



ALLONUS Tech Co., LTD.

Daniel Kwon

Director

December 17, 2024

23-3, Sanmakgongdannam 4-gil

Yangsan-si, 50568

REPUBLIC OF KOREA

Re: K241616

Trade/Device Name: ALLONUS Tech Prosthetics

Regulation Number: 21 CFR 872.3630

Regulation Name: Endosseous Dental Implant Abutment

Regulatory Class: Class II

Product Code: NHA

Dated: November 20, 2024

Received: November 20, 2024

Dear Daniel Kwon:

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](mailto: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

## Indications for Use

510(k) Number (if known)

K241616

Device Name

ALLONUS Tech Prosthetic

Indications for Use (Describe)

ALLONUS Tech Prosthetic is intended for use with dental implants as a support for single or multiple-unit prosthetic restorations in the maxilla or mandible of partially or fully edentulous patient. It is including; cemented retained, screw-retained, or overdenture restorations.

It is compatible with the following systems:

- Astra OsseoSpeed EV(K130999) 3.0
- Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm
- Tapered Internal Implants (K071638) (K143022) 3.4, 3.8, 4.6, 5.8 mm
- BioHorizons Laser-Lok Implant System (K093321) 3.0 mm
- Conelog Screw-Line (K113779) 3.3, 3.8, 4.3, 5.0 mm
- Osstem TSIII SA (K121995) 3.5 (3.7) , 4.0 (4.2) , 4.5 (4.6) , 5.0 (5.1), 6.0 (6.0), 7.0 (6.8) mm (Mini, Regular)
- Megagen AnyRidge Internal Implant System (K140091) 4.0, 4.4, 4.9, 5.4 (3.1)
- Neodent Implant System - GM Helix (K163194, K180536) 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)
- Nobel Active 3.0 (K102436) 3.0
- Nobel Active Internal Connection Implant (K071370) NP RP
- Nobelactive Wide Platform (Wp) (K133731) WP
- Straumann BLX Implant (K173961, K181703, K191256) 3.5, 3.75, 4.5, 5.5, 6.5 (RB, WB)
- Straumann 02.9 mm Bone Level Tapered Implants, SC CARES Abutments (K162890) 2.9 (SC)
- Straumann® Bone Level Tapered Implants (K140878) 3.3, 4.1, 4.8 (NC, RC)
- Zimmer 3.1mmD Dental Implant System (K142082) 3.1 (2.9)
- (Ti-base only) Screw Vent® and Tapered Screw Vent® (K013227) 3.7(3.5), 4.7(4.5), 6.0(5.7)

All digitally designed abutments and/or coping for use with the abutments are intended to be sent to a ALLONUS Tech-validated milling center for manufacture.

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

### K241616

#### 1) Submitter

Submitter ALLONUS Tech Co., Ltd.  
23-3, Sanmakgongdannam 4-gil, Yangsan-si, Gyeongsangnam-do, Republic of Korea

Contact Daniel Kwon  
Email allonustech@gmail.com

Phone +1 949 232 7117  
Date prepared : 12/16/2024

#### 2) Device Information

Trade Name ALLONUS Tech Prosthetic

Common Name Endosseous dental implant abutment

Classification Name Abutment, Implant, Dental, Endosseous

Regulation Number 21 CFR 872.3630

Device Classification Class II

Product Code NHA

#### 3) Predicate Device

##### Primary Predicate:

K150203 Medentika CAD/CAM Abutment, Medentika GmbH

##### Reference Devices:

K120414 Astra OsseoSpeed EV by Astra Tech, Inc.

K093321 BioHorizons Laser-Lok Implant System

K071638 Tapered Internal Implants

K143022 BioHorizons Tapered Internal Implants by BIOHORIZONS IMPLANT SYSTEMS, INC.

|         |                                                                                                                                                                         |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| K113779 | Conelog Screw-Line by CAMLOG Biotechnologies GmbH.                                                                                                                      |
| K121995 | OSSTEM TS Fixture System, OSSTEM Implant Co., Ltd.                                                                                                                      |
| K182091 | Osstem Abutment System, Osstem Implant Co., Ltd.                                                                                                                        |
| K140091 | Xpeed AnyRidge Internal Implant System, MegaGen Implant Co., Ltd.                                                                                                       |
| K110955 | AnyRidge Internal Implant System, MegaGen Implant Co., Ltd.                                                                                                             |
| K163194 | Neodent Implant System - GM Helix                                                                                                                                       |
| K180536 | Neodent Implant System - GM Helix                                                                                                                                       |
| K102436 | Nobel Active 3.0, Nobel Biocare AB                                                                                                                                      |
| K111581 | 15 Esthetic Abutment NobelActive 03.0 1.5mm, 15 Esthetic Abutment NobelActive 03.0 3mm, 15 Esthetic Abutment NobelActive, Nobel Biocare AB                              |
| K162890 | BLT 02.9mm SC, SLA Or SLActive, RXD, Loxim, SC Closure Cap And Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutment, Straumann USA, LLC |
| K140878 | Straumann® Bone Level Tapered Implants (NC, RC)                                                                                                                         |
| K173961 | Straumann BLX Implant (RB, WB)                                                                                                                                          |
| K181703 | Straumann BLX Line Extension – Implants, SRAs and Anatomic Abutments by Institut Straumann AG                                                                           |
| K191256 | Straumann BLX Ø3.5 mm Implants by Institut Straumann AG                                                                                                                 |
| K142082 | Zimmer 3.1mm Dental Implant; 2.9mm Angled Abutment; Straight Hex, 2.9mm Contour Abutment, Zimmer Dental Inc.                                                            |
| K013227 | Screw Vent® and Tapered Screw Vent                                                                                                                                      |
| K241485 | TruAbutment DS, TruAbutment Inc.                                                                                                                                        |
| K234142 | TiGEN Abutment, PMMA Abutment and Scan Healing Abutment, MegaGen Implant Co., Ltd.                                                                                      |
| K072570 | NOBELACTIVE MULTI UNIT ABUTMENT by NOBEL BIO CARE AB                                                                                                                    |
| K171142 | Healing Cap Multi-Unit Titanium by NOBEL BIO CARE AB                                                                                                                    |
| K123988 | ANYONETM INTERNAL IMPLANT SYSTEM by MEGAGEN IMPLANT CO., LTD                                                                                                            |

#### 4) General Description

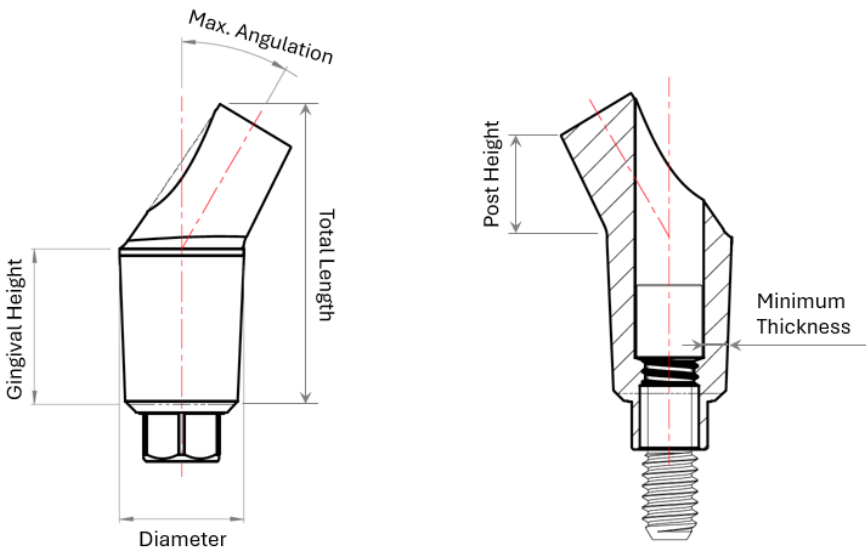
##### Pre-Milled Blank

ALLONUS Tech Prosthetic is made of titanium alloy (Ti-6Al-4V ELI, ASTM F136) intended for use as an aid in prosthetic restoration. It consists of Pre-Milled Blank abutment. It has a pre-manufactured connection interface that fits directly to an endosseous dental implant. The connection platform design includes both engaging and non-engaging designs.

Pre-Milled Blank has a pre-manufactured implant interface connection interface with a customizable cylindrical area-by CAD/CAM- above the implant-abutment interface.

All digitally designed abutments and/or coping for use with the abutments are intended to be sent to a ALLONUS Tech-validated milling center for manufacture.

##### Pre-Milled Blank Design Limitation:

|  |                                                                                                                                                                               |                                                                                                                                                        |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Design Parameter                                                                    | When machined at an angle of 0°                                                                                                                                               | When machined at any angle above 0°                                                                                                                    |
| Diameter (Ø, mm)                                                                    | 3.3~8.0 (Neodent GM, NobelActive)<br>3.5~8.0 (AstraEV, Zimmer Eztetic)<br>3.6~8.0 (Bone Level)<br>3.8~8.0 (BioHorizon, BLX)<br>3.9~8.0 (Conelog)<br>4.0~8.0 (Osstem, Megagen) | 3.3 (Neodent GM, NobelActive)<br>3.5 (Astra EV, Zimmer Eztetic)<br>3.6 (Bone Level)<br>3.8 (BioHorizon, BLX)<br>3.9 (Conelog)<br>4.0 (Osstem, Megagen) |
| Total Length                                                                        | 12mm                                                                                                                                                                          | 11.077mm (Astra EV)                                                                                                                                    |

|                                                                                                        |     |                                                                                                                                                                                    |
|--------------------------------------------------------------------------------------------------------|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                        |     | 11.37 (BioHorizon)<br>11.191 (BLX)<br>11.225 (Bone Level)<br>11.228 (ConeLog)<br>11.247 (Osstem, Megagen)<br>11.002 (Neodent GM)<br>11.008 (NobelActive)<br>11.05 (Zimmer Eztetic) |
| Minimum Gingival Height (mm)                                                                           | 0.5 | 0.5                                                                                                                                                                                |
| Maximum Gingival Height (mm)                                                                           | 5.0 | 6.0 (Astra EV, BioHorizon, Conelog, BLX, Bone Level, Osstem, Megagen, NobelActive, Neodent GM, Zimmer Eztetic)                                                                     |
| Minimum Wall Thickness (mm)                                                                            | 0.4 | 0.3 (Astra EV)<br>0.37 (BLX)<br>0.4 (BioHorizon, Conelog, Bone Level, Osstem, NobelActive, Neodent GM)<br>0.5 (Megagen)<br>0.6 (Zimmer Eztetic)                                    |
| Minimum post height for single-unit restorations (length above the abutment collar / gingival height): | 4.0 | 4.0 (Astra EV, BioHorizon, Conelog, BLX, Osstem, Megagen, NobelActive, Neodent GM, Zimmer Eztetic)<br>4.3 (Bone Level)                                                             |

#### Ti-Base Abutment

Ti Base consists of a two-piece abutment, where the titanium base is a pre-manufactured component of the abutment that will be used to support a CAD/CAM-designed zirconia superstructure (the second part of the two-piece abutment) that composes the final abutment. Ti Base is provided non-sterile therefore must be sterilized after the cementation of the patient-specified superstructure.

#### Raw material blanks

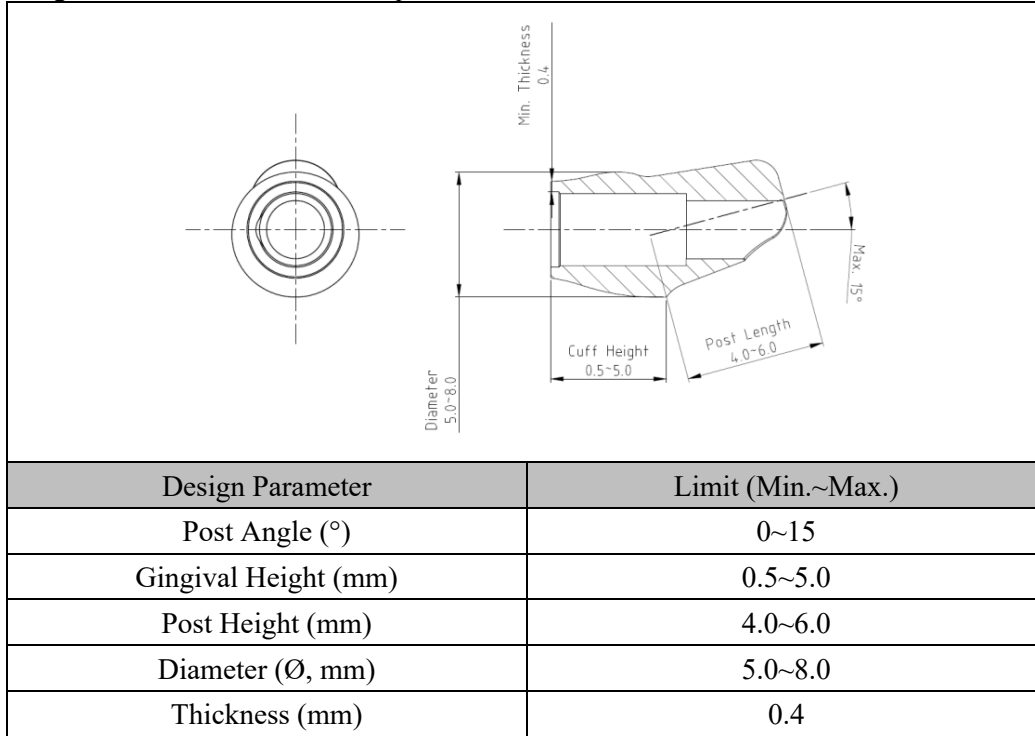
- InCoris Zi (ZrO2) by Sirona Dental Systems GmbH, L size blanks, cleared under K123664.

#### Cement

- RelyX Unicem 2Automix by 3M ESPE, cleared under K100756.



#### Design Limitation for Zirconia superstructure:



#### Multi-unit Abutment and Components

Multi-unit Abutment which are placed into the dental implant to provide support for the prosthetic restoration. The abutments are made of Titanium grade Ti-6Al-4V ELI (meets ASTM Standard F-136). Multi-unit Abutment includes abutments and components (Multi-unit Healing Cap, Multi-unit Temporary cylinder, Multi-unit Ti-cylinder). Multi-unit Abutment are provided in various gingival cuff height ranging from 1 to 6 mm.

## 5) Indications for Use

ALLONUS Tech Prosthetic is intended for use with dental implants as a support for single or multiple-unit prosthetic restorations in the maxilla or mandible of partially or fully edentulous patient. It is including; cemented retained, screw-retained, or overdenture restorations.

It is compatible with the following systems:

- Astra OsseoSpeed EV(K130999) 3.0
- Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm
- Tapered Internal Implants (K071638) (K143022) 3.4, 3.8, 4.6, 5.8 mm
- BioHorizons Laser-Lok Implant System (K093321) 3.0 mm
- Conelog Screw-Line (K113779) 3.3, 3.8, 4.3, 5.0 mm
- Osstem TSIII SA (K121995) 3.5 (3.7) , 4.0 (4.2) , 4.5 (4.6) , 5.0 (5.1), 6.0 (6.0), 7.0 (6.8) mm (Mini, Regular)
- Megagen AnyRidge Internal Implant System (K140091) 4.0, 4.4, 4.9, 5.4 (3.1)
- Neodent Implant System - GM Helix (K163194, K180536) 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)
- Nobel Active 3.0 (K102436) 3.0
- Nobel Active Internal Connection Implant (K071370) NP RP
- Nobelactive Wide Platform (Wp) (K133731) WP
- Straumann BLX Implant (K173961, K181703, K191256) 3.5, 3.75, 4.5, 5.5, 6.5 (RB, WB)
- Straumann 02.9 mm Bone Level Tapered Implants, SC CARES Abutments (K162890) 2.9 (SC)
- Straumann® Bone Level Tapered Implants (K140878) 3.3, 4.1, 4.8 (NC, RC)
- Zimmer 3.1mmD Dental Implant System (K142082) 3.1 (2.9)
- (Ti-base only) Screw Vent® and Tapered Screw Vent® (K013227) 3.7(3.5), 4.7(4.5), 6.0(5.7)

All digitally designed abutments and/or coping for use with the abutments are intended to be sent to a ALLONUS Tech-validated milling center for manufacture.

## 6) Substantial Equivalence Comparison

### Pre-Milled Blank

| Attributes                        | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Primary Predicate Device                                                                                                                                                                                  | Reference Device                                        | Reference Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Part Name                         | Pre-Milled Blank                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Medentika Preface CAD/CAM Abutments                                                                                                                                                                       | TiGEN Abutment; PMMA Abutment and Scan Healing Abutment | TruAbutment DS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 510(K) No.                        | K241616                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | K150203                                                                                                                                                                                                   | K234142)                                                | K241485                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Applicant                         | ALLONUS Tech Co., Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Medentika GmbH                                                                                                                                                                                            | MegaGen Co., Ltd.                                       | TruAbutment Inc                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Trade Name                        | ALLONUS Tech Prosthetic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Medentika CAD/CAM Abutment                                                                                                                                                                                | TiGEN Abutment; PMMA Abutment and Scan Healing Abutment | TruAbutment DS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Classification Name               | Endosseous Dental Implant Abutments (872.3630)                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Endosseous Dental Implant Abutments (872.3630)                                                                                                                                                            | Endosseous Dental Implant Abutments (872.3630)          | Endosseous Dental Implant Abutments (872.3630)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Product Code                      | NHA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | NHA                                                                                                                                                                                                       | NHA                                                     | NHA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Material                          | Ti-6Al-4V ELI (ASTM F136)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Ti-6Al-4V ELI (ASTM F136)                                                                                                                                                                                 | Ti-6Al-4V ELI                                           | Ti-6Al-4V ELI                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Surface Treatment                 | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | None                                                                                                                                                                                                      | None                                                    | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Indications For Use/ Intended Use | ALLONUS Tech Prosthetic is intended for use with dental implants as a support for single or multiple-unit prosthetic restorations in the maxilla or mandible of partially or fully edentulous patient. It is including; cemented retained, screw-retained, or overdenture restorations.<br><br>It is compatible with the following systems:<br><br>• Astra OsseoSpeed EV(K130999) 3.0<br>• Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm<br>• Tapered Internal Implants (K071638) (K143022) 3.4, 3.8, 4.6, 5.8 mm | Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. |                                                         | The TiGEN Abutment, PMMA Abutment and Scan Healing Abutment are intended for use on endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in prosthetic rehabilitation.<br><br>The PMMA Abutment is indicated to be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. They must be placed out of occlusion and are for temporary use (3 months).<br><br>For TiGEN Abutment and PMMA Abutment, all digitally designed abutments for use with PMMA Abutment and TiGEN Abutment are intended to be sent to a MegaGen-validated milling center for manufacture. | TruAbutment DS is a patient-specific CAD/CAM abutment, directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. It is compatible with the following systems:<br>Astra OsseoSpeed EV (K130999, K120414) : 3.0, 3.6, 4.2, 4.8, 5.4 mm.<br>Biomet 3i Full OSSEOTITE Tapered Certain (K130949) : 3.25, 4.0, 5.0, 6.0 mm.<br>DIO UF(II) Internal Submerged (K161987, K170608, K173975) : 3.3, 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 (Narrow, Regular) mm.<br>Neoss ProActive® (K083561) : 3.25, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 (NP, SP) mm.<br>Osstem TS (K161604) : 3.0, 3.5 (3.7), 4.0 (4.2), 4.5 (4.6), 5.0 (5.1), 6.0 (6.0), 7.0 (6.8) (Mini, Regular) mm.<br>Camlog Screw-Line (K083496) |
|                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                           |                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
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|                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                           |                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

| Attributes                       | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Primary Predicate Device                                                                                                                                                                                                                                                                                                                                                                                                                                       |                         |   |               | Reference Device                                        | Reference Device           |   |                         |               |                        |   |                         |                         |                                  |   |                    |                    |                                                                                                                                                                                                                                     |  |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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| Part Name                        | Pre-Milled Blank                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Medentika Preface CAD/CAM Abutments                                                                                                                                                                                                                                                                                                                                                                                                                            |                         |   |               | TiGEN Abutment; PMMA Abutment and Scan Healing Abutment | TruAbutment DS             |   |                         |               |                        |   |                         |                         |                                  |   |                    |                    |                                                                                                                                                                                                                                     |  |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                  | <ul style="list-style-type: none"><li>BioHorizons Laser-Lok Implant System (K093321) 3.0 mm</li><li>Conelog Screw-Line (K113779) 3.3, 3.8, 4.3, 5.0 mm</li><li>Osstem TSIII SA (K121995) 3.5 (3.7) , 4.0 (4.2) , 4.5 (4.6) , 5.0 (5.1), 6.0 (6.0), 7.0 (6.8) mm (Mini, Regular)</li><li>Megagen AnyRidge Internal Implant System (K140091) 4.0, 4.4, 4.9, 5.4 (3.1)</li><li>Neodent Implant System - GM Helix (K163194, K180536) 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)</li><li>Nobel Active 3.0 (K102436) 3.0</li><li>Nobel Active Internal Connection Implant (K071370) NP RP</li><li>Nobelactive Wide Platform (Wp) (K133731) WP</li><li>Straumann BLX Implant (K173961, K181703, K191256) 3.5, 3.75, 4.5, 5.5, 6.5 (RB, WB)</li><li>Straumann 02.9 mm Bone Level Tapered Implants, SC CARES Abutments (K162890) 2.9 (SC)</li><li>Straumann® Bone Level Tapered Implants (K140878) 3.3, 4.1, 4.8 (NC, RC)</li></ul> | <table><tr><td>Straumann Standard</td><td>N</td><td>3.3, 4.1, 4.8</td><td>3.5(NNC), 4.8, 6.5</td></tr><tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr><tr><td>Astra Tech OsseoSpeed™</td><td>S</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td></tr><tr><td>Dentsply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr></table> | Straumann Standard      | N | 3.3, 4.1, 4.8 | 3.5(NNC), 4.8, 6.5                                      | Zimmer Tapered Screw-vent® | R | 3.3, 3.7, 4.1, 4.7, 6.0 | 3.5, 4.5, 5.7 | Astra Tech OsseoSpeed™ | S | 3.0, 3.5, 4.0, 4.5, 5.0 | 3.0, 3.5, 4.0, 4.5, 5.0 | Dentsply Friadent® Frialit/XiVE® | T | 3.4, 3.8, 4.5, 5.5 | 3.4, 3.8, 4.5, 5.5 | Medentika PreFace is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center. |  |  |  |  | <p>: 3.3, 3.8, 4.3, 5.0, 6.0 mm.<br/>Conelog Screw-Line (K113779)<br/>: 3.3, 3.8, 4.3, 5.0 mm.<br/>Implant Direct Legacy2 (K192221)<br/>: 3.2 mm.<br/>BioHorizons Internal (K093321, K071638, K143022)<br/>: 3.0, 3.4, 3.8, 4.6, 5.8 mm.<br/>MegaGen AnyRidge Internal Implant (K140091)<br/>: 3.5, 4.0, 4.5, 5.0, 5.5 (3.5) mm.<br/>All digitally designed abutments and/or copings for use with<br/>the TruAbutment DS abutments are intended to be sent to a<br/>TruAbutment-validated milling center for manufacture.<br/>TruAbutment DS is compatible with the following devices:<br/>Astra OsseoSpeed EV (K130999, K120414)<br/>Implant Body Diameter (mm): 3.0 / Implant Platform (mm):<br/>3.0 / Internal Spline connection.<br/>Implant Body Diameter (mm): 3.6 / Implant Platform (mm):<br/>3.6 / Internal Spline connection.<br/>Implant Body Diameter (mm): 4.2 / Implant Platform (mm):<br/>4.2 / Internal Spline connection.<br/>Implant Body Diameter (mm): 4.8 / Implant Platform (mm):<br/>4.8 / Internal Spline connection.<br/>Implant Body Diameter (mm): 5.4 / Implant Platform (mm):<br/>5.4/ Internal Spline connection.<br/>Biomet 3i Full OSSEOTITE Tapered Certain (K130949)<br/>Implant Body Diameter (mm): 3.25 / Implant Platform (mm): 3.4 / Internal Hex connection.<br/>Implant Body Diameter (mm): 4.0 / Implant Platform (mm): 4.1 / Internal Hex connection.<br/>Implant Body Diameter (mm): 5.0 / Implant Platform (mm): 5.0 / Internal Hex connection.<br/>Implant Body Diameter (mm): 6.0 / Implant Platform</p> |
| Straumann Standard               | N                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 3.3, 4.1, 4.8                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 3.5(NNC), 4.8, 6.5      |   |               |                                                         |                            |   |                         |               |                        |   |                         |                         |                                  |   |                    |                    |                                                                                                                                                                                                                                     |  |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Zimmer Tapered Screw-vent®       | R                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 3.3, 3.7, 4.1, 4.7, 6.0                                                                                                                                                                                                                                                                                                                                                                                                                                        | 3.5, 4.5, 5.7           |   |               |                                                         |                            |   |                         |               |                        |   |                         |                         |                                  |   |                    |                    |                                                                                                                                                                                                                                     |  |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Astra Tech OsseoSpeed™           | S                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 3.0, 3.5, 4.0, 4.5, 5.0                                                                                                                                                                                                                                                                                                                                                                                                                                        | 3.0, 3.5, 4.0, 4.5, 5.0 |   |               |                                                         |                            |   |                         |               |                        |   |                         |                         |                                  |   |                    |                    |                                                                                                                                                                                                                                     |  |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dentsply Friadent® Frialit/XiVE® | T                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 3.4, 3.8, 4.5, 5.5                                                                                                                                                                                                                                                                                                                                                                                                                                             | 3.4, 3.8, 4.5, 5.5      |   |               |                                                         |                            |   |                         |               |                        |   |                         |                         |                                  |   |                    |                    |                                                                                                                                                                                                                                     |  |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

| Attributes | Subject Device                                                                                                                                                                                                                                                                   | Primary Predicate Device            | Reference Device                                        | Reference Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|---------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Part Name  | Pre-Milled Blank                                                                                                                                                                                                                                                                 | Medentika Preface CAD/CAM Abutments | TiGEN Abutment; PMMA Abutment and Scan Healing Abutment | TruAbutment DS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|            | <ul style="list-style-type: none"> <li>• Zimmer 3.1mmD Dental Implant System (K142082) 3.1 (2.9)</li> </ul> <p>All digitally designed abutments and/or coping for use with the abutments are intended to be sent to a ALLONUS Tech-validated milling center for manufacture.</p> |                                     |                                                         | <p>(mm): 6.0 / Internal Hex connection.<br/>DIO UF(II) Internal Submerged (K161987, K170608, K173975)<br/>Implant Body Diameter (mm): 3.3 /Implant Platform (mm):<br/>Narrow / Internal Hex connection.<br/>Implant Body Diameter (mm): 3.8 /Implant Platform (mm):<br/>Regular / Internal Hex connection.<br/>Implant Body Diameter (mm): 4.0 /Implant Platform (mm):<br/>Regular / Internal Hex connection.<br/>Implant Body Diameter (mm): 4.5 /Implant Platform (mm):<br/>Regular / Internal Hex connection.<br/>Implant Body Diameter (mm): 5.0 /Implant Platform (mm):<br/>Regular / Internal Hex connection.<br/>Implant Body Diameter (mm): 5.5 /Implant Platform (mm):<br/>Regular / Internal Hex connection.<br/>Implant Body Diameter (mm): 6.0 /Implant Platform (mm):<br/>Wide / Internal Hex connection.<br/>Implant Body Diameter (mm): 6.5 /Implant Platform (mm):<br/>Wide / Internal Hex connection.<br/>Implant Body Diameter (mm): 7.0 /Implant Platform (mm):<br/>Wide / Internal Hex connection.<br/>Neoss ProActive® (K083561)<br/>Implant Body Diameter (mm): 3.25 / Implant Platform (mm): 3.5 / Internal Hex connection.<br/>Implant Body Diameter (mm): 3.5 /Implant Platform (mm):<br/>4.0 / Internal Hex connection.<br/>Implant Body Diameter (mm): 4.0 /Implant Platform (mm):<br/>4.0 / Internal Hex connection.<br/>Implant Body Diameter (mm): 4.5 /Implant Platform (mm):</p> |

| Attributes | Subject Device   | Primary Predicate Device            | Reference Device                                        | Reference Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|------------|------------------|-------------------------------------|---------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Part Name  | Pre-Milled Blank | Medentika Preface CAD/CAM Abutments | TiGEN Abutment; PMMA Abutment and Scan Healing Abutment | TruAbutment DS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|            |                  |                                     |                                                         | <p>4.0 / Internal Hex connection.<br/>Implant Body Diameter (mm): 5.0 / Implant Platform (mm):</p> <p>4.0 / Internal Hex connection.<br/>Implant Body Diameter (mm): 5.5 / Implant Platform (mm):</p> <p>4.0 / Internal Hex connection.<br/>Implant Body Diameter (mm): 6.0 / Implant Platform (mm):</p> <p>4.0 / Internal Hex connection.<br/>Osstem TS (K161604)<br/>Implant Body Diameter (mm): 3.0 / Implant Platform (mm):</p> <p>2.1 / Internal Hex connection.<br/>Implant Body Diameter (mm): 3.5 / Implant Platform (mm):</p> <p>2.1 / Internal Hex connection.<br/>Implant Body Diameter (mm): 4.0 / Implant Platform (mm):</p> <p>2.5 / Internal Hex connection.<br/>Implant Body Diameter (mm): 4.5 / Implant Platform (mm):</p> <p>2.5 / Internal Hex connection.<br/>Implant Body Diameter (mm): 5.0 / Implant Platform (mm):</p> <p>2.5 / Internal Hex connection.<br/>Implant Body Diameter (mm): 6.0 / Implant Platform (mm):</p> <p>2.5 / Internal Hex connection.<br/>Implant Body Diameter (mm): 7.0 / Implant Platform (mm):</p> <p>2.5 / Internal Hex connection.<br/>Camlog Screw-Line (K083496)<br/>Implant Body Diameter (mm): 3.3 / Implant Platform (mm):</p> <p>3.3 / Tube-in-tube connection.<br/>Implant Body Diameter (mm): 3.8 / Implant Platform (mm):</p> <p>3.8 / Tube-in-tube connection.<br/>Implant Body Diameter (mm): 4.3 / Implant Platform (mm):</p> <p>4.3 / Tube-in-tube connection.</p> |

| Attributes                                                                                            | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Primary Predicate Device                                                                                                                                                                                                                                                  | Reference Device                                        | Reference Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                     |                                                                                                                                                                                      |                                                                                           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| Part Name                                                                                             | Pre-Milled Blank                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Medentika Preface CAD/CAM Abutments                                                                                                                                                                                                                                       | TiGEN Abutment; PMMA Abutment and Scan Healing Abutment | TruAbutment DS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                     |                                                                                                                                                                                      |                                                                                                                                                               |                          |                          |                                                                                                                                                                                                                   |                              |     |     |                              |     |                                                                                                                                                                                                                                                                           |                             |     |                                                                                                                                                                                                                                               |                                                                                                       |     |  |                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |        |      |                             |                        |                                     |                                     |                             |                             |                          |                          |    |        |      |  |  |   |   |  |  |  |    |        |     |  |  |   |     |  |  |  |    |        |     |  |  |   |     |  |  |  |    |        |      |  |  |   |   |  |  |  |    |        |      |  |  |   |   |  |  |  |     |        |      |  |  |   |     |  |  |  |     |        |     |  |  |   |   |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                           |                                                         | Implant Body Diameter (mm): 5.0 /Implant Platform (mm):<br>5.0 / Tube-in-tube connection.<br>Implant Body Diameter (mm): 6.0 /Implant Platform (mm):<br>6.0/ Tube-in-tube connection.<br>Conelog Screw-Line (K113779)<br>Implant Body Diameter (mm): 3.3 /Implant Platform (mm):<br>3.3 / Conical abutment connection.<br>Implant Body Diameter (mm): 3.8 /Implant Platform (mm):<br>3.8 / Conical abutment connection.<br>Implant Body Diameter (mm): 4.3 /Implant Platform (mm):<br>4.3 / Conical abutment connection.<br>Implant Body Diameter (mm): 5.0 /Implant Platform (mm):<br>5.0 / Conical abutment connection. |                                     |                                                                                                                                                                                      |                                                                                           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| Restoration                                                                                           | Single-unit, Multi-unit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        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                          | Single-unit                                             | Single-unit, Multi-unit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                     |                                                                                                                                                                                      |                                                                                           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|  |   |     |  |  |  |     |        |     |  |  |   |   |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Design Limits (Min.~Max.)                                                                             | <table><tr><th>Design Parameter</th><th>When machined at an angle of 0°</th><th>When machined at any angle above 0°</th></tr><tr><td>Diameter (Ø, mm)</td><td>*1.3-4.0 (Neodent GM, NobelActive)<br/>*1.5-4.0 (AutoEV, Zimmer Esthetic)<br/>*1.6-4.0 (Bone Level)<br/>*1.8-4.0 (BioHorizon, BLX)<br/>*1.9-4.0 (Conelog)<br/>*4.0-4.0 (Osstem, Megapars)</td><td>*1.3 (Neodent GM, NobelActive)<br/>*1.5 (Auto EV, Zimmer Esthetic)<br/>*1.6 (Bone Level)<br/>*1.8 (BioHorizon, BLX)<br/>*1.9 (Conelog)<br/>*4.0 (Osstem, Megapars)</td></tr><tr><td>Total Length</td><td>12mm</td><td>*11.07mm (Auto EV)<br/>*11.17 (BioHorizon)<br/>*11.19 (BLX)<br/>*11.225 (Bone Level)<br/>*11.228 (Conelog)<br/>*11.247 (Osstem, Megapars)<br/>*11.060 (Neodent GM)<br/>*11.000 (NobelActive)<br/>*11.05 (Zimmer Esthetic)</td></tr><tr><td>Minimum Gingival Height (mm)</td><td>0.5</td><td>0.5</td></tr><tr><td>Maximum Gingival Height (mm)</td><td>5.0</td><td>*6.0 (Auto EV, BioHorizon, Conelog, BLX, Bone Level, Osstem, Megapars, NobelActive, Neodent GM, Zimmer Esthetic)<br/>*6.3 (Auto EV)<br/>*6.37 (BLX)<br/>*6.4 (BioHorizon, Conelog, Bone Level, Osstem, NobelActive, Neodent GM)<br/>*6.5 (Megapars)<br/>*6.6 (Zimmer Esthetic)</td></tr><tr><td>Minimum Wall Thickness (mm)</td><td>0.4</td><td>*6.0 (Auto EV, BioHorizon, Conelog, BLX, Bone Level, Osstem, Megapars, NobelActive, Neodent GM, Zimmer Esthetic)<br/>*4.0 (Auto EV, BioHorizon, Conelog, BLX, Osstem, Megapars, NobelActive, Neodent GM, Zimmer Esthetic)<br/>*4.3 (Bone Level)</td></tr><tr><td>Minimum post height for single-unit restorations (length above the abutment collar / gingival height)</td><td>4.0</td><td></td></tr></table> | Design Parameter                                                                                                                                                                                                                                                          | When machined at an angle of 0°                         | When machined at any angle above 0°                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Diameter (Ø, mm)                    | *1.3-4.0 (Neodent GM, NobelActive)<br>*1.5-4.0 (AutoEV, Zimmer Esthetic)<br>*1.6-4.0 (Bone Level)<br>*1.8-4.0 (BioHorizon, BLX)<br>*1.9-4.0 (Conelog)<br>*4.0-4.0 (Osstem, Megapars) | *1.3 (Neodent GM, NobelActive)<br>*1.5 (Auto EV, Zimmer Esthetic)<br>*1.6 (Bone Level)<br>*1.8 (BioHorizon, BLX)<br>*1.9 (Conelog)<br>*4.0 (Osstem, Megapars) | Total Length             | 12mm                     | *11.07mm (Auto EV)<br>*11.17 (BioHorizon)<br>*11.19 (BLX)<br>*11.225 (Bone Level)<br>*11.228 (Conelog)<br>*11.247 (Osstem, Megapars)<br>*11.060 (Neodent GM)<br>*11.000 (NobelActive)<br>*11.05 (Zimmer Esthetic) | Minimum Gingival Height (mm) | 0.5 | 0.5 | Maximum Gingival Height (mm) | 5.0 | *6.0 (Auto EV, BioHorizon, Conelog, BLX, Bone Level, Osstem, Megapars, NobelActive, Neodent GM, Zimmer Esthetic)<br>*6.3 (Auto EV)<br>*6.37 (BLX)<br>*6.4 (BioHorizon, Conelog, Bone Level, Osstem, NobelActive, Neodent GM)<br>*6.5 (Megapars)<br>*6.6 (Zimmer Esthetic) | Minimum Wall Thickness (mm) | 0.4 | *6.0 (Auto EV, BioHorizon, Conelog, BLX, Bone Level, Osstem, Megapars, NobelActive, Neodent GM, Zimmer Esthetic)<br>*4.0 (Auto EV, BioHorizon, Conelog, BLX, Osstem, Megapars, NobelActive, Neodent GM, Zimmer Esthetic)<br>*4.3 (Bone Level) | Minimum post height for single-unit restorations (length above the abutment collar / gingival height) | 4.0 |  | - Post Angle (°): 0~30<br>-Diameter (Ø, mm): 3.0~7.0 | <table><tr><th>System</th><th>Type</th><th>Minimum wall thickness (mm)</th><th>Maximum angulation (°)</th><th>Minimum gingival collar height (mm)</th><th>Maximum gingival collar height (mm)</th><th>Minimum gingival collar (°)</th><th>Maximum gingival collar (°)</th><th>Minimum post height (mm)</th><th>Maximum post height (mm)</th></tr><tr><td>AR</td><td>Holder</td><td>0.67</td><td></td><td></td><td>5</td><td>4</td><td></td><td></td><td></td></tr><tr><td>AO</td><td>Holder</td><td>0.7</td><td></td><td></td><td>5</td><td>4.5</td><td></td><td></td><td></td></tr><tr><td>MN</td><td>Holder</td><td>0.5</td><td></td><td></td><td>5</td><td>3.5</td><td></td><td></td><td></td></tr><tr><td>BD</td><td>Holder</td><td>0.71</td><td></td><td></td><td>5</td><td>4</td><td></td><td></td><td></td></tr><tr><td>BD</td><td>Holder</td><td>0.46</td><td></td><td></td><td>5</td><td>4</td><td></td><td></td><td></td></tr><tr><td>AOO</td><td>Holder</td><td>0.05</td><td></td><td></td><td>3</td><td>4.8</td><td></td><td></td><td></td></tr><tr><td>AOE</td><td>Holder</td><td>0.3</td><td></td><td></td><td>5</td><td>4</td><td></td><td></td><td></td></tr></table><br>AR: XPEED AnyRidge Internal System<br>AO: AnyOne Internal Implant System<br>MN: MiNi Internal Implant System<br>BD: BLUEDIAMOND IMPLANT System<br>AOO: AnyOne Onestage Implant System<br>AOE: AnyOne External Implant System | System | Type | Minimum wall thickness (mm) | Maximum angulation (°) | Minimum gingival collar height (mm) | Maximum gingival collar height (mm) | Minimum gingival collar (°) | Maximum gingival collar (°) | Minimum post height (mm) | Maximum post height (mm) | AR | Holder | 0.67 |  |  | 5 | 4 |  |  |  | AO | Holder | 0.7 |  |  | 5 | 4.5 |  |  |  | MN | Holder | 0.5 |  |  | 5 | 3.5 |  |  |  | BD | Holder | 0.71 |  |  | 5 | 4 |  |  |  | BD | Holder | 0.46 |  |  | 5 | 4 |  |  |  | AOO | Holder | 0.05 |  |  | 3 | 4.8 |  |  |  | AOE | Holder | 0.3 |  |  | 5 | 4 |  |  |  | Minimum and Maximum abutment angle (°):<br>0~25<br>Minimum and Maximum gingival (cuff) height (mm): 0.5~6.0<br>Minimum and Maximum diameter at abutment/implant interface (□,mm): 3.3~8.0<br>Minimum and Maximum length of abutment (mm): 6.0~11.0<br>Minimum wall thickness at the abutment/implant interface (mm): 0.4<br>Minimum and Maximum length of abutment post (length above the abutment collar/gingival height) (mm): 4.0~7.0 |
| Design Parameter                                                                                      | When machined at an angle of 0°                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | When machined at any angle above 0°                                                                                                                                                                                                                                       |                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                     |                                                                                                                                                                                      |                                                                                           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|  |   |     |  |  |  |     |        |     |  |  |   |   |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Diameter (Ø, mm)                                                                                      | *1.3-4.0 (Neodent GM, NobelActive)<br>*1.5-4.0 (AutoEV, Zimmer Esthetic)<br>*1.6-4.0 (Bone Level)<br>*1.8-4.0 (BioHorizon, BLX)<br>*1.9-4.0 (Conelog)<br>*4.0-4.0 (Osstem, Megapars)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | *1.3 (Neodent GM, NobelActive)<br>*1.5 (Auto EV, Zimmer Esthetic)<br>*1.6 (Bone Level)<br>*1.8 (BioHorizon, BLX)<br>*1.9 (Conelog)<br>*4.0 (Osstem, Megapars)                                                                                                             |                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                     |                                                                                                                                                                                      |                                                                                                                                                               |                          |                          |                                                                                                                                                                                                                   |                              |     |     |                              |     |                                                                                                                                                                                                                                                                           |                             |     |                                                                                                                                                                                                                                               |                                          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|  |   |     |  |  |  |     |        |     |  |  |   |   |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Total Length                                                                                          | 12mm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | *11.07mm (Auto EV)<br>*11.17 (BioHorizon)<br>*11.19 (BLX)<br>*11.225 (Bone Level)<br>*11.228 (Conelog)<br>*11.247 (Osstem, Megapars)<br>*11.060 (Neodent GM)<br>*11.000 (NobelActive)<br>*11.05 (Zimmer Esthetic)                                                         |                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                     |                                                                                                                                                                                      |                                                                                                                                                               |                          |                          |                                                                                                                                                                                                                   |                              |     |     |                              |     |                                                                                                                                                                                                                                                                           |                             |     |                                                                                                                                                                                                                                               |                                          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|  |   |     |  |  |  |     |        |     |  |  |   |   |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Minimum Gingival Height (mm)                                                                          | 0.5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 0.5                                                                                                                                                                                                                                                                       |                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                     |                                                                                                                                                                                      |                                                                                                                                                               |                          |                          |                                                                                                                                                                                                                   |                              |     |     |                              |     |                                                                                                                                                                                                                                                                           |                             |     |                                                                                                                                                                                                                                               |                                          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|  |   |     |  |  |  |     |        |     |  |  |   |   |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Maximum Gingival Height (mm)                                                                          | 5.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | *6.0 (Auto EV, BioHorizon, Conelog, BLX, Bone Level, Osstem, Megapars, NobelActive, Neodent GM, Zimmer Esthetic)<br>*6.3 (Auto EV)<br>*6.37 (BLX)<br>*6.4 (BioHorizon, Conelog, Bone Level, Osstem, NobelActive, Neodent GM)<br>*6.5 (Megapars)<br>*6.6 (Zimmer Esthetic) |                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                     |                                                                                                                                                                                      |                                                                                                                                                               |                          |                          |                                                                                                                                                                                                                   |                              |     |     |                              |     |                                                                                                                                                                                                                                                                           |                             |     |                                                                                                                                                                                                                                               |                               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|      |  |  |   |     |  |  |  |     |        |     |  |  |   |   |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Minimum Wall Thickness (mm)                                                                           | 0.4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | *6.0 (Auto EV, BioHorizon, Conelog, BLX, Bone Level, Osstem, Megapars, NobelActive, Neodent GM, Zimmer Esthetic)<br>*4.0 (Auto EV, BioHorizon, Conelog, BLX, Osstem, Megapars, NobelActive, Neodent GM, Zimmer Esthetic)<br>*4.3 (Bone Level)                             |                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                     |                                                                                                                                                                                      |                                                                                                                                                               |                          |                          |                                                                                                                                                                                                                   |                              |     |     |                              |     |                                                                                                                                                                                                                                                                           |                             |     |                                                                                                                                                                                                                                               |                                          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|  |   |     |  |  |  |     |        |     |  |  |   |   |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Minimum post height for single-unit restorations (length above the abutment collar / gingival height) | 4.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                 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|  |   |     |  |  |  |     |        |     |  |  |   |   |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| System                                                                                                | Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Minimum wall thickness (mm)                                                                                                                                                                                                                                               | Maximum angulation (°)                                  | Minimum gingival collar height (mm)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Maximum gingival collar height (mm) | Minimum gingival collar (°)                                                                                                                                                          | Maximum gingival collar (°)                                                                                                                                   | Minimum post height (mm) | Maximum post height (mm) |                                                                                                                                                                                                                   |                              |     |     |                              |     |                                                                                                                                                                                                                                                                           |                             |     |                                                                                                                                                                                                                                               |                                          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|  |   |     |  |  |  |     |        |     |  |  |   |   |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| AR                                                                                                    | Holder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         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|  |   |     |  |  |  |     |        |     |  |  |   |   |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| AO                                                                                                    | Holder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         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|  |   |     |  |  |  |     |        |     |  |  |   |   |  |  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| MN                                                                                                    | Holder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         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| BD                                                                                                    | Holder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         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| AOO                                                                                                   | Holder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         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| AOE                                                                                                   | Holder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         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| Sterile                                                                                               | Non-sterile                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    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                          | Non-sterile                                             | Non-sterile                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                     |                                                                                                                                                                                      |                                                                                           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| Attributes              | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Primary Predicate Device            | Reference Device                                        | Reference Device |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|---------------------------------------------------------|------------------|
| Part Name               | Pre-Milled Blank                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Medentika Preface CAD/CAM Abutments | TiGEN Abutment; PMMA Abutment and Scan Healing Abutment | TruAbutment DS   |
| Substantial Equivalence | <p>The subject device, Pre-Milled Blank has similar indications for use and is made of the same material with no surface treatment, restoration, sterile compared to that of the predicated Medentika Preface CAD/CAM Abutments. The design limits are slightly different. The design limits are slightly different. The subject device design limits are within the diameter range and angle range of the predicate device. Therefore, the Pre-Milled Blank and Medentika Preface CAD/CAM Abutments are substantially equivalent devices.</p> <p>The maximum gingival height of TruAbutment DS of K241485 was 6. The minimum thickness of the Megagen TiGEN Abutment in K234142 was 0.3.</p> |                                     |                                                         |                  |



## Ti Base

| Attributes                        | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Primary Predicate Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                    |                           |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
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| Part Name                         | Ti Base                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Medentika TiBase CAD/CAM Abutments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                    |                           |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
| 510(K) No.                        | K241616                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | K150203                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                    |                           |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
| Applicant                         | ALLONUS Tech Co., Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Medentika GmbH                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                    |                           |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
| Trade Name                        | ALLONUS Tech Prosthetic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Medentika CAD/CAM Abutment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                    |                           |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
| Classification Name               | Endosseous Dental Implant Abutments (872.3630)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Endosseous Dental Implant Abutments (872.3630)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                    |                           |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
| Product Code                      | NHA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | NHA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                    |                           |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
| Material                          | Ti-6Al-4V ELI (ASTM F136)<br>Zirconia Oxide                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Ti-6Al-4V ELI (ASTM F136)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                    |                           |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
| Surface Treatment                 | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                    |                           |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
| Indications For Use/ Intended Use | ALLONUS Tech Prosthetic is intended for use with dental implants as a support for single or multiple-unit prosthetic restorations in the maxilla or mandible of partially or fully edentulous patient. It is including; cemented retained, screw-retained, or overdenture restorations.<br><br>It is compatible with the following systems: <ul style="list-style-type: none"><li>• Astra OsseoSpeed EV(K130999) 3.0</li><li>• Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm</li><li>• Tapered Internal Implants (K071638) (K143022) 3.4, 3.8, 4.6, 5.8 mm</li><li>• BioHorizons Laser-Lok Implant System (K093321) 3.0 mm</li><li>• Conelog Screw-Line (K113779) 3.3, 3.8, 4.3, 5.0 mm</li><li>• Osstem TSIII SA (K121995) 3.5 (3.7) , 4.0 (4.2) , 4.5 (4.6) , 5.0 (5.1), 6.0 (6.0), 7.0 (6.8) mm (Mini, Regular)</li><li>• Megagen AnyRidge Internal Implant System (K140091) 4.0, 4.4, 4.9, 5.4 (3.1)</li><li>• Neodent Implant System - GM Helix (K163194, K180536) 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)</li><li>• Nobel Active 3.0 (K102436) 3.0</li><li>• Nobel Active Internal Connection Implant (K071370) NP RP</li><li>• Nobelactive Wide Platform (Wp) (K133731) WP</li><li>• Straumann BLX Implant (K173961, K181703, K191256) 3.5, 3.75, 4.5, 5.5, 6.5 (RB, WB)</li><li>• Straumann 02.9 mm Bone Level Tapered Implants, SC CARES Abutments (K162890) 2.9 (SC)</li></ul> | Medentika TiBase CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. <table><tr><th>Implant System Compatibility</th><th>Series</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr><tr><td>Nobel Biocare Replace™ Select</td><td>E</td><td>3.5, 4.3, 5.0, 6.0</td><td>3.5, 4.3, 5.0, 6.0</td></tr><tr><td>Nobel Biocare NobelActive™</td><td>F</td><td>3.5, 4.3, 5.0</td><td>3.5, 3.9 (4.3), 3.9 (5.0)</td></tr><tr><td>Biomet 3i Osseotite® Certain®</td><td>H</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr><tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr><tr><td>Nobel Biocare Brånemark</td><td>K</td><td>3.3, 3.75, 4.0, 5.0</td><td>3.5, 4.1, 4.1, 5.1</td></tr><tr><td>Straumann Bone Level</td><td>L</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr><tr><td>Straumann Standard</td><td>N</td><td>3.3, 4.1, 4.8</td><td>3.5(NNC), 4.8, 6.5</td></tr><tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr><tr><td>Astra Tech OsseoSpeed™</td><td>S</td><td>3.5, 4.0, 4.5, 5.0</td><td>3.5, 4.0, 4.5, 5.0</td></tr><tr><td>Dentsply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr><tr><td>Dentsply Friadent® Ankylos®</td><td>Y</td><td>3.5, 4.5, 5.5, 7.0</td><td>3.5, 4.5, 5.5, 7.0</td></tr></table> | Implant System Compatibility                                                                                                                                                                                                       | Series                    | Implant Diameter (mm) | Platform Diameter (mm) | Nobel Biocare Replace™ Select | E | 3.5, 4.3, 5.0, 6.0 | 3.5, 4.3, 5.0, 6.0 | Nobel Biocare NobelActive™ | F | 3.5, 4.3, 5.0 | 3.5, 3.9 (4.3), 3.9 (5.0) | Biomet 3i Osseotite® Certain® | H | 3.25, 4.0, 5.0 | 3.4, 4.1, 5.0 | Biomet 3i Osseotite® | I | 3.25, 3.75, 4.0, 5.0 | 3.4, 4.1, 5.0 | Nobel Biocare Brånemark | K | 3.3, 3.75, 4.0, 5.0 | 3.5, 4.1, 4.1, 5.1 | Straumann Bone Level | L | 3.3, 4.1, 4.8 | 3.3, 4.1, 4.8 | Straumann Standard | N | 3.3, 4.1, 4.8 | 3.5(NNC), 4.8, 6.5 | Zimmer Tapered Screw-vent® | R | 3.3, 3.7, 4.1, 4.7, 6.0 | 3.5, 4.5, 5.7 | Astra Tech OsseoSpeed™ | S | 3.5, 4.0, 4.5, 5.0 | 3.5, 4.0, 4.5, 5.0 | Dentsply Friadent® Frialit/XiVE® | T | 3.4, 3.8, 4.5, 5.5 | 3.4, 3.8, 4.5, 5.5 | Dentsply Friadent® Ankylos® | Y | 3.5, 4.5, 5.5, 7.0 | 3.5, 4.5, 5.5, 7.0 |
|                                   | Implant System Compatibility                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Series                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Implant Diameter (mm)                                                                                                                                                                                                              | Platform Diameter (mm)    |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
|                                   | Nobel Biocare Replace™ Select                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | E                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3.5, 4.3, 5.0, 6.0                                                                                                                                                                                                                 | 3.5, 4.3, 5.0, 6.0        |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
|                                   | Nobel Biocare NobelActive™                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | F                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3.5, 4.3, 5.0                                                                                                                                                                                                                      | 3.5, 3.9 (4.3), 3.9 (5.0) |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
|                                   | Biomet 3i Osseotite® Certain®                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | H                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3.25, 4.0, 5.0                                                                                                                                                                                                                     | 3.4, 4.1, 5.0             |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
|                                   | Biomet 3i Osseotite®                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | I                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3.25, 3.75, 4.0, 5.0                                                                                                                                                                                                               | 3.4, 4.1, 5.0             |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
|                                   | Nobel Biocare Brånemark                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | K                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3.3, 3.75, 4.0, 5.0                                                                                                                                                                                                                | 3.5, 4.1, 4.1, 5.1        |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
|                                   | Straumann Bone Level                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | L                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3.3, 4.1, 4.8                                                                                                                                                                                                                      | 3.3, 4.1, 4.8             |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
|                                   | Straumann Standard                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | N                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3.3, 4.1, 4.8                                                                                                                                                                                                                      | 3.5(NNC), 4.8, 6.5        |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
|                                   | Zimmer Tapered Screw-vent®                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | R                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3.3, 3.7, 4.1, 4.7, 6.0                                                                                                                                                                                                            | 3.5, 4.5, 5.7             |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
|                                   | Astra Tech OsseoSpeed™                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | S                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3.5, 4.0, 4.5, 5.0                                                                                                                                                                                                                 | 3.5, 4.0, 4.5, 5.0        |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
|                                   | Dentsply Friadent® Frialit/XiVE®                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | T                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3.4, 3.8, 4.5, 5.5                                                                                                                                                                                                                 | 3.4, 3.8, 4.5, 5.5        |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
|                                   | Dentsply Friadent® Ankylos®                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3.5, 4.5, 5.5, 7.0                                                                                                                                                                                                                 | 3.5, 4.5, 5.5, 7.0        |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |
|                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Medentika TiBase is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center. |                           |                       |                        |                               |   |                    |                    |                            |   |               |                           |                               |   |                |               |                      |   |                      |               |                         |   |                     |                    |                      |   |               |               |                    |   |               |                    |                            |   |                         |               |                        |   |                    |                    |                                  |   |                    |                    |                             |   |                    |                    |

| Attributes                | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Primary Predicate Device                                                                                     |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Part Name                 | Ti Base                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Medentika TiBase CAD/CAM Abutments                                                                           |
|                           | <ul style="list-style-type: none"> <li>• Straumann® Bone Level Tapered Implants (K140878) 3.3, 4.1, 4.8 (NC, RC)</li> <li>• Zimmer 3.1mmD Dental Implant System (K142082) 3.1 (2.9)</li> <li>• Screw Vent® and Tapered Screw Vent® (K013227) 3.7(3.5), 4.7(4.5), 6.0(5.7)</li> </ul> <p>All digitally designed abutments and/or coping for use with the abutments are intended to be sent to a ALLONUS Tech-validated milling center for manufacture.</p>                                                                                            |                                                                                                              |
| Prosthesis Attachment     | Cement-retained, Screw-retained                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Cement-retained, Screw-retained                                                                              |
| Restoration               | Single-unit, Multi-unit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Single-unit, Multi-unit                                                                                      |
| Design Limits (Min.~Max.) | <ul style="list-style-type: none"> <li>- Post Angle (°): 0~15</li> <li>- Gingival Height (mm): 0.5~5.0</li> <li>- Post Height (mm): 4.0~6.0</li> <li>-Diameter (Ø, mm): 5.0~8.0</li> <li>-Thickness (mm): 0.4</li> </ul>                                                                                                                                                                                                                                                                                                                             | <ul style="list-style-type: none"> <li>- Post Angle (°): 0~30</li> <li>-Diameter (Ø, mm): 3.0~7.0</li> </ul> |
| Sterile                   | Non-sterile                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Non-sterile                                                                                                  |
| Substantial Equivalence   | <p>The Subject device, Ti Base has similar indications for use, design limits and is made of the same material with no surface treatment, restoration, sterile compared to that of the predicated Medentika TiBase CAD/CAM Abutments. The design limits are slightly different. The subject device design limits are within the diameter range and angle range of the predicate device. And that doesn't affect to intended use or function. Therefore, the Ti Base and Medentika TiBase CAD/CAM Abutments are substantially equivalent devices.</p> |                                                                                                              |

### Multi-Unit Abutment

| Attributes                        | Subject Device                                                                                                                                                                                                                   | Reference Device                                                                                                                                                                               |
|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Part Name                         | Multi-unit Straight Abutment<br>Multi-unit Angled Abutment                                                                                                                                                                       | Nobel Active Multi Unit Abutment                                                                                                                                                               |
| 510(K) No.                        | K241616                                                                                                                                                                                                                          | K072570                                                                                                                                                                                        |
| Applicant                         | ALLONUS Tech Co., Ltd.                                                                                                                                                                                                           | Nobel Biocare AB                                                                                                                                                                               |
| Trade Name                        | ALLONUS Tech Prosthetic                                                                                                                                                                                                          | NobelActive Multi Unit Abutment                                                                                                                                                                |
| Classification Name               | Endosseous Dental Implant Abutments(872.3630)                                                                                                                                                                                    | Endosseous Dental Implant Abutments(872.3630)                                                                                                                                                  |
| Product Code                      | NHA                                                                                                                                                                                                                              | NHA                                                                                                                                                                                            |
| Material                          | Ti-6Al-4V ELI (ASTM F136)                                                                                                                                                                                                        | Titanium vanadium alloy                                                                                                                                                                        |
| Indications For Use/ Intended Use | ALLONUS Tech Prosthetic is intended for use with dental implants as a support for single or multiple-unit prosthetic restorations in the maxilla or mandible of partially or fully edentulous patient. It is including; cemented | NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. |

| Attributes          | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Reference Device                 |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Part Name           | Multi-unit Straight Abutment<br>Multi-unit Angled Abutment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Nobel Active Multi Unit Abutment |
|                     | <p>retained, screw-retained, or overdenture restorations.</p> <p>It is compatible with the following systems:</p> <ul style="list-style-type: none"> <li>• Astra OsseoSpeed EV(K130999) 3.0</li> <li>• Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm</li> <li>• Tapered Internal Implants (K071638) (K143022) 3.4, 3.8, 4.6, 5.8 mm</li> <li>• BioHorizons Laser-Lok Implant System (K093321) 3.0 mm</li> <li>• Conelog Screw-Line (K113779) 3.3, 3.8, 4.3, 5.0 mm</li> <li>• Osstem TSIII SA (K121995) 3.5 (3.7) , 4.0 (4.2) , 4.5 (4.6) , 5.0 (5.1), 6.0 (6.0), 7.0 (6.8) mm (Mini, Regular)</li> <li>• Megagen AnyRidge Internal Implant System (K140091) 4.0, 4.4, 4.9, 5.4 (3.1)</li> <li>• Neodent Implant System - GM Helix (K163194, K180536) 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)</li> <li>• Nobel Active 3.0 (K102436) 3.0</li> <li>• Nobel Active Internal Connection Implant (K071370) NP RP</li> <li>• Nobelactive Wide Platform (Wp) (K133731) WP</li> <li>• Straumann BLX Implant (K173961, K181703, K191256) 3.5, 3.75, 4.5, 5.5, 6.5 (RB, WB)</li> <li>• Straumann 02.9 mm Bone Level Tapered Implants, SC CARES Abutments (K162890) 2.9 (SC)</li> <li>• Straumann® Bone Level Tapered Implants (K140878) 3.3, 4.1, 4.8 (NC, RC)</li> <li>• Zimmer 3.1mmD Dental Implant System (K142082) 3.1 (2.9)</li> </ul> <p>All digitally designed abutments and/or coping for use with the abutments are intended to be sent to a ALLONUS Tech-validated milling center for manufacture.</p> |                                  |
| Diameter(mm)        | 4.8                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 4.8                              |
| Gingival Height(mm) | 1, 2, 3, 4, 5, 6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 1.5, 2.5, 3.5, 4.5               |
| Angle(°)            | 0, 17, 29                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 0, 17, 30                        |
| Sterile             | Non-sterile                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Non-sterile                      |

| Attributes              | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Reference Device                 |
|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Part Name               | Multi-unit Straight Abutment<br>Multi-unit Angled Abutment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Nobel Active Multi Unit Abutment |
| Substantial Equivalence | The subject device, Multi-Unit Straight Abutment, Multi-Unit Angled Abutment has similar indications for use and is made of same titanium alloy with no surface treatment, is supplied non-sterile compared to that of Nobel Active Multi Unit Abutment. The subject device's diameter is slightly big, gingival height is slightly different, angles are within the predicate device's range. And that doesn't affect to intended use or function. Therefore, the Multi-Unit Straight Abutment, Multi-Unit Angled Abutment, and Nobel Active Multi Unit Abutment are substantially equivalent devices. |                                  |

### Multi-Unit Healing Cap

| Attributes                        | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Reference Device                              |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Part Name                         | Multi-Unit Healing Cap                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Healing Cap Multi-unit Titanium               |
| 510(K) No.                        | K241616                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | K171142                                       |
| Applicant                         | ALLONUS Tech Co., Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Nobel Biocare AB                              |
| Trade Name                        | ALLONUS Tech Prosthetic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Healing Cap Multi-Unit Titanium               |
| Classification Name               | Endosseous Dental Implant Abutments(872.3630)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Endosseous Dental Implant Abutments(872.3630) |
| Product Code                      | NHA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | NHA                                           |
| Material                          | Ti-6Al-4V ELI (ASTM F136)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Ti-6Al-4V ELI (ASTM F136)                     |
| Indications For Use/ Intended Use | <p>ALLONUS Tech Prosthetic is intended for use with dental implants as a support for single or multiple-unit prosthetic restorations in the maxilla or mandible of partially or fully edentulous patient. It is including; cemented retained, screw-retained, or overdenture restorations.</p> <p>It is compatible with the following systems:</p> <ul style="list-style-type: none"> <li>• Astra OsseoSpeed EV(K130999) 3.0</li> <li>• Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm</li> <li>• Tapered Internal Implants (K071638) (K143022) 3.4, 3.8, 4.6, 5.8 mm</li> <li>• BioHorizons Laser-Lok Implant System (K093321) 3.0 mm</li> <li>• Conelog Screw-Line (K113779) 3.3, 3.8, 4.3, 5.0 mm</li> <li>• Osstem TSIII SA (K121995) 3.5 (3.7) , 4.0 (4.2) , 4.5 (4.6) , 5.0 (5.1), 6.0 (6.0), 7.0 (6.8) mm (Mini, Regular)</li> <li>• Megagen AnyRidge Internal Implant System (K140091) 4.0, 4.4, 4.9, 5.4 (3.1)</li> <li>• Neodent Implant System - GM Helix (K163194, K180536) 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)</li> </ul> |                                               |
|                                   | <p>The Healing Cap Multi-unit Titanium is a premanufactured prosthetic component to be directly connected to the dental abutment during soft tissue healing to protect the internal connection of the abutments and prepare the soft tissue for the prosthetic procedure. Maximum intra-oral use is 180-days.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                               |

| Attributes              | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Reference Device                |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Part Name               | Multi-Unit Healing Cap                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Healing Cap Multi-unit Titanium |
|                         | <ul style="list-style-type: none"> <li>• Nobel Active 3.0 (K102436) 3.0</li> <li>• Nobel Active Internal Connection Implant (K071370) NP RP</li> <li>• Nobelactive Wide Platform (Wp) (K133731) WP</li> <li>• Straumann BLX Implant (K173961, K181703, K191256) 3.5, 3.75, 4.5, 5.5, 6.5 (RB, WB)</li> <li>• Straumann 02.9 mm Bone Level Tapered Implants, SC CARES Abutments (K162890) 2.9 (SC)</li> <li>• Straumann® Bone Level Tapered Implants (K140878) 3.3, 4.1, 4.8 (NC, RC)</li> <li>• Zimmer 3.1mmD Dental Implant System (K142082) 3.1 (2.9)</li> </ul> <p>All digitally designed abutments and/or coping for use with the abutments are intended to be sent to a ALLONUS Tech-validated milling center for manufacture.</p> |                                 |
| Diameter(mm)            | 5.1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 4.8                             |
| Length(mm)              | 12                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 12                              |
| Substantial Equivalence | <p>The subject device, Multi-Unit Healing Cap has similar indications for use, same length, and is made of the same material, is supplied non-sterile compared to that of Healing Cap Multi-unit Titanium. The subject device's diameter is slightly big, and that doesn't affect to intended use or function. Therefore, the Multi-Unit Healing Cap and Healing Cap Multi-unit Titanium are substantially equivalent devices.</p>                                                                                                                                                                                                                                                                                                      |                                 |

### Multi-Unit Temporary Cylinder

| Attributes                        | Subject Device                                                                                                                    | Reference Device                                                                                                                                                    |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Part Name                         | Multi-Unit Temporary Cylinder                                                                                                     | Temporary Cylinder                                                                                                                                                  |
| 510(K) No.                        | K241616                                                                                                                           | K123988                                                                                                                                                             |
| Applicant                         | ALLONUS Tech Co., Ltd.                                                                                                            | MegaGen Implant Co., Ltd.                                                                                                                                           |
| Trade Name                        | ALLONUS Tech Prosthetic                                                                                                           | Anyone™ Internal Implant System                                                                                                                                     |
| Classification Name               | Endosseous Dental Implant Abutments(872.3630)                                                                                     | Endosseous Dental Implant Abutments(872.3630)                                                                                                                       |
| Product Code                      | NHA                                                                                                                               | NHA                                                                                                                                                                 |
| Material                          | Ti-6Al-4V ELI (ASTM F136)                                                                                                         | Ti-6Al-4V ELI (ASTM F136)                                                                                                                                           |
| Indications For Use/ Intended Use | ALLONUS Tech Prosthetic is intended for use with dental implants as a support for single or multiple-unit prosthetic restorations | The AnyOne™ Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for |

| Attributes              | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Reference Device                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Part Name               | Multi-Unit Temporary Cylinder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Temporary Cylinder                                                                                                                                                                                                                                                                                                                                                                                                       |
|                         | <p>in the maxilla or mandible of partially or fully edentulous patient. It is including; cemented retained, screw-retained, or overdenture restorations.</p> <p>It is compatible with the following systems:</p> <ul style="list-style-type: none"> <li>• Astra OsseoSpeed EV(K130999) 3.0</li> <li>• Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm</li> <li>• Tapered Internal Implants (K071638) (K143022) 3.4, 3.8, 4.6, 5.8 mm</li> <li>• BioHorizons Laser-Lok Implant System (K093321) 3.0 mm</li> <li>• Conelog Screw-Line (K113779) 3.3, 3.8, 4.3, 5.0 mm</li> <li>• Osstem TSIII SA (K121995) 3.5 (3.7) , 4.0 (4.2) , 4.5 (4.6) , 5.0 (5.1), 6.0 (6.0), 7.0 (6.8) mm (Mini, Regular)</li> <li>• Megagen AnyRidge Internal Implant System (K140091) 4.0, 4.4, 4.9, 5.4 (3.1)</li> <li>• Neodent Implant System - GM Helix (K163194, K180536) 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)</li> <li>• Nobel Active 3.0 (K102436) 3.0</li> <li>• Nobel Active Internal Connection Implant (K071370) NP RP</li> <li>• Nobelactive Wide Platform (Wp) (K133731) WP</li> <li>• Straumann BLX Implant (K173961, K181703, K191256) 3.5, 3.75, 4.5, 5.5, 6.5 (RB, WB)</li> <li>• Straumann 02.9 mm Bone Level Tapered Implants, SC CARES Abutments (K162890) 2.9 (SC)</li> <li>• Straumann® Bone Level Tapered Implants (K140878) 3.3, 4.1, 4.8 (NC, RC)</li> <li>• Zimmer 3.1mmD Dental Implant System (K142082) 3.1 (2.9)</li> </ul> <p>All digitally designed abutments and/or coping for use with the abutments are intended to be sent to a ALLONUS Tech-validated milling center for manufacture.</p> | <p>dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function.</p> <p>Smaller implants (less than 06.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.</p> |
| Diameter(mm)            | 5.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 4.8                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Length(mm)              | 12                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | -                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Substantial Equivalence | <p>The subject device, Multi-Unit Temporary Cylinder has similar indications for use, diameter and is made of the same material, is supplied non-sterile compared to that of Temporary Cylinder. The subject device's diameter is slightly big, and that doesn't affect to intended use or</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                          |

| Attributes | Subject Device                                                                                                      | Reference Device   |
|------------|---------------------------------------------------------------------------------------------------------------------|--------------------|
| Part Name  | Multi-Unit Temporary Cylinder                                                                                       | Temporary Cylinder |
|            | function. Therefore, the Multi-Unit Temporary Cylinder and Temporary Cylinder are substantially equivalent devices. |                    |

### Multi-Unit Ti-Cylinder

| Attributes                        | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Reference Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Part Name                         | Multi-Unit Ti-Cylinder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | EZ Post Cylinder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 510(K) No.                        | K241616                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | K123988                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Applicant                         | ALLONUS Tech Co., Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | MegaGen Implant Co., Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Trade Name                        | ALLONUS Tech Prosthetic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Anyone™ Internal Implant System                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Classification Name               | Endosseous Dental Implant Abutments(872.3630)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Endosseous Dental Implant Abutments(872.3630)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Product Code                      | NHA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | NHA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Material                          | Ti-6Al-4V ELI (ASTM F136)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Ti-6Al-4V ELI (ASTM F136)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Surface Treatment                 | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Indications For Use/ Intended Use | <p>ALLONUS Tech Prosthetic is intended for use with dental implants as a support for single or multiple-unit prosthetic restorations in the maxilla or mandible of partially or fully edentulous patient. It is including; cemented retained, screw-retained, or overdenture restorations.</p> <p>It is compatible with the following systems:</p> <ul style="list-style-type: none"> <li>• Astra OsseoSpeed EV(K130999) 3.0</li> <li>• Astra OsseoSpeed EV(K120414) 3.6, 4.2, 4.8, 5.4 mm</li> <li>• Tapered Internal Implants (K071638) (K143022) 3.4, 3.8, 4.6, 5.8 mm</li> <li>• BioHorizons Laser-Lok Implant System (K093321) 3.0 mm</li> <li>• Conelog Screw-Line (K113779) 3.3, 3.8, 4.3, 5.0 mm</li> <li>• Osstem TSIII SA (K121995) 3.5 (3.7) , 4.0 (4.2) , 4.5 (4.6) , 5.0 (5.1), 6.0 (6.0), 7.0 (6.8) mm (Mini, Regular)</li> <li>• Megagen AnyRidge Internal Implant System (K140091) 4.0, 4.4, 4.9, 5.4 (3.1)</li> <li>• Neodent Implant System - GM Helix (K163194, K180536) 3.5, 3.75, 4.0, 4.3, 5.0 (3.0) 6.0 (3.0)</li> <li>• Nobel Active 3.0 (K102436) 3.0</li> <li>• Nobel Active Internal Connection Implant (K071370) NP RP</li> <li>• Nobelactive Wide Platform (Wp) (K133731) WP</li> </ul> | <p>The AnyOne™ Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function.</p> <p>Smaller implants (less than 06.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.</p> |

| Attributes              | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Reference Device |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| Part Name               | Multi-Unit Ti-Cylinder                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | EZ Post Cylinder |
|                         | <ul style="list-style-type: none"> <li>• Straumann BLX Implant (K173961, K181703, K191256) 3.5, 3.75, 4.5, 5.5, 6.5 (RB, WB)</li> <li>• Straumann 02.9 mm Bone Level Tapered Implants, SC CARES Abutments (K162890) 2.9 (SC)</li> <li>• Straumann® Bone Level Tapered Implants (K140878) 3.3, 4.1, 4.8 (NC, RC)</li> <li>• Zimmer 3.1mmD Dental Implant System (K142082) 3.1 (2.9)</li> </ul> <p>All digitally designed abutments and/or coping for use with the abutments are intended to be sent to a ALLONUS Tech-validated milling center for manufacture.</p> |                  |
| Diameter(mm)            | 5.2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 5.0              |
| Substantial Equivalence | <p>The subject device, Multi-Unit Cylinder has similar indications for use, diameter and is made of the same material, is supplied non-sterile compared to that of EZ Post Cylinder. The subject device's diameter is slightly big, and that doesn't affect to intended use or function. Therefore, the Multi-Unit Cylinder and EZ Post Cylinder are substantially equivalent devices.</p>                                                                                                                                                                         |                  |

## 7) Performance Testing

The subject device was tested to evaluate its substantial equivalence according to the following standards.

The tests below were performed for the subject device:

- Fatigue Test according to ISO 14801:2016
- End-User Steam Sterilization Test according to ISO 17665-1:2006, 17665-2:2009 and ANSI/AAMI ST79:2010.
- Biocompatibility tests according to ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.

Non-clinical test data was used to evaluate the proposed device's substantial equivalence compared to the predicate device. The results of the above tests have met the criteria of the standard and demonstrated substantial equivalence with the reference devices.

Non-clinical testing was conducted in accordance with FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments," and it consisted of testing finished assembled implant/abutment systems of the worstcase scenario through fatigue testing.



Dimensional analysis and reverse engineering of the implant-to-abutment connection platform were performed, using the OEM implant body, OEM abutment, OEM abutment screw. The reverse

engineering included an assessment of maximum and minimum dimensions of critical design aspects and tolerances of the OEM implant body, OEM abutment, OEM abutment screw, along with cross-sectional images of the submission device and compatible implant body. The testing demonstrated implant to abutment compatibility and has established substantial equivalency of the proposed device with reference devices.

Clinical testing was not necessary to establish substantial equivalency of the proposed device.

#### **8) MR safety environment**

'Non-clinical worst-case MRI review was performed to evaluate the subject devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." *Journal of Testing and Evaluation* 4 9.2 (2019): 783-795). Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

The non-clinical testing results demonstrate that the subject devices are substantially equivalent to the predicate devices.'

#### **9) Conclusion**

The documentation submitted in this 510(k) demonstrates the ALLONUS Tech Prosthetic is substantially equivalent to the predicate devices.