July 28, 2021

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

Re: K211225
Trade/Device Name: MIS Ti-base abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 28, 2021
Received: June 30, 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,

for Andrew Steen
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
MIS Ti-base abutment

Indications for Use *(Describe)*
MIS Ti-base abutment is a titanium base placed onto MIS dental implants to provide support for customized cement-retained or screw retained single or multiple-unit restorations. It is used with a digitally designed mesostructure. MIS Ti-base and the mesostructure make up a two- piece abutment used in conjunction with MIS dental implants, to be placed in the upper or lower jaw arches, in order to restore masticatory function.

Narrow platform Ti-bases are indicated for use only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws.

MIS short implants are to be used only with straight abutments. Mesostructures for use with the MIS Ti-base abutment are to be made from inCoris ZI, IPS e.max® CAD Abutment or VITA ENAMIC® (IS), designed and manufactured using Sirona CEREC SW version 4.6.1 software.

MIS Ti-base abutments are intended for use with the following MIS implants:
- C1 conical connection implant system
- V3 conical connection implant system
- SEVEN internal hex implant system
- M4 internal hex implant system
- Lance+ internal hex implant system

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
for
MIS Ti-base abutment (K211225)

1. Submitter:

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

Contact Person: Rebecca Sporer
Telephone Number: 717-849-4793
Fax Number: 717-849-4343
Email: rebecca.sporer@dentsplysirona.com

Date Prepared: June 28, 2021

2. Device Name:

- Trade/Proprietary Name: MIS Ti-base abutment
- Common/Usual Name: Dental abutment
- Classification Name: Endosseous dental implant abutment
- Regulation Number: 872.3630
- Product Code: NHA
- Device Class: Class II
- Classification Panel: Dental Devices Panel

3. Predicate Device(s):

Primary predicate device:

- MIS Ti-base abutment cleared under K191152.

Reference devices:

- IPS e.max® CAD Abutment Solutions cleared under K191382
- VITA ENAMIC® Implant Solutions (IS) cleared under K153645
- Multilink Hybrid Abutment Cement cleared under K130436
- Sirona Dental CAD/CAM System cleared under K181520

4. Device Description:

The subject MIS Ti-base abutments are endosseous dental implant abutments intended to be connected to MIS dental implants and used to support CAD/CAM customized cement-retained or screw retained single or multiple-unit restorations.

MIS Ti-base abutments consist of a titanium base and a prosthetic screw, both made of TI-6Al-4V ELI complying with ASTM F136. The prosthetic screw tightens the finished CAD/CAM abutment to the dental implant.

MIS Ti-base abutments are the bottom-half/base of a two-piece custom ceramic-titanium abutment consisting of a ceramic coping/mesostructure and a titanium base.

The top-half custom ceramic coping/mesostructure or crown is intended to be fabricated from Sirona inCoris ZI zirconium oxide ceramic block, IPS e.max® CAD ceramic block, or from IPS e.max® CAD ceramic block or VITA ENAMIC® (IS) ceramic block and designed and milled using Sirona chairside Dental CAD/CAM System, with software version: CEREC SW version 4.6.1. The mesostructure design will be subject to the Sirona system controls, such as: A maximum angulation of 20° and minimum wall thickness of 0.5mm for inCoris ZI and e.max materials and 0.8mm for VITA ENAMIC material.

It is not permitted to reduce the Ti-base's diameter, shorten the Ti-base or modify its implant-abutment connection and emergence profile in any way.

The subject, pre-fabricated titanium base abutment is designed with interface compatibility to specific MIS dental implant systems. The subject MIS Ti-base abutments are MIS conical connection and internal hex connection Ti-base abutments, and their connection is compatible with MIS conical connection C1 and V3 implants, and MIS SEVEN, M4 and Lance+ internal hex implants, which are not subject to this submission and were previously cleared.

5. Indications for Use:

MIS Ti-base abutment is a titanium base placed onto MIS dental implants to provide support for customized cement-retained or screw retained single or multiple-unit restorations. It is used with a digitally designed mesostructure. MIS Ti-base and the mesostructure make up a two- piece abutment used in conjunction with MIS dental implants, to be placed in the upper or lower jaw arches, in order to restore masticatory function.

Narrow platform Ti-bases are indicated for use only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws.

MIS short implants are to be used only with straight abutments. Mesostructures for use with the MIS Ti-base abutment are to be made from inCoris ZI, IPS e.max® CAD Abutment or VITA ENAMIC® (IS), designed and manufactured using Sirona CEREC SW version 4.6.1 software.

MIS Ti-base abutments are intended for use with the following MIS implants:

- C1 conical connection implant system
- V3 conical connection implant system
- SEVEN internal hex implant system
- M4 internal hex implant system
- Lance+ internal hex implant system

6. Substantial Equivalence Discussion:

The subject MIS Ti-base abutments have the same intended use as the predicate MIS Ti-base abutments cleared under K191152. They are intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations, in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity.

The difference between the subject and predicate Ti-base is the material from which the CAD/CAM mesostructure is to be fabricated. The predicate MIS Ti-base abutments are indicated for use with an inCoris mesostructure designed and milled with Sirona Dental CAD/CAM System, while the subject MIS Ti-base abutments are indicated for use with an IPS e.max CAD or VIRA ENAMIC (IS) mesostructure. Both subject and predicate MIS Ti-base abutments are indicated for use with the same MIS dental implants.

The principal of operation of the predicate and subject MIS Ti-base abutments is the same. The digitally designed mesostructure is cemented to the Ti-base to make up a two-piece abutment. This two-piece abutment is attached to the implant by a prosthetic screw.

Table 1 – Comparison of MIS Ti-base abutment Characteristics

Trade Name	MIS Ti-base abutments	MIS Ti-base abutments
510(k) Number	Subject	K191152
Manufacturer	MIS Implants Technologies Ltd.	MIS Implants Technologies Ltd.
Device Class	Class II	Class II
Product Code(s)	NHA	NHA
Regulation Description	Endosseous dental implant abutment	Endosseous dental implant abutment
Regulation Number	872.3630	872.3630
Indications for use:	MIS Ti-base abutment is a titanium base placed onto MIS dental implants to provide support for customized cement-retained or screw retained single or multiple-unit restorations. It is used with a digitally designed mesostructure. MIS Ti-base and the mesostructure make up a two-piece abutment used in conjunction with MIS dental implants, to be placed in the upper or lower jaw arches, in order to restore masticatory function. Narrow platform Ti-bases are indicated for use only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. MIS short implants are to be used only with straight abutments. Mesostructures for use with the MIS Ti-base abutment are to be made from inCoris ZI, IPS e.max® CAD Abutment or VITA ENAMIC® (IS), designed and manufactured using Sirona CEREC SW version 4.6.1 Software. MIS Ti-base abutments are intended for use with the following MIS implants: C1 conical connection implant system, V3 conical connection implant system, SEVEN internal hex implant system, M4 internal hex implant system and Lance+ internal hex implant system.	MIS Ti-base abutment is a titanium base placed onto MIS dental implants to provide support for customized cement-retained or screw retained single or multiple-unit restorations. It is used with a digitally designed mesostructure. MIS Ti-base and the mesostructure make up a two-piece abutment used in conjunction with MIS dental implants, to be placed in the upper or lower jaw arches, in order to restore masticatory function. Narrow platform Ti-bases are indicated for use only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. MIS short implants are to be used only with straight abutments. Mesostructures for use with the MIS Ti-base abutment are to be made from inCoris ZI, designed and manufactured using Sirona CEREC SW version 4.6.1 Software. MIS Ti-base abutments are intended for use with the following MIS implants: C1 conical connection implant system, V3 conical connection implant system, SEVEN internal hex implant system, M4 internal hex implant system and Lance+ internal hex implant system.
Ti-base Material	Abutment and Abutment screw Ti 6Al 4V ELI per ASTM	Abutment and Abutment screw Ti-6Al-4V per ASTM F136
Implant to abutment Connection	• Conical connection • Internal hex connection	• Conical connection • Internal hex connection
Restoration	• Single-unit • Multiple-unit	• Single-unit • Multiple-unit

Trade Name	MIS Ti-base abutments	MIS Ti-base abutments
Prosthesis Attachment	• Cement-retained • Screw-retained	• Cement-retained • Screw-retained
Platforms	• NP 3.3 • SP 3.75, 3.9, 4.2, 4.3, 5.0 • WP 5.0, 6.0	• NP 3.3 • SP 3.75, 3.9, 4.2, 4.3, 5.0 • WP 5.0, 6.0
Gingiva Height	• NP: 0.5, 1.5 mm • SP: 0.5, 1.5, 3.0 mm • WP: 0.5, 1.5, 3.0 mm	• NP: 0.5, 1.5 mm • SP: 0.5, 1.5, 3.0 mm • WP: 0.5, 1.5, 3.0 mm
Post Height	Minimum 4.0 mm	Minimum 4.0 mm
Compatible implant system	• MIS C1 Conical Connection • MIS V3 Conical Connection • MIS SEVEN Internal Hex • MIS M4 Internal Hex • MIS Lance+ Internal Hex	• MIS C1 Conical Connection • MIS V3 Conical Connection • MIS SEVEN Internal Hex • MIS M4 Internal Hex • MIS Lance+ Internal Hex
Compatible implant diameter (mm)	• NP: C1/V3/ SEVEN/M4/Lance+: 3.3 • SP: C1/ SEVEN/M4/Lance+: 3.75, 4.2 V3: 3.9, 4.3, 5.0 • WP: C1: 5.0 SEVEN/M4/Lance+: 5.0, 6.0	• NP: C1/V3/ SEVEN/M4/Lance+: 3.3 • SP: C1/ SEVEN/M4/Lance+: 3.75, 4.2 V3: 3.9, 4.3, 5.0 • WP: C1: 5.0 SEVEN/M4/Lance+: 5.0, 6.0
Finished CAD/CAM Abutment Angulation	0° - 20°	0° - 20°
Two-piece Abutment Mesostructure Material	• inCoris ZI • IPS e.max • VITA ENAMIC (IS)	InCoris ZI zirconium oxide
Sterilization Method	Product provided non-sterile	Product provided non-sterile
Sterilization by end user	Moist steam sterilization	Moist steam sterilization

7. Non-Clinical Performance Data:

As part of demonstrating the substantial equivalence of MIS Ti-base abutments to the predicate device (K191152) listed in this 510(k) submission, MIS Implants Technologies completed a number of non-clinical performance tests:

- Biocompatibility - The subject device is manufactured using identical manufacturing methods, in the same manufacturing facility, and using the same raw material as the previously cleared predicate device, K191152. The subject device has the same patient contact duration and type as the identified predicate device. For these reasons, biocompatibility testing was not required to support substantial equivalence of the subject device. Consideration of biocompatibility requirements was made with reference to Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

- Biocompatibility (two-piece abutments mesostructure) – The final two-piece CAD/CAM abutments which are constructed utilizing the subject MIS Ti-base components are completed with CAM milled mesostructures composed of the IPS e.max or VITA ENAMIC (IS) material. The IPS e.max material is cleared under K191382 the VITA ENAMIC (IS) material is cleared under K153645. No modifications to the materials are included in this premarket notification. Therefore, no new biocompatibility data relating to the IPS e.max or VITA ENAMIC (IS) material was included in this submission in support of substantial equivalence.

- Fatigue Testing – Mechanical testing of MIS Ti-base abutments in accordance to *ISO 14801:2016* was conducted. The worst case abutments chosen for the tests were the narrowest abutments from both narrow and standard platforms, with a 20° mesostructure which is the maximum angulation possible in the Sirona Dental CAD/CAM System. Both IPS e.max and VITA ENAMIC (IS) mesostructures were tested. The test articles were able to withstand 2,000,000 cycles without failure at a substantially equivalent load to the cited predicates. The fatigue test conducted on the standard platform worst case abutment supports the wide platform abutments as the SP is a worst case in terms of diameter and wall thickness, and both SP and WP abutments are made of the same material. The results of fatigue testing support substantialequivalence. Fatigue testing was conducted with reference to the Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.

- Sterilization Testing – MIS Ti-base abutments are supplied non-sterile and intended to be steam sterilized by the user.

    - For inCoris ZI mesostructure: the steam sterilization parameters were validated according to ANSI/AAMI/ISO 17665- 1:2006 and ANSI/AAMI/ISO 17665-2:2009 for two methods: gravity displacement steam sterilization and pre vacuum steam sterilization. Sterilization validation of the recommended sterilization process for the subject devices was conducted with reference to Guidance for Industry and FDA Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.

- For IPS e.max and VITA ENAMIC (IS) mesostructures: the recommended steam sterilization parameters are according to the parameters that were validated in the predicate K191382 and K153645 respectively.

- Reverse engineering analysis was not conducted in support of substantial equivalence due to the fact that the subject MIS Ti-base Abutments are proposed for compatibility only with MIS dental implant systems. Dentsply Sirona is the sponsor/applicant of this premarket notification as the Owner/Operator of MIS Implants Technologies, Ltd.

- Software verification and validation testing was provided for the subject abutment design library to demonstrate use with the "chairside" CAD/CAM software, CEREC SW version 4.6.1. Software verification and validation testing was conducted to demonstrate that the restrictions prevent design of the mesostructure component outside of design limitations. In addition, the encrypted abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified within the abutment design library.

8. Clinical Performance Data:

There was no human clinical data included in support of substantial equivalence. The non-clinical testing detailed in this submission support the substantial equivalence of the device.

9. Summary:

The comparison between the subject device and the predicate devices has shown that the indications for use, principles of operation, technological characteristics and materials are the same. The results of non- clinical performance testing support a conclusion that the subject device is at least equivalent to the predicate devices with respect to dynamic fatigue performance.

10. Conclusion Regarding Substantial Equivalence:

The subject MIS Ti-base abutments have the same intended use, incorporate the same fundamental technology, and have similar indications for use as the predicate (K191152). Test data to verify the performance of MIS Ti- base abutments has been provided including: dynamic fatigue and sterilization validation and the results of this testing, combined with the design and intended use comparison with the predicate device, support substantial equivalence.