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

January 8, 2025

Re: K242661
Trade/Device Name: TRI-matrix® X-Force Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: August 30, 2024
Received: December 16, 2024

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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

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

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

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

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

Sincerely,

Andrew I. Steen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242661

Device Name

TRI-matrix® X-Force Implants

Indications for Use *(Describe)*

TRI-matrix® X-Force implants are intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI-matrix® X-Force implants allow 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® X-Force implants with lengths of 18, 20, or 22 mm, when placed in the maxilla, are indicated only for multiple unit restorations in splinted applications that utilize at least two implants.

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.

510(k) Summary
TRI Dental Implants Int. AG
TRI-matrix® X-Force Implants

January 7, 2024

ADMINISTRATIVE INFORMATION

Manufacturer Name	TRI Dental Implants Int. AG Boesch 80A/Postfach 419 CH-6331, Huenenberg, Switzerland Telephone: +41-32-510-1606 Fax: +41-32-510-1606
Official Contact	Sandro Venanzoni, Chief Technology Officer
Representative/Consultant	Floyd G. Larson, MS, MBA Kevin Thomas, PhD PaxMed International, LLC 1925 Palomar Oaks Way, Suite 210 Carlsbad, CA 92008 Telephone: +1-858-792-1235 Fax: +1-858-792-1236 Email: flarson@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	TRI-matrix® X-Force Implants
Common Name	Dental implant
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B (Dental Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device

K203660, TRI-matrix® Implant Line, TRI Dental Implants Int. AG

Reference Devices

K151916, TRI® Dental Implant System, TRI Dental Implants Int. AG
K212785, Blue Sky Bio Implant System, Blue Sky Bio, LLC
K230108, Straumann® BLC and TLC Implants, Straumann USA, LLC (on behalf of Institut Straumann AG)
K192221, Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts, Implant Direct Sybron Manufacturing, LLC

INDICATIONS FOR USE STATEMENT

TRI-matrix® X-Force implants are intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI-matrix® X-Force implants allow 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® X-Force implants with lengths of 18, 20 or 22 mm, when placed in the maxilla, are indicated only for multiple unit restorations in splinted applications that utilize at least two implants.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for TRI-matrix X-Force implants, a line extension of the TRI-matrix implant line previously cleared in K203660. TRI-matrix X-Force implants are tissue-level endosseous dental implants that are an adaptation of the TRI-matrix Tissue Level implants cleared in K203660, with the same prosthetic interface, but with modified external features. They are intended for use in the mandible or maxilla to restore chewing function. This submission includes only implants, and they are compatible with prosthetic components previously cleared in K203660 as part of the TRI-matrix implant line, including the TRI-matrix Crown Abutment.

TRI-matrix X-Force implants have a tapered body, double-lead threads and self-cutting flutes. A grit-blasted and acid-etched surface, named the TRI SBA Surface, is applied to the endosseous portion of the implant. TRI-matrix X-Force implants incorporate a pink anodized, machined, 1.8 mm transgingival collar that is not treated with the TRI SBA Surface. Compared with TRI-matrix implants previously cleared in K203660, TRI-matrix X-Force implants have a modified thread design more suited to immediate placement and restoration, a more tapered apical portion (smaller apical diameter for a given coronal diameter), and more aggressive apical cutting flutes.

TRI-matrix X-Force 3.3 mm diameter implants have a platform diameter of 3.7 mm. TRI-matrix X-Force 3.7 mm and 4.1 mm diameter implants are available in two (2) platform diameters: 3.7 mm and 4.5 mm. TRI-matrix X-Force 4.7 mm diameter and 5.7 mm diameter implants have a platform diameter of 4.5 mm. The combinations of subject device implant body and platform diameters and implant lengths are summarized in Table 1 *Summary of Subject Device TRI-matrix X-Force Implant Sizes*.

Table 1. Summary of Subject Device TRI-matrix X-Force Implant Sizes

Body Ø, mm	**Platform Ø, (Implant/Abutment connection), mm**	**Length, mm**							
3.3	3.7	8	10	12	14	16			
3.7	3.7, 4.5	8	10	12	14	16	18	20	22
4.1	3.7, 4.5	8	10	12	14	16	18	20	22
4.7	4.5	8	10	12	14	16			
5.7	4.5	8	10	12	14	16			

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included:

Referenced from the primary predicate device K203660:

- sterilization validation according to ISO 17665-1 and ISO 17665-2;

Provided in this submission:

- biocompatibility evaluation according to ISO 10993-5 and ISO 10993-12
- worst-case analysis and static and dynamic testing according to ISO 14801 on subject devices to demonstrate that static and dynamic testing referenced from the primary predicate device K203660 demonstrates the subject implants do not create a new worst-case as compared to this predicate device with identical connection platform.

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 reference devices 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 reference devices.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate K203660. 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 and special requirements for implants with lengths of 18 mm, 20 mm and 22 mm. Substantial equivalence of the latter is supported by the reference device K212785. The 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.

The designs of the subject TRI-matrix X-Force implants, the primary predicate implants (K203660) and implants of reference device K151916 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 ranges of dimensions of body diameter, platform diameter and endosseous length, for the TRI-matrix X-Force implants are within the ranges of the primary predicate device K203660 and the reference device K151916 except that the subject device includes longer implants (18 mm, 20 mm and 22 mm) for Ø 3.7 and Ø 4.1, and one shorter implant (8 mm) for Ø 3.3. In both cases, suitable reference devices have been identified. Long implants are substantially equivalent in diameter and length, and in Indications for Use, to reference device K212785. The range of implant lengths for Ø 3.3 subject device implants is substantially equivalent to that of Straumann TLC implants cleared in reference device K230108.

The subject device implants 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 K203660 and the reference device K151916. They are grit-blasted and acid-etched, as are the implants of the primary predicate K203660 and the reference device K151916. The subject device implants have a pink collar that is anodized using a standard anodization process that is identical to the anodization process used on tissue level implants cleared in K203660.

All subject device implants are provided sterile by gamma irradiation, the identical sterilization method used for sterile components in K203660.

Risks associated with the subject device implant designs are mitigated by engineering analysis demonstrating that they are not a new worst-case relative to implants of the primary predicate K203660

and by mechanical testing of implants and prosthetic components provided in in K203660. The mechanical testing data and engineering rationale demonstrate that the subject device implants in combination with compatible TRI Dental Implants angled abutments have sufficient strength for their intended use.

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

CONCLUSION

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

Table 2. Substantial Equivalence – Indications for Use Statement

	Indications for Use Statement
Subject Device	
TRI-matrix® X-Force Implant Line TRI Dental Implants Int. AG	TRI-matrix® X-Force implants are intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI-matrix® X-Force implants allow 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® X-Force implants with lengths of 18, 20, 22, or 24 mm, when placed in the maxilla, are indicated only for multiple unit restorations in splinted applications that utilize at least two implants.
Primary Predicate Device	
K203660 TRI-matrix® Implant Line TRI Dental 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. 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.
Reference Device	
K151916 TRI® Dental Implant System TRI Dental 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. TRI Dental Implant System 6.5 mm implants are intended for delayed loading only.
Reference Device	
K212785 Blue Sky Bio Implant System Blue Sky Bio, LLC	Blue Sky Bio Long Implant System is intended for surgical placement in the bone of the upper jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. Implants may be used with single-stage or two-stage procedures, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Blue Sky Bio Long implants can be placed bicortically in cases of reduced bone density. Blue Sky Bio Long implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Blue Sky Bio Long Implant System with a 45º angulation are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.

<table>
<tr><td colspan="2">Reference Device</td></tr>
<tr><td>K230108
Straumann® BLC and TLC Implants

Straumann USA, LLC</td><td>Straumann® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.</td></tr>
<tr><td colspan="2">Reference Device</td></tr>
<tr><td>K192221
Legacy 2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants;
Legacy2, Legacy3, Legacy4 fixture-mounts

Implant Direct Sybron Manufacturing, LLC</td><td>Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, and Legacy4 dental implants are two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework.

Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.
• Narrow (3.2mmD) implants: Indicated for single-tooth replacement (mandibular central and lateral incisors; maxillary lateral incisors), multiple-tooth replacements or denture stabilization.
• Short (<10mm) 3.7mm implants: Indicated for single-tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization.

The Legacy 2, Legacy3, and Legacy4 fixture-mounts are intended for use with the corresponding dental implants (Legacy2, Legacy3, and Legacy4, respectively). The fixture-mounts can function as an abutment. As an abutment, fixture-mounts are intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns or bridges for edentulous or partially edentulous patients.
• Fixture-mounts as an abutment for narrow (3.2mmD) implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.
• Fixture-mounts as an abutment for short (8mm) 3.7mmD implants: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors.

Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, and Legacy4 implants are compatible with the following abutments.
<table>
<tr><th>Manufacturer</th><th>Abutment Line</th><th>Platform Diameter</th></tr>
<tr><td>Implant Direct</td><td>Legacy</td><td>3.0mm, 3.5mm, 4.5mm, 5.7mm</td></tr>
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Table 3. Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
		K203660	K151916	K212785	K230108
	TRI-matrix® X-Force Implant Line	TRI-matrix® Implant Line	TRI® Dental Implant System	Blue Sky Bio Implant System	Straumann® BLC and TLC Implants
	TRI Dental Implants Int. AG	TRI Dental Implants Int. AG	TRI Dental Implants Int. AG	Blue Sky Bio, LLC	Straumann USA, LLC
Reason for Predicate / Reference Device	**Not applicable**	**Implant designs, prosthetic interface**	**Implant designs**	**Long implants**	**Range of Ø 3.3 mm implant lengths**
Implant Design					
Tissue Level Body Diameters x Endosseous Lengths (mm) (Also see Table 4) Platform Diameters (mm) or names	**TRI-matrix® X-Force** Ø 3.3 x 8, 10, 12, 14, 16 Ø 3.7 x 8, 10, 12, 14, 16, 18, 20, 22 Ø 4.1 x 8, 10, 12, 14, 16, 18, 20, 22 Ø 4.7 x 8, 10, 12, 14, 16 Ø 5.7 x 8, 10, 12, 14, 16 3.7 (for 3.3, 3.7, and 4.1 mm body) 4.5 (for 3.7, 4.1, 4.7, and 5.7 mm body)	**TRI-matrix® Tissue-Level** Ø 3.3 x 10, 11.5, 13 Ø 3.75 x 8, 10, 11.5, 13 Ø 4.1 x 6.5, 8, 10, 11.5, 13 Ø 4.7 x 6.5, 8, 10, 11.5, 13 3.7 (for 3.3, 3.75, and 4.1 mm body) 4.5 (for 3.75, 4.1, and 4.7 mm body)	**TRI Octa** Ø 3.75 x 8, 10, 11.5, 13 Ø 4.1 x 6.5, 8, 10, 11.5, 13 Ø 4.7 x 6.5, 8, 10, 11.5, 13 4.8		**Straumann TLC Implants** Ø 3.3 x 8, 10, 12, 14, 16, 18 NT/RT
Bone Level Body Diameters x Lengths (mm) Platform Diameters (mm)		**TRI-matrix® Bone-Level** Ø 3.75 x 8, 10, 11.5, 13, 16 Ø 4.1 x 6.5, 8, 10, 11.5, 13, 16 Ø 4.7 x 6.5, 8, 10, 11.5, 13, 16 3.7 (for 3.75 and 4.1 mm body) 4.5 (for 4.7 mm body)	**TRI-Vent, TRI Narrow** Ø 3.3 x 10, 11.5, 13, 16 (TRI-Narrow) Ø 3.75 x 8, 10, 11.5, 13, 16 Ø 4.1 x 6.5, 8, 10, 11.5, 13, 16 Ø 4.7 x 6.5, 8, 10, 11.5, 13, 16 3.2 (for 3.3 mm body TRI-Narrow) 3.5 (for 3.75, 4.1, and 4.7 mm body)	**Blue Sky Bio Long Implant System** Ø 3.7 x 20, 22.5, 25 Ø 4.3 x 20, 22.5, 25 Ø 5.0 x 20, 22.5, 25 3.5	
Connection	Internal	Internal	Internal	Internal, External	Internal
Material					
Implant	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)	Titanium-13 Zirconium alloy
Surface	Grit-blasted and acid-etched; Pink anodized collar	Grit-blasted and acid-etched; Pink anodized collar	Grit-blasted and acid-etched; Pink anodized collar	Not stated	SLActive® and SLA®
How Provided					
Implant	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by gamma irradiation
Usage	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use

Table 3. Substantial Equivalence – Technological Characteristics (continued)

Comparison	Subject Device	Reference Device
	TRI-matrix® X-Force Implant Line TRI Dental Implants Int. AG	K192221 Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts Implant Direct Sybron Manufacturing, LLC
Reason for Predicate / Reference Device	**Not applicable**	**Implant diameters and lengths**
Implant Design		
Tissue Level Body Diameters x Endosseous Lengths (mm) (Also see Table 4) Platform Diameters (mm) or names	**TRI-matrix® X-Force** Ø 3.3 x 8, 10, 12, 14, 16 Ø 3.7 x 8, 10, 12, 14, 16, 18, 20, 22 Ø 4.1 x 8, 10, 12, 14, 16, 18, 20, 22 Ø 4.7 x 8, 10, 12, 14, 16 Ø 5.7 x 8, 10, 12, 14, 16 3.7 (for 3.3, 3.7, and 4.1 mm body) 4.5 (for 3.7, 4.1, 4.7, and 5.7 mm body)	
Bone Level Body Diameters x Lengths (mm) Platform Diameters (mm)		3.2 x 8, 10, 11.5, 13, 16 3.7 x 6, 8, 10, 11.5, 13, 16 4.2 x 6, 8, 10, 11.5, 13, 16 4.7 x 6, 8, 10, 11.5, 13, 16 5.2 x 6, 8, 10, 11.5, 13, 16 5.7 x 6, 8, 10, 11.5, 13, 16 7.0 x 6, 8, 10, 11.5, 13 3.0, 3.5, 4.5, 5.7
Connection	Internal	Internal
Material		
Implant	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)
Surface	Grit-blasted and acid-etched; Pink anodized collar	Grit-blasted and acid-etched;
How Provided		
Implant	Sterile by gamma irradiation	Sterile by gamma irradiation
Usage	Single patient, single use	Single patient, single use