13, 16	Green / None (“wet”)
MIS Lance+/Lance+ Clear WP	Internal hex	6.0	8, 10, 11.5, 13	Green / None (“wet”)
Cover screw NP	Internal hex	3.3	4.7	Yellow
Cover screw SP	Internal hex	3.8	4.7	Purple

Cover screw WP	Internal hex	4.55	4.8	Green
Cover screw NP	Conical connection	3.3	5.5	Yellow
Cover screw SP	Conical connection	3.8	5.8	Purple
Cover screw WP	Conical connection	5.0	6.2	Green

5. Indications for Use:

MIS Internal Hex Implant Dental System MIS M4 Implant System **Subject Device**	**MIS Dental Implants Systems** • MIS C1 Implant System • MIS Seven Implant System **Subject Device**	**MIS Lance+ Conical Connection Implant System** • • MIS Lance+ Implant System • MIS Lance+ Conical Connection Implant System **Subject Device**
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 short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.	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 SEVEN short implants are to be used only with straight abutments.	MIS Dental Implant System is intended to be surgically placed in the bone of the upper and lower jaw arches to provide support for prosthetic device, 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 in 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.

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]					
Attribute	**-MIS M4 Implant System**	**-MIS C1 Implant System -MIS Seven Implant System**	**-MIS Lance+ Conical Connection Implant System -MIS Lance+ Implant System**	**-MIS Lynx Conical Connection Implant System**	**Comparison**
	MIS Implant System Subject Device	**MIS Implant System Subject Device**	**MIS Implant System Subject Device**	**Predicate Device**	N/A
510(k) Submitter/Holder	Dentsply Sirona Inc	Dentsply Sirona Inc	Dentsply Sirona Inc	Dentsply Sirona Inc	N/A
510(k) number	K251647	K251647	K251647	K241692	N/A
Indications for use (IFU) statement	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	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.	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.	MIS Dental Implant System is intended to be surgically placed in the bone of the upper and lower jaw arches to provide support for prosthetic device, 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 in appropriate.	Similar – The IFU statements are similar, with the exception of the of the limitation statement for short implants for M4, C1, and SEVEN. This limitation statement does not apply to Lynx, Lance+, and Lance + Conical.

	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 short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.	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 SEVEN short implants are to be used only with straight abutments.	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.	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.	
Technological Characteristics - 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
Sterility Method	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation	Same
SAL	10^{-6}	10^{-6}	10^{-6}	10^{-6}	Same
Shelf Life	1 year	1 year	1 year	1 year	Same
Packaging					
Primary	N/A – The M4	Inner tube	Inner tube which	Inner tube which	Similar – there is

Packaging (CLEAR Packaging Configuration)	Implant System is not offered in CLEAR Packaging.	which contains the implant and cover screw in sodium chloride (NaCl) solution	contains the implant and cover screw in sodium chloride (NaCl) solution	contains the implant and cover screw in sodium chloride (NaCl) solution	no change to the packaging materials, however there are slight changes to the design of the inner tube dimensions, inner tube cap, and inner tube titanium stage and ring. These minor design changes do not impact the device safety or performance as demonstrated by the results of performance testing, shelf, and sterilization.
Primary Packaging (Dry Packaging Configuration)	Inner tube which contains the implant and cover screw packaged in air	Inner tube which contains the implant and cover screw packaged in air	Inner tube which contains the implant and cover screw packaged in air	Inner tube which contains the implant and cover screw packaged in air	Similar – there is no change to the packaging materials, however there are slight changes to the design of the inner tube dimensions, inner tube cap, and inner tube titanium stage and ring. These minor design changes do not impact the device safety or performance as demonstrated by the results of performance testing, shelf, and sterilization.
Secondary Packaging	Blister pack with heat-seal coated Tyvek	Blister pack with heat-seal coated Tyvek	Blister pack with heat-seal coated Tyvek	Blister pack with heat-seal coated Tyvek	Same
Tertiary Packaging	cardboard box	cardboard box	cardboard box	cardboard box	Same
Performance Testing					
Hydrophilicity	N/A – The M4 Implant System is not offered in CLEAR Packaging.	Pass	Pass	Pass	Same – All CLEAR samples tested met the acceptance criteria of 0-5° Contact Angle

Performance Data
Summary of non-clinical tests conducted for determination of substantial equivalence:

Hydrophilicity testing, which is an internal test method, was performed per sessile drop test, on the proposed implants to support substantial equivalence and to demonstrate the minor changes to the primary packaging from the predicate device do not impact the requirement of a super-hydrophilic surface for the wet-packed implants over the shelf life of the device.

In all instances, the subject device functioned as intended and all test results observed were as expected.

The testing generated strong evidence that the subject devices are found to be substantially equivalent to the predicate device

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

- Biocompatibility Testing per ISO 10993-1, *Biological evaluation of medical devices*
- Sterilization per ISO 11737-1:2018 *Sterilization of health care products Microbiological methods*
- Transportation Testing per *ASTM D4169-22 - Standard Practice for Performance Testing of Shipping Containers and Systems* and *ASTM D4332-22 - Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing*
- Shelf Life Testing per *ISO 11607-1:2019 Packaging for terminally sterilized medical devices-Part1: Requirements for materials, sterile barrier systems and packaging systems, ASTM F 1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration, ASTM F88/F88M-23 Standard Test Method for Seal Strength of Flexible Barrier Materials, ASTM F2096-11 (Reapproved 2019) Standard Test for detecting gross leaks in packaging by internal pressurization (Bubble test), ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices, and 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*
- Fatigue Testing per ISO 14801:2016 *Dentistry - Implants – Dynamic fatigue tests for endosseous dental implant* and FDA's Guidance - *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*
- Surface Modification Characterization by SEM (scanning electron microscope) to demonstrate surface cleanliness

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

Clinical testing was not necessary to demonstrate equivalence.

Conclusions
The subject devices, MIS Implant Systems and the predicate device have the same intended use and similar indications for use. MIS Implant Systems and the predicate device have the similar technological characteristics and principles of operation. The proposed change for the primary and secondary packaging of the implant and cover screw is similar to the primary packaging and the same as the secondary packaging for the Lynx Conical Connection Implant System, cleared under 510(k) K241692.

No other changes have been made to the implant design, technological characteristics or intended use since the most recently cleared 510(k) for each of the MIS Implants Systems.

The minor differences in primary packaging do not present different questions of safety or effectiveness than the predicate device because the subject device functions to the same packaging performance specifications as the predicate device. Thus, the primary packaging for the subject device, MIS Implant Systems, is substantially equivalent to the primary packaging of the predicate device.

The subject device is substantially equivalent as the predicate device.