June 17, 2021

Dentsply Sirona
Rebecca Sporer
Regulatory Affairs Specialist
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K210886
Trade/Device Name: MIS Lance+ Conical Connection Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: March 24, 2021
Received: March 25, 2021

Dear Rebecca Sporer:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K210886

Device Name
MIS Lance+ Conical Connection Dental Implant System

Indications for Use *(Describe)*
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.

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."

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

510(k) SUMMARY

K210886

1.0 Submitter Information:

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

Contact Person: Rebecca Sporer
Title: Regulatory Affairs Specialist
Telephone Number: 717-849-4793
Fax Number: 717-849-4343

Date Prepared: 17 June 2021

2.0 Device Name

- Proprietary Name: MIS Lance+ Conical Connection Dental Implant System
- Classification Name: Endosseous dental implant
- CFR Number: 872.3640
- Device Class: Class II
- Product Code: DZE

3.0 Predicate Device

The predicate and reference device that have been identified relating to the substantial equivalence of the proposed MIS Lance+ Conical Connection Implants entailing a modification of the MIS Lance+ Internal Hex Dental Implant System (K192149) with the conical connection of the MIS C1 Conical Connection Dental Implant System (K172505 for C1 Narrow platform implants and K112162 for C1 standard and wide platform implants). The proposed MIS Lance+ Conical Connection Implants will be offered as well in a wet packaging like the MIS implants cleared under MIS CLEAR Dental Implant System (K200102).

Predicate Device Name	**510(k)**	**Company Name**
MIS Dental Implant System (MIS Lance+ Internal Hex Dental Implant System)	K192149	MIS Implants Technologies Ltd. (Dentsply Sirona)
Reference Device Name	**510(k)**	**Company Name**
MIS C1 Narrow Platform Conical Connection Dental Implant System (MIS C1 Conical Connection Dental Implant System)	K172505	MIS Implants Technologies Ltd. (Dentsply Sirona)
MIS C1 Conical Connection Dental Implant System – Standard and wide platforms	K112162	MIS Implants Technologies Ltd. (Dentsply Sirona)
MIS CLEAR Dental Implant System	K200102	MIS Implants Technologies Ltd. (Dentsply Sirona)

4.0 Device Description

The proposed MIS Lance+ Conical Connection Implant are dental implants with a cylindrical and conical shaped outer profile. The implants have an internal conical implant-abutment connection geometry with an anti-rotation index of six positions for standard and wide platforms and four positions for narrow platform. The conical implant-abutment connection is identical to the internal conical connection geometry incorporated in the design of the reference device MIS C1 Conical Connection Implants (K172505). The implant abutment connection surface of the MIS Lance+ Conical Connection Implant is anodized for coloring coding purposes to indicate the platform. The color coding is identical to the reference devices MIS C1 Conical Connection Implant System (K172505).

The MIS Lance+ Conical Connection Implants are intended to be used in combination with a variety of conical connection abutments (cover screws, healing caps, cement-retained abutments and screw-retained abutments, which were previously cleared for use with the MIS C1 Conical Connection Dental Implant System (K172505 for NP abutments and K112162 for SP and WP abutments). These abutments are manufactured with a conical connection compatible with the implants interface. Dental implant abutments are intended to be used in the upper or lower jaw used for supporting tooth replacements to restore chewing function. The abutments in combination with two-stage endosseous implants are intended to be used as a foundation for anchoring tooth replacements in either jaw. Restorations range from replacing one single tooth to fixed partial dentures using cement-retained supra-constructions. No new Abutments are being proposed as part of this submission.

In addition, the proposed MIS Lance+ Conical Connection Implants will be provided in a wet package configuration immersed in NaCl solution as cleared under K200102 and branded as "CLEAR". The MIS CLEAR Lance+ Conical Connection Implants which are intended to be packaged in NaCl solution are not anodized.

5.0 Indication for Use

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.

6.0 Substantial Equivalence Discussion

For the purposes of substantial equivalence, the proposed MIS Lance+ Conical Connection Implants are compared to the predicate device MIS Lance + Internal Hex Implant System (K192149) with the reference device MIS C1 Conical Connection Dental Implant System (K172505) included in support of substantial equivalence. The proposed MIS Lance+ Conical Connection Implant System does not include short implants; this is noted in the difference in indications for use as seen in Table 6.1. The comparison table below (Tables 6.1 and 6.2) summarizes the proposed implants to the predicate devices with respect to indications for use, technological characteristics, materials and performance testing to demonstrate that the data provided for the proposed implants supports equivalence to the predicate device.

Table 6.1 - Indication for Use Comparison		
	Subject Device **MIS Lance+ Conical Connection Implant System**	**Predicate Device** **MIS Lance+ Internal Hex Dental Implant System (K192149)**
Indication for Use	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.	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. MIS short implants are to be used only with straight abutments.

Table 6.2 – Technological Characteristics comparison between the subject, predicate and reference Implant devices				
Trade Name	**Proposed Device MIS Dental Implant System**	**Predicate Device MIS Dental Implants System (Lance +) (K192149)**	**Reference Device MIS C1 Conical Connection Dental Implant System (K172505)**	**Equivalence Comparison**
Material	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136	No difference.
Surface Treatment	**For dry packaged Implants:** Anodized, sand blasted and acid etched **For wet packaged Implants:** Sand blasted and acid etched	Sand blasted and acid etched	Anodized, sand blasted and acid etched **For wet packaged Implants:** Sand blasted and acid etched	The proposed Implants which will be packed in NaCL solution will have the same surface treatment as the predicate device. The implants packed in Air ("dry") has the same surface treatment as the predicate device but the internal part of the implant will be anodized like the reference device.
Connection Type	Conical with Index Cone angulation 12°	Internal hexagon	Conical with Index Cone angulation 12°	The aim of the modification of the Lance+ Implant to a conical connection is based on the connection type of the C1 Implant.
Body Design	Tapered, conical shape, threaded	Tapered, conical shape, threaded	Tapered, threaded	No difference. Only change on Implant Abutment connection from internal hexagon to conical with index.
Apex	Domed apex	Domed apex	Domed apex	No difference
Thread	Triple	Triple	Dual	No difference. Only change on Implant Abutment connection from internal hexagon to conical connection with index.
Type of Implant	Bone level implant	Bone level implant	Bone level implant	No difference
Implant Platform	Standard Platform (SP), Wide Platform (WP), Narrow Platform (NP)	SP, WP, NP	SP, WP, NP	No difference
Implant Diameters	SP: Ø 3.75 mm, 4.20 mm, WP: Ø 5.00 mm NP: Ø 3.30 mm	SP: Ø 3.75 mm, 4.20 mm, WP: Ø 5.00 mm, 6.00 mm NP: Ø 3.30 mm	SP: Ø 3.75 mm, 4.20 mm, WP: Ø 5.00 mm, NP: Ø 3.30 mm	The new proposed implants will not like the predicate device the Implant Diameter of 6.00 mm since the prosthetic from C1 which is intended to be used do not support that size.
Implant Lengths	SP, WP: 8, 10, 11.5, 13, 16 mm NP: 10, 11.5, 13, 16 mm	8, 10, 11.5, 13, 16 mm	8, 10, 11.5, 13, 16 mm	No difference

Table 6.2 – Technological Characteristics comparison between the subject, predicate and reference Implant devices				
Trade Name	**Proposed Device MIS Dental Implant System**	**Predicate Device MIS Dental Implants System (Lance +) (K192149)**	**Reference Device MIS C1 Conical Connection Dental Implant System (K172505)**	**Equivalence Comparison**
Inner Package Medium	Air or NaCL solution	Air or NaCL solution	Air or NaCL solution	No difference. The wet packaging branded as CLEAR is cleared under K200102
Sterilization Method	Radiation	Radiation	Radiation	No difference
Shelf Life	**For dry packaged Implants:** 5 years **For wet packaged CLEAR Implants (K200102):** 2 years	**For dry packaged Implants:** 5 years **For wet packaged CLEAR Implants (K200102):** 1 year	**Dry packaged Implants:** 5 years	The extended shelf-life for the CLEAR packaging was validated with performance testing.

7.0 Non-Clinical Performance Data

As part of demonstrating the substantial equivalence of the proposed MIS Lance+ Conical Connection Implant System to the predicate and reference devices, MIS Implants Technologies completed a number of non-clinical performance tests:

- Fatigue Testing – Comparative mechanical testing of the proposed MIS Lance+ Conical Connection Implants and MIS C1 Conical Connection Implants in accordance to ISO 14801:2016 was conducted and demonstrated the subject implants do not create a new worst-case as compared to this predicate device with identical connection platform.. The test articles were able to withstand 5,000,000 cycles without failure at a substantially equivalent load to the cited predicate and reference device.

- Biocompatibility Testing- The proposed MIS Lance+ Conical Connection Implants are made from the same material, and undergo the same surface treatments: acid-etching, sand blasting and anodizing. They are manufactured under the same processing conditions and at the same manufacturing location as the predicate device, MIS Lance+ Internal Hex Dental Implant (K192149) and for the MIS CLEAR Implants (K200102). Therefore, no further biocompatibility testing was conducted in support of substantial equivalence.

- Sterilization Testing –Sterilization validation tests were conducted on each group of packaging type (dry and wet) products in compliance with both ANSI/AAMI/ISO 11137-1 and ANSI/AAMI/ISO 11137-2. Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements weremet.

- Shelf Life Testing – for the products which are supplied sterile, shelf life studies were completed by an independent testing laboratory. In in order to validate the integrity of the final package, the studies were conducted in accordance with ISO 11607-1. Dry packaged implants utilized real-time aging for 5 years per ISO 11607-1:2019 and ASTM F1929-15. Wet packaged implants utilized accelerated aging simulating two years per ASTM F1980 to demonstrate a two-year shelf-life for both package integrity (sterile barrier). Device performance (hydrophilicity) Device performance (hydrophilicity) was demonstrated with accelerated aging testing similar to the reference device K200102.

- For products supplied sterile, a LAL test is conducted periodically to verify the endotoxin limit is within acceptance criteria according to USP 85, USP 161 and ANSI/AAMI/ ST72.

8.0 Clinical Performance Data

No human clinical data were included to support substantial equivalence.

9.0 Conclusion Regarding Substantial Equivalence

The proposed MIS Lance+ conical connection implants have the same intended use, incorporate the same fundamental technology, and have the same indications for use as the predicate and reference devices. The results of the testing support a determination of substantial equivalence.