TRI Dental Implants Int. AG
℅ Floyd Larson
President
PaxMed International, LLC
12264 El Camino Real
Suite 400
San Diego, California 92130

December 21, 2021

Re: K203660
Trade/Device Name: TRI-matrix® Implant Line
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 19, 2021
Received: November 22, 2021

Dear Floyd Larson:

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)*

K203660

Device Name

TRI-matrix® Implant Line

Indications for Use *(Describe)*

The TRI-matrix® Implant Line is intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI-matrix® Implant Line allows for one and two stage surgical procedures. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. TRI-matrix® Implant Line 6.5 mm implants are intended for delayed loading only.

The TRI-matrix® Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the TRI-matrix® Crown Abutment to the endosseous implant.

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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# 510(k) Summary
# TRI Dental Implants Int. AG
# TRI-matrix® Implant Line

December 21, 2021

## ADMINISTRATIVE INFORMATION


| | |
|---|---|
| Manufacturer Name | TRI Dental Implants Int. AG<br>Boesch 80A/Postfach 419<br>CH-6331, Huenenberg, Switzerland<br>Telephone: +41-32-510-1606<br>Fax: +41-32-510-1606 |
| Official Contact | Sandro Venanzoni, Chief Technology Officer |
| Representative/Consultant | Floyd G. Larson, MS, MBA<br>Kevin Thomas, PhD<br>PaxMed International, LLC<br>12264 El Camino Real, Suite 400<br>San Diego, CA 92130<br>Telephone: +1-858-792-1235<br>Fax: +1-858-792-1236<br>Email: flarson@paxmed.com<br>kthomas@paxmed.com |


## DEVICE NAME AND CLASSIFICATION

| | |
|---|---|
| Trade/Proprietary Name | TRI-matrix® Implant Line |
| Common Name | Dental implant |
| Regulation Number | 21 CFR 872.3640 |
| Regulation Name | Endosseous dental implant |
| Regulatory Class | Class II |
| Product Code | DZE, NHA |
| Classification Panel | Dental Products Panel |
| Reviewing Division | DHT1B: Division of Dental Devices |

## PREDICATE DEVICE INFORMATION

Primary Predicate Device
K151916, TRI® Dental Implant System, TRI Dental Implants Int. AG

Additional Predicate Device
K172225, ATLANTIS® Abutment for MIS Implant, Dentsply Sirona

## INDICATIONS FOR USE STATEMENT

The TRI-matrix® Implant Line is intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI-matrix® Implant Line allows for one and two-stage surgical procedures. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. TRI-matrix® Implant Line 6.5 mm implants are intended for delayed loading only.

The TRI-matrix® Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the TRI-matrix® Crown Abutment to the endosseous implant.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for the TRI-matrix® Implant Line, a series of bone-level and tissue-level root-form endosseous dental implants, corresponding healing components, abutments, and abutment screws intended for use in the mandible or maxilla to restore chewing function. The permanent abutment design in the product line is a patient-specific abutment manufactured using CAD-CAM technology, which also may be manufactured as a direct final direct restoration. The manufacture of these abutments and restorations will be at TRI Dental Implant Int. AG facilities after receipt of the digital design file of the patient-matched components from the dentist or dental lab.

TRI-matrix Bone-Level implants are intended for bone-level placement and are available in three (3) body diameters (3.75, 4.1 and 4.7 mm). The 3.75 mm body diameter is provided in five (5) lengths (8, 10, 11.5, 13, and 16 mm) and the 4.1 and 4.7 mm body diameters are provided in six (6) lengths (6.5, 8, 10, 11.5, 13, and 16 mm). TRI-matrix Bone-Level 3.75 and 4.1 mm diameter implants have a platform diameter of 3.7 mm and TRI-matrix Bone-Level 4.7 mm diameter implants have a platform diameter of 4.5 mm.

TRI-matrix Tissue-Level implants are intended for tissue-level placement and are available in four (4) body diameters (3.3, 3.75, 4.1 and 4.7 mm). The 3.3 mm body diameter is provided in three lengths (10, 11.5, and 13 mm). The 3.75 mm body diameter is provided in four lengths (8, 10, 11.5, and 13 mm). The 4.1 and 4.7 mm body diameters are provided in five lengths (6.5, 8, 10, 11.5, and 13 mm). TRI-matrix Tissue-Level 3.3 mm diameter implants have a platform diameter of 3.7 mm. TRI-matrix Tissue-Level 3.75 and 4.1 mm diameter implants are available in two platform diameters: 3.7 and 4.5 mm. TRI-matrix Tissue-Level 4.7 mm diameter implants have a platform diameter of 4.5 mm.

Healing components and abutment components for the TRI-matrix Implant Line include Surgical Cover Screw, Healing Collar, Provisional Abutment (Temporary Abutment), and patient-specific Crown Abutment. Abutment screws for the TRI-matrix Implant Line include Replacement Retaining Screw, which are designed to attach the subject device Provisional Abutment, Crown Abutment, or direct final restoration to the implant.

Crown Abutments are patient-specific abutments, fabricated using CAD/CAM technology at a TRI Dental Implants Int. AG manufacturing site. Each abutment is designed according to prescription instructions from the clinician to support a screw-retained prosthesis. The Crown Abutment is different from a normal Titanium Blank abutment because the implant-abutment connection is manufactured at the same time as the patient-specific portion (i.e., there is no stock component). Crown Abutments are fabricated in two platform diameters of 3.7 and 4.5 mm and are attached to the compatible implant with a separate screw. Crown Abutments are available as Zirconia Crown Abutments or Titanium Crown Abutments. The material of Zirconia Crown Abutments will conform to ISO 13356, *Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*. The material of Titanium Crown Abutments will conform to ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*.

A Crown Abutment also may function as a substructure in zirconia that serves as the single-unit or multi-unit final restoration, using the full digital workflow with third-party planning software. For each material

there is an associated CAD software file within the full digital workflow that defines the specific screw, interface, and torque used for the direct restoration.

The design parameters for patient-specific Crown Abutments, direct final restorations or direct provisional restorations are:

Abutment diameter range – 4 to 13 mm
Maximum abutment height – 15 mm
Minimum abutment height above the trans-mucosal collar (post height) for
single-unit restorations – 4 mm
Maximum gingival height from the implant/abutment interface:
5 mm for a restoration on a bone-level implant,
3 mm for a restoration on a tissue-level implant
Minimum gingival height – 0.5 mm
Maximum angulation correction – 15°

Zirconia Crown Abutments and Titanium Crown Abutments will be milled from zirconia blanks and titanium alloy blanks respectively, each conforming to the standards cited above. Design parameters shown above are specified in labeling and are included in the CAD library provided by TRI Dental Implants Int. AG.

The subject device implants, healing components and abutments (except for the Zirconia Crown Abutment), and abutment screws are made of titanium alloy conforming to ASTM F136.

The grit-blasting and acid-etching procedure is applied to the endosseous surface of all subject device dental implants and is identical to the process used to manufacture the dental implants cleared in K151916.

Selected implants and abutments manufactured from titanium alloy (ASTM F136) are anodized using standard electrolytic passivation processing to increase the thickness of the natural oxide layer on the surface and to impart a distinctive surface color; no dyes or coloring additives are used. This anodization process is identical to the anodization process used on abutments cleared in K151916. Titanium alloy subject device components are manufactured from the same materials, are treated with the same surface treatments and are manufactured in the same facilities using the same manufacturing processes as used for devices previously cleared in K151916.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: sterilization validation for titanium alloy components according to ISO 17665-1 and ISO 17665-2 referenced from the primary predicate device K151916, and validation for zirconia components; biocompatibility testing for titanium alloy components according to ISO 10993-5 and ISO 10993-12 referenced from the primary predicate device K151916, and testing for zirconia components; static compression and compression fatigue testing according to ISO 14801; surface area analysis of the subject device compared with data on the primary predicate device referenced from K151916; bacterial endotoxin testing for products provided sterile; and analysis for potential wear of assemblies of titanium alloy implants, zirconia abutments and titanium alloy screws subjected to cyclic loading in saline, using optical microscopy, scanning electron microscopy (SEM), energy dispersive X-ray (EDX) analysis and confocal microscopy, including analysis of particles. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the additional predicate device listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and additional predicate device.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate K151916. Slight differences in the language of the subject device and primary predicate device IFUS do not affect the intended use as an endosseous dental implant for support of a prosthesis to restore chewing function. Minor differences between the IFUS for the subject device and the primary predicate include the specific device names. These minor differences do not impact substantial equivalence because both IFUS express equivalent intended use to facilitate dental prosthetic restorations and are expressed equivalently using different specific wording.

Similarly, the differences between the subject device IFUS and that of the additional predicate device and reference device are related to the specific device names and inclusion of additional products. None of these minor differences impact substantial equivalence because all IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

The subject TRI-matrix® Implant Line designs are substantially equivalent to those of the primary predicate K151916. The ranges of dimensions of body diameter, endosseous length, and platform diameter for the TRI-matrix® Bone-Level and TRI-matrix® Tissue-Level implants are within the corresponding ranges of the primary predicate K151916. TRI-matrix Bone-Level and TRI-matrix Tissue-Level implants and the primary predicate implants also are substantially equivalent in terms of endosseous thread form designs, prosthesis attachment (screw-retained), restorations (single-unit or multi-unit), abutment-implant interface (internal connection), material and surface treatment.

The subject device healing component and abutment screw designs are substantially equivalent to the healing component and abutment screw designs of the primary predicate K151916. The subject device and primary predicate K151916 both include designs for Surgical Cover Screws, Healing Collars, Provisional Abutments (temporary abutments), and abutment screws. The ranges of dimensions of platform diameter and gingival height for the subject healing components are within the corresponding ranges of the primary predicate K151916. The subject healing components and the primary predicate K151916 healing components are substantially equivalent in terms of prosthesis attachment (screw-retained), restorations (single-unit or multi-unit), abutment-implant interface (internal connection) and material. The subject abutment screws and the primary predicate K151916 abutment screws are substantially equivalent in terms of material.

The additional predicate device K172225 is for support of substantial equivalence of the subject Crown Abutment designs. The ranges of platform diameter and design parameters for the subject Crown Abutment are within the corresponding ranges of the additional predicate K172225.

The subject Crown Abutment and the additional predicate device K172225 also are substantially equivalent in terms of prosthesis attachment (screw-retained, cement-retained), restorations (both are intended for use with an endosseous implant to function as a substructure that serves as the final restoration), abutment-implant interface (internal connection) and material (titanium alloy conforming to ASTM F136 or zirconia conforming to ISO 13356).

The subject device implants that are less than 7 mm in length are substantially equivalent in size, surface area and function to the primary predicate device cleared in K151916.

The subject device implants, healing components, abutments and abutment screws are manufactured from titanium alloy conforming to ASTM F136 using the identical material and processing used for titanium alloy components cleared in the primary predicate K151916. Tissue-level implants, healing components, and screws manufactured from titanium alloy are anodized using a standard anodization process that is identical to the anodization process used on abutments cleared in K151916.

All subject device implants, Surgical Cover Screws, and Healing Collars are provided sterile by gamma irradiation, the identical sterilization method used for sterile components in K151916. The subject device abutments (Provisional Abutment, Zirconia Crown Abutment) and abutment screws are provided non-sterile to be moist heat (steam) sterilized prior to clinical use, the identical sterilization method used for non-sterile components in K151916. The moist heat sterilization cycle recommended in labeling has been validated for all subject device materials to a sterility assurance level (SAL) of $10^{-6}$.

Confirmatory biocompatibility testing for the subject device zirconia materials was performed to demonstrate substantial equivalence with regard to biocompatibility. Cytotoxicity testing was performed according to ANSI/AAMI/ISO 10993-5 *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*, and ISO 10993-12 *Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*.

Mechanical performance testing of the subject device was performed according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants.* The fatigue limit data demonstrated that constructs of the subject device abutments manufactured to worst-case parameters, in combination with the compatible subject device implants and used according to the proposed labeling, have sufficient strength for their intended use and are substantially equivalent to predicate devices with regard to mechanical performance.

Minor differences in the designs, dimensions or sizes among the subject device, the primary predicate device, the additional predicate devices, and the reference device do not affect substantial equivalence. These minor differences do not impact safety or effectiveness because these differences are mitigated by the mechanical performance testing.

CONCLUSION

The subject device, the primary predicate device, and the additional predicate device have the same intended use, have similar technological characteristics, and are made of the same materials. The subject device, the primary predicate device, and the additional predicate device encompass the same range of physical dimensions, are packaged in the same materials, and are to be sterilized using the same methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

**Table of Substantial Equivalence – Indications for Use Statement**

| | **Indications for Use Statement** |
|---|---|
| **Subject Device** | |
| K203660<br>TRI-matrix®<br>Implant Line<br>TRI Dental<br>Implants Int. AG | The TRI-matrix® Implant Line is intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI-matrix® Implant Line allows for one and two stage surgical procedures. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. TRI-matrix® Implant Line 6.5 mm implants are intended for delayed loading only.<br><br>The TRI-matrix® Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the TRI-matrix® Crown Abutment to the endosseous implant. |
| **Primary Predicate Device** | |
| K151916<br>TRI® Dental<br>Implant System<br>TRI Dental<br>Implants Int. AG | The TRI® Dental Implant System is intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI® Dental Implant System allows for one and two-stage surgical procedures. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.<br>TRI Dental Implant System 6.5 mm implants are intended for delayed loading only. |

<table>
<tr><th>Additional Predicate Device</th><th></th></tr>
<tr><td>K172225<br>ATLANTIS®<br>Abutment for MIS<br>Implant<br>Dentsply Sirona</td><td>
The ATLANTIS® Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS® Abutment to the endosseous implant.<br><br>
The ATLANTIS® Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS® Crown Abutment to the endosseous implant.<br><br>
The ATLANTIS® Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS® Conus Abutment to the endosseous implant.<br><br>
ATLANTIS® Abutment for MIS implant is compatible with MIS implant from MIS Implant System. MIS short implants (6mm) are to be used only with straight abutments.<br><br>
ATLANTIS® products are compatible with the implants shown in the table below.<br><br>
Implant manufacturer – MIS-IMPLANT TECHNOLOGIES INC
<table>
<tr><th>Trade Name</th><th>Abutment Platform Diameter</th><th>Implant Diameter</th></tr>
<tr><td>MIS Implant M4 & SEVEN Narrow</td><td>Ø3.30 mm</td><td>Ø3.30 mm</td></tr>
<tr><td>MIS Implant M4 & SEVEN Standard</td><td>Ø3.75 and 4.2 mm</td><td>Ø3.75 and 4.2 mm</td></tr>
<tr><td>MIS Implant M4 & SEVEN Wide Platform</td><td>Ø5.0 and 6.0 mm</td><td>Ø5.0 and 6.0 mm</td></tr>
</table>
</td></tr>
</table>

## Table of Substantial Equivalence – Technological Characteristics – Implants

| Characteristic | Subject Device<br>TRI Dental Implants Int. AG<br>TRI-matrix® Implant Line<br>K203660 | Primary Predicate Device<br>TRI Dental Implants Int. AG<br>TRI® Dental Implant System<br>K151916 |
|---|---|---|
| **Reason for Predicate / Reference Device** | **Not applicable** | **Implant designs** |
| **Implant Design** | | |
| | **TRI-matrix® Bone-Level** | **TRI-Vent** |
| Body Diameters x Lengths (mm) | Ø 3.75 x 8, 10, 11.5, 13, 16<br>Ø 4.1 x 6.5, 8, 10, 11.5, 13, 16<br>Ø 4.7 x 6.5, 8, 10, 11.5, 13, 16 | Ø 3.75 x 8, 10, 11.5, 13, 16<br>Ø 4.1 x 6.5, 8, 10, 11.5, 13, 16<br>Ø 4.7 x 6.5, 8, 10, 11.5, 13, 16 |
| Platform Diameters (mm) | 3.7 (for 3.75 and 4.1 mm body)<br>4.5 (for 4.7 mm body) | 3.5 (for 3.75, 4.1, and 4.7 mm body) |
| | **TRI-matrix® Tissue-Level** | **TRI-Narrow, TRI-Octa** |
| Body Diameters x Lengths (mm) | Ø 3.3 x 10, 11.5, 13<br>Ø 3.75 x 8, 10, 11.5, 13<br>Ø 4.1 x 6.5, 8, 10, 11.5, 13<br>Ø 4.7 x 6.5, 8, 10, 11.5, 13 | Ø 3.3 x 10, 11.5, 13, 16 (TRI-Narrow)<br>Ø 3.75 x 8, 10, 11.5, 13 (TRI-Octa)<br>Ø 4.1 x 6.5, 8, 10, 11.5, 13 (TRI-Octa)<br>Ø 4.7 x 6.5, 8, 10, 11.5, 13 (TRI-Octa) |
| Platform Diameters (mm) | 3.7 (for 3.3, 3.75, and 4.1 mm body)<br>4.5 (for 3.75, 4.1, and 4.7 mm body) | 3.2 (for 3.3 mm body TRI-Narrow)<br>4.8 (for 3.75, 4.1, and 4.7 mm body TRI-Octa) |
| Connection | Internal | Internal |
| **Material** | | |
| Implant | Titanium alloy (Ti-6Al-4V ELI) | Titanium alloy (Ti-6Al-4V ELI) |
| Surface | Grit-blasted and acid-etched<br>Pink anodized collar<br>(Tissue Level) | Grit-blasted and acid-etched<br>Pink anodized collar<br>(Tissue Level) |
| **How Provided** | | |
| Implant | Sterile by gamma irradiation | Sterile by gamma irradiation |
| Usage | Single patient, single use | Single patient, single use |

## Table of Substantial Equivalence – Technological Characteristics

## Surgical Cover Screw

| Characteristic | Subject Device | Primary Predicate Device | Comparison |
|---|---|---|---|
| | TRI Dental Implants Int. AG<br>TRI-matrix Implant Line<br>K203660 | TRI Dental Implants Int. AG<br>TRI® Dental Implant System<br>K151916 | |
| Used for | Primary surgery to second-stage surgery | Primary surgery to second-stage surgery | Same |
| Material Composition | Titanium alloy (Ti-6Al-4V ELI) | Titanium alloy (Ti-6Al-4V ELI) | Same |
| Finishing Techniques | As-machined | As-machined | Same |
| Platform Diameters, mm | 3.7, 4.5 | 3.1, 3.5 | Match implant diameters |
| How Provided | Sterile by gamma irradiation | Sterile by gamma irradiation | Same |
| Packaging | Packaged with implant | Packaged with implant | Same |
| Usage | Single patient, single use | Single patient, single use | Same |

## Table of Substantial Equivalence – Technological Characteristics

## Healing Collar

| Characteristic | Subject Device | Primary Predicate Device | Comparison |
|---|---|---|---|
| | TRI Dental Implants Int. AG<br>TRI-matrix Implant Line<br>K203660 | TRI Dental Implants Int. AG<br>TRI® Dental Implant System<br>K151916 | |
| Used for | After implant placement before restoration, tissue contouring | After implant placement before restoration, tissue contouring | Same |
| Material Composition | Titanium alloy (Ti-6Al-4V ELI) | Titanium alloy (Ti-6Al-4V ELI) | Same |
| Finishing Techniques | Pink anodized | Pink anodized | Same |
| Platform Diameters, mm | 3.7, 4.5 | 3.2, 3.5, 4.8 | Match implant diameters |
| Prosthetic Diameters, mm | 3.7, 4.5, 5 | 3.5, 4.5 | Similar |
| Gingival Heights, mm | 1.5, 3.0, 4.0, 4.5, 5.0, 6.0 | 3.0, 4.5, 5.0, 6.0 | Similar |
| How Provided | Sterile by gamma irradiation | Sterile by gamma irradiation | Same |
| Usage | Single patient, single use | Single patient, single use | Same |

## Table of Substantial Equivalence – Technological Characteristics
## Provisional Abutment

| Characteristic | Subject Device | Primary Predicate Device | Comparison |
|---|---|---|---|
| | TRI Dental Implants Int. AG<br>TRI-matrix Implant Line<br>K203660 | TRI Dental Implants Int. AG<br>TRI® Dental Implant System<br>K151916 | |
| Used for | Provisional (temporary) restorations, for healing period, tissue contouring | Provisional (temporary) restorations, for healing period, tissue contouring | Same |
| Material Composition | Titanium alloy (Ti-6Al-4V ELI) | Titanium alloy (Ti-6Al-4V ELI) | Same |
| Finishing Techniques | As-machined | As-machined | Same |
| Platform Diameters, mm | 3.7, 4.5 | 3.2, 3.5, 4.8 | Match implant diameters |
| Prosthetic Diameters, mm | 4.2, 4.9. 5.1, | 3.5, 4.5 | Similar |
| Gingival Heights, mm | 0.6, 1.75 | 3.0, 4.5, 5.0, 6.0 | Within range |
| Restoration | Single-unit, Multi-unit | Single-unit, Multi-unit | Same |
| How Provided | Non-sterile | Non-sterile | Same |
| Implant Interface | Engaging, Non-engaging | Engaging, Non-engaging | Same |
| Usage | Single patient, single use | Single patient, single use | Same |

## Table of Substantial Equivalence – Technological Characteristics
## Titanium Crown Abutment

| Characteristic | Subject Device | Additional Predicate Device | Comparison |
|---|---|---|---|
| | TRI Dental Implants Int. AG<br>TRI-matrix Implant Line<br>K203660 | Dentsply Sirona<br>ATLANTIS® Abutment for MIS Implant<br>K172225 | |
| Used for | Restoration by cementing final crown | Restoration by cementing final crown | Same |
| Material Composition | Titanium alloy (Ti-6Al-4V ELI) | Titanium alloy (Ti-6Al-4V ELI | Same |
| Platform Diameters, mm | 3.7, 4.5 | 3.3, 3.75, 4.2, 5.0, 6.0 | Within range |
| Abutment Angle | Straight, up to 15° | Straight, up to 30° | Within range |
| Implant Connection | Internal | Internal hex | Same |
| Restoration | Single-unit, Multi-unit | Single-unit, Multi-unit | Same |
| How Provided | Non-sterile | Non-sterile | Same |
| Prosthesis Attachment | Screw-retained, Cement-retained | Screw-retained, Cement-retained | Same |
| Usage | Single patient, single use | Single patient, single use | Same |

## Table of Substantial Equivalence – Technological Characteristics
## Zirconia Crown Abutment

| Characteristic | Subject Device | Additional Predicate Device | Comparison |
|---|---|---|---|
| | TRI Dental Implants Int. AG<br><br>TRI-matrix Implant Line<br><br>K203660 | Dentsply Sirona<br><br>ATLANTIS® Abutment for MIS Implant<br><br>K172225 | |
| Used for | Restoration by laboratory finishing techniques | Restoration by laboratory finishing techniques | Same |
| Material Composition | Zirconia (Y-TZP, ISO 13356) | Zirconia (Y-TZP, ISO 13356) | Same |
| Platform Diameters, mm | 3.7, 4.5 | 3.3, 3.75, 4.2, 5.0, 6.0 | Within range |
| Abutment Angle | Straight, up to 15° | Straight, up to 30° | Within range |
| Implant Connection | Internal | Internal hex | Similar |
| Restoration | Single-unit, Multi-unit | Single-unit, Multi-unit | Same |
| How Provided | Non-sterile | Non-sterile | Same |
| Prosthesis Attachment | Screw-retained, Cement-retained | Screw-retained, Cement-retained | Same |
| Usage | Single patient, single use | Single patient, single use | Same |

## Table of Substantial Equivalence – Technological Characteristics
## Abutment Screws

| Characteristic | Subject Device | Primary Predicate Device | Comparison |
|---|---|---|---|
| | TRI Dental Implants Int. AG<br><br>TRI-matrix Implant Line<br><br>K203660 | TRI Dental Implants Int. AG<br><br>TRI® Dental Implant System<br><br>K151916 | |
| Used for | Retention of abutments, crowns | Retention of abutments, crowns | Same |
| Material Composition | Titanium alloy (Ti-6Al-4V ELI) | Titanium alloy (Ti-6Al-4V ELI) | Same |
| Finishing Techniques | Gold anodized | Gold anodized | Same |
| Screw Head Diameters, mm | 2.25, 2.6, 2.8, 3.25 | 2.1, 2.3 | Similar |
| Screw Thread | 1-72 UNF | 1-72 UNF | Same |
| How Provided | Non-sterile | Non-sterile | Same |
| Usage | Single patient, single use | Single patient, single use | Same |