September 3, 2020

Dentsply Sirona
Karl Nittinger
Vice President, Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K200102
Trade/Device Name: MIS Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: September 2, 2020
Received: September 3, 2020

Dear Karl Nittinger:

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200102

Device Name
MIS Dental Implant Systems

Indications for Use *(Describe)*
MIS Dental Implant Systems are 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.
The long MIS (18 & 20 mm) implants can be used in a tilted manner.
MIS short implants are to be used only with straight abutments. M4 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.

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

510(k) SUMMARY
For
MIS Dental Implant Systems

1.0 Submitter Information:

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

Contact Person: Karl Nittinger
Email: karl.nittinger@dentsplysirona.com
Telephone Number: 717-487-4424
Fax Number: 717-849-4343

Date Prepared: 03 - September - 2020

2.0 Device Name:

- Proprietary Name: MIS Dental Implant Systems
- Classification Name: Endosseous dental implant
- CFR Number: 872.3640
- Device Class: Class II
- Product Code: DZE

3.0 Predicate Device:

Predicate Device Name	**510(k)**	**Company Name**
MIS Internal Hex Dental Implant System (MIS SEVEN Internal Hex Dental Implant System)	K180282	MIS Implants Technologies Ltd. (Dentsply Sirona)
Reference Device Name	**510(k)**	**Company Name**
MIS Dental Implant System (MIS Lance+ Internal Hex Dental Implant System)	K192149	MIS Implants Technologies Ltd. (Dentsply Sirona)
MIS C1 Narrow Platform Conical Connection Dental Implant System, MIS C1 Wide Platform Conical Connection Abutments (MIS C1 Conical Connection Dental Implant System)	K172505	MIS Implants Technologies Ltd. (Dentsply Sirona)
MIS V3 Conical Connection Dental Implant System	K163349	MIS Implants Technologies Ltd. (Dentsply Sirona)
Conical Connection Implants	K112162	MIS Implants Technologies Ltd. (Dentsply Sirona)
Straumann® Bone Level Tapered Implant	K140878	Institute Straumann AG

4.0 Device Description

The subject MIS Dental Implant Systems are endosseous dental implant devices which are modified as subject to this premarket notification with a revised sterile packaging configuration. There are no modifications subject to this premarket notification which relate to the geometric or material composition design of the subject dental implant devices themselves.

The individual product variants of the MIS Dental Implant Systems which are modified as subject to this premarket notification will be rebranded "MIS CLEAR".

The subject implants are identical to the predicate and reference MIS implant systems in terms of their indications for use, design, constituent materials and manufacturing process. The subject MIS Dental Implant Systems only differ in their final packaging configuration, as subject to this premarket notification. The subject, predicate and reference MIS Dental Implants Systems are supplied in a double tube packaging configuration, wherein the outer tube serves as the sterile barrier, and the implant device is located within the inner tube. While the predicate and reference MIS Dental Implants Systems are supplied within a "dry" inner package tube, the subject devices as modified in this premarket notification are supplied in a modified inner tube containing liquid, in the form of NaCl solution. The liquid environment is intended to maintain the super-hydrophilic property (contact angle exhibited by water in contact with the surface is equal to zero degrees) of the subject MIS Dental Implants Systems, as subject to this premarket notification, until their use in patients. The outer tube serving as the sterile barrier is unchanged compared to the predicate and reference devices.

5.0 Indications for Use

MIS Dental Implant Systems are 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.

The long MIS (18 & 20 mm) implants can be used in a tilted manner.

MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.

6.0 Substantial Equivalence Discussion

A comparative summary of the similarities and differences between the indications for use of the subject and predicate device is given in Table 6.1 below. The subject indications for use are inclusive of the full MIS Dental Implant System. Table 6.2 compares the technological characteristics of the subject MIS Dental Implant Systems with the predicate and reference implant systems. Under this premarket notification, there is no change in the implants themselves. The only change under this premarket notification is the modification to the inner packaging of the implants.

Table 6.1-Indications for Use Comparison		
	<u>Subject Device</u> MIS Dental Implant Systems	**<u>Predicate Device</u> MIS Dental Implant Systems (K180282)**
Indications for Use	MIS Dental Implant Systems are 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 (Ø 3.3 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 in using two or more narrow implants adjacent to one another. The long MIS (18 & 20 mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.	MIS Dental Implant Systems are 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 (Ø 3.3 mm & 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. Mandibular central and lateral incisors must be splinted in using two or more narrow implants adjacent to one another. The long MIS (18 & 20 mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.

Table 6.2: Technological Characteristics comparison between the subject, predicate and reference Implant devices				
	Subject Device **MIS Dental Implant Systems**	**Predicate Device** **MIS Internal Hex Dental Implant Systems** **K180282**	**Reference Devices** **MIS Dental Implant Systems** **K192149, K172505, K163349, K112162**	**Reference Device** **Straumann® Bone Level Tapered Implant** **K140878**
Manufacturer	MIS Implants Technologies Ltd. (Dentsply Sirona)	MIS Implants Technologies Ltd. (Dentsply Sirona)	MIS Implants Technologies Ltd. (Dentsply Sirona)	Institute Straumann AG
Connection Type	Internal hexagon or Conical connection	Internal hexagon	Internal hexagon (K192149) Conical connection (K172505,K163349,K112162)	Narrow CrossFit® (NC) Regular CrossFit® (RC)
Material(s)	Titanium Alloy	Titanium Alloy	Titanium Alloy	CP Titanium Grade 4
Surface Treatment	Anodized, sand blasted, and acid etched	Anodized, sand blasted, and acid etched	Anodized, sand blasted, and acid etched (K172505, K163349, K112162) Sand blasted and acid etched (K192149)	Sand blasted and acid etched
Body Design	Tapered, threaded	Tapered, threaded	Tapered, threaded	Tapered, threaded
Implant Diameters	C1 Implants: 3.30, 3.75, 4.20, 5.00 mm V3 Implants: 3.30, 3.90, 4.30, 5.00 mm SEVEN Implants: 3.30, 3.75, 4.20, 5.00, 6.00 mm Lance+ Implants: 3.30, 3.75, 4.20, 5.00, 6.00 mm	M4 and SEVEN Implants: 3.30, 3.75, 4.20, 5.00, 6.00 mm.	C1 Implants: 3.30, 3.75, 4.20, 5.00 mm V3 Implants: 3.30, 3.90, 4.30, 5.00 mm Lance+ Implants: 3.30, 3.75, 4.20, 5.00, 6.00 mm	3.3, 4.1, 4.8 mm
Implant Lengths	8, 10, 11.5, 13, 16, 18, 20 mm	8, 10, 11.5, 13, 16, 18, 20 mm	8, 10, 11.5, 13, 16 mm	8, 10, 12, 14, 16 mm
Inner Package Medium	NaCl solution	Air	Air	NaCl solution

Table 6.2: Technological Characteristics comparison between the subject, predicate and reference Implant devices				
	Subject Device **MIS Dental Implant Systems**	**Predicate Device** **MIS Internal Hex Dental Implant Systems** **K180282**	**Reference Devices** **MIS Dental Implant Systems** **K192149, K172505, K163349, K112162**	**Reference Device** **Straumann® Bone Level Tapered Implant** **K140878**
Reusability	Single use	Single use	Single use	Single use
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation

As shown in the summary comparison of technological characteristics in Table 6.2, the subject MIS Implants Systems as subject to this premarket notification are identical in design to the predicate (K180282) and reference (K192149, K172505, K163349, K112162) devices. The subject MIS Implants Systems are comprised of the same MIS implant system variants ("C1", "V3", "SEVEN", and "Lance+") as are the predicate (K180282) and reference (K192149, K172505, K163349, and K112162) devices. There are no design modifications to the implant devices subject to this premarket notification and therefore, the subject MIS Implant Systems devices composed of the identical titanium alloy material, feature the identical anodized, sand blasted, and acid etched surface treatment, and are characterized by the identical tapered and threaded body design as do the predicate (K180282) and reference (K192149, K172505, K163349, and K112162) devices.

The subject MIS Implants Systems devices and the predicate (K180282) and reference (K192149, K172505, K163349, K112162) devices are offered in diameters of 3.30 mm – 6.00 mm and in implants lengths of 8 mm – 20 mm. The sole difference of the MIS Implant Systems devices as subject to this premarket notification is the fact that, unlike the predicate (K180282) and reference (K192149, K172505, K163349, K112162) devices, the subject devices are packed in a medium of NaCl solution within their sterile barrier.

The Straumann Bone Level Tapered dental implant reference device (K140878) is included in support of substantial equivalence for the purpose of identifying a cleared dental implant with the same intended use, similar material composition (commercially pure titanium), similar geometric design (implant diameters and lengths ranges are within those of the subject MIS Dental Implant Systems) and also immersed within the sterile barrier in a NaCl solution.

As summarized in Section 7.0 of this 510(k) Summary, non-clinical testing has been conducted relating to the package configuration difference between the subject MIS Dental Implant Systems and the predicate (K180282) and reference (K192149, K172505, K163349, K112162) devices and the results of these non-clinical studies support substantial equivalence.

7.0 Non-Clinical Performance Data

Non-clinical testing data submitted, referenced, or relied upon to support substantial equivalence includes:

- Cytotoxicity: Cytotoxicity testing was performed to verify that no toxic materials are present on the subject dental implants, even after they are immersed in the NaCl solution in the proposed packaging following a one year accelerated shelf-life simulation. Data supports no cytotoxic effects are present in the subject dental implants.
- Chemical Characterization: Testing in the form of Chemical Characterization was performed to assure no foreign materials are found on the subject dental implants following the transition to the proposed packaging configuration. Data supports that no foreign or unexpected materials are present on the subject dental implants following one year accelerated shelf-life simulation.
- Sterilization: A full sterilization validation test was performed to establish the sterilization dose used for the proposed packaging configuration achieves sterility assurance level (SAL) of at least 10^{-6}, in accordance with ISO 11137-1:2015 and ISO 11137-2:2015. The testing showed that the bioburden, the sterility test and the endotoxin assay met the predetermined requirements.
- Transportation: A transportation simulation followed by visual inspection were made to assure the proposed packaging modification survives transportation conditions, in accordance with ASTM 4332-14 and ASTM D 4169-16. As the outer packaging and packaging materials constituting the sterile barrier are unchanged and are identical to the outer packaging used for the predicate and reference MIS dental implant devices, shelf life and package integrity validations are referenced to support substantial equivalence.
- Hydrophilicity testing: In order to establish that the super-hydrophilic characteristic of the subject dental implants are maintained throughout the life-time of the implants, hydrophilicity testing was performed following one year accelerated shelf-life simulations. Data supports the subject dental implants preserve their super-hydrophilic properties even after one year accelerated shelf-life.
- Fatigue Testing: It is maintained that the NaCl environment of the packaging of the subject implants should have no affect over the mechanical endurance limit of the implants. Since there were no changes in the implants' design when compared to the reference devices, mechanical testing of the predicate devices in accordance to ISO 14801:2016 *Dental-implants Dynamic Fatigue Test for Endosseous Dental Implants* is referenced to support substantial equivalence in K112162, K172505, K164439, K180282 and K192149.

8.0 Clinical Performance Data

No human clinical data was included in this premarket notification to support the substantial equivalence of the subject MIS Dental Implant Systems to the predicate and reference MIS Dental Implant Systems (K112162, K172505, K163349, K180282, K192149).

9.0 Conclusion Regarding Substantial Equivalence

The subject MIS Dental Implant Systems are endosseous dental implants which are intended to be used by dental clinicians for prosthetic restoration in the maxilla and mandible. The subject devices incorporate the same fundamental technology and intended use as the predicate and reference MIS implants. The proposed indications for use are inclusive of the full MIS Dental Implant System.

Non-clinical bench testing has been conducted and included in this premarket notification to demonstrate the performance of the subject MIS Dental Implant Systems against their design, functional and safety requirements. The comparison of the indications for use, technological characteristics, with the inclusion of the results of nonclinical testing, support a conclusion of substantial equivalence of the subject MIS Dental Implant Systems to the predicate and reference devices.