Medentika GmbH
% Floyd Larson
President
PaxMed International, LLC
1925 Palomar Oaks Way
Suite 210
Carlsbad, California 92008

April 22, 2025

Re: K242542
Trade/Device Name: Medentika CAD/CAM Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: April 19, 2025
Received: April 21, 2025

Dear Floyd Larson:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

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

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

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

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

Sincerely,

Andrew I. Steen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K242542

Device Name

Medentika CAD/CAM Abutments

Indications for Use *(Describe)*

PreFace abutment, TI-Forms abutment, Titanium base 2nd generation, and Titanium base ASC Flex are intended for use with dental implants as a support for single or multiple tooth protheses in the maxilla or mandible of a partially or fully edentulous patient. Abutment-level prosthetic components (Multi-unit Titanium Base, Multi-unit Titanium Cap, MedentiBASE Titanium Base) are intended for use as a support for multi-unit screw-retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient.

All digitally designed abutments for use with PreFace abutment, TI-Forms abutment, Titanium base 2nd generation, Titanium base ASC Flex, Multi-unit Titanium Base, Multi-unit Titanium Cap, and MedentiBASE Titanium Base are intended to be sent to an FDA-registered Medentika validated milling center for manufacture or to be manufactured according to the digital dentistry workflow, which integrates multiple components: Scans from desktop and intra oral scanners, CAD and CAM software and milling machine with associated accessories.

Medentika abutments for the Nobel Biocare Nobel Active® 3.0 mm, Dentsply Sirona Astra Tech OsseoSpeed EV® 3.0 mm and TX® 3.0 mm, Straumann Bone Level 2.9 implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

Implant System Compatibility Series:

Series of the medical device	Manufacturer of the implant system	Compatible implant system	Implant Diameters (mm)	Platform Diameters (mm)
E-Series	Nobel Biocare	Replace™ Select	3.5, 4.3, 5.0, 6.0	3.5, 4.3, 5.0, 6.0
EV-Series	DENTSPLY Implants	ASTRA TECH OsseoSpeed® EV	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4
F-Series	Nobel Biocare	NobelActive®	3.0, 3.5, 4.3, 5.0, 5.5	3.0, NP 3.5, RP 4.3/5.0, WP 5.5
GM-Series	Neodent	Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM
H-Series	ZimVie	Certain / T3® Certain	3.25, 4.0, 5.0	3.4, 4.1, 5.0
I-Series	ZimVie	External Hex / T3® External Hex	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0
K-Series	Nobel Biocare	Brånemark System® NobelSpeedy®, Groovy®	3.3, 3.75, 4.0, 5.0	3.5, 4.1, 5.1
L-Series	Straumann	Bone Level	2.9, 3.3, 4.1, 4.8	SC, NC, RC
LX-Series	Straumann	BLX / BLC	3.3, 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB
MG-Series	Megagen	AnyRidge	3.5, 4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4	3.5
N-Series	Straumann	Tissue Level	3.3, 4.1, 4.8	NNC, RN, WN
OT-Series	OSSTEM Implant HiOssen Implant®	TS-System ET-System	3.5, 4.0, 4.5, 5.0, 6.0, 7.0 3.5, 4.0, 4.5, 5.0, 6.0, 7.0	Mini, Regular
R-Series	ZimVie	Tapered Screw-Vent®	3.3, 3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7
S-Series	Dentsply Implants	ASTRA TECH OsseoSpeed® TX	3.0, 3.5, 4.0, 4.5, 5.0	3.0, 3.5/4.0, 4.5/5.0
T-Series	Dentsply Implants	XiVE® S	3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5, 5.5
Y-Series	Dentsply Implants	Ankylos C/X	3.5, 4.5, 5.5, 6.5	2.53

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

Medentika® GmbH
Medentika CAD/CAM Abutments

April 22, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name	Medentika® GmbH Hammweg 8-10 76529 Huegelsheim, Germany Telephone +497229 69912-0
Official Contact	Tobias Ludwig, Head of Innovation and Prosthetic Solutions
Representative/Consultant	Floyd G. Larson, MS, MBA Kevin A. Thomas, PhD PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Medentika CAD/CAM Abutments
Common Names	Dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Secondary Product Code	PNP
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (OHT 1: Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B, Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K221301 DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices
K170838 Medentika CAD/CAM TiBases, Medentika GmbH
K223113 Medentika CAD/CAM TiBases, Medentika GmbH
K150203 Medentika CAD/CAM Abutments, Medentika GmbH
K191123 Multi-unit Abutments, Medentika GmbH
K180564 Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM TiBases, Medentika GmbH
K200100 Abutment Design, 3Shape A/S

K193352, AbutmentCAD, exocad GmbH

Reference Devices for new OEM Compatibilities
K123870 Xpeed® AnyRidge® Internal Implant System, MegaGen Implant Co., Ltd.
K140091 Xpeed AnyRidge Internal Implant System, MegaGen Implant Company, Limited
K163194 Neodent Implant System - GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A.
K162890 Straumann Ø2.9 mm Bone Level Tapered Implants, Institut Straumann AG
K173961 Straumann® BLX Implant System, Institut Straumann AG
K180536 Neodent Implant System - GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A.
K181703 Straumann® BLX Line Extension - Implants, SRAs and Anatomic Abutments, Institut Straumann AG
K201225 Neodent Implant System - GM Helix Implants 7.0, JJGC Indústria e Comércio de Materiais Dentários S.A.
K210855 Straumann BLX Implant System, Institut Straumann AG
K212533 BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants, Institut Straumann AG
K230108 Straumann® BLC and TLC Implants, Institut Straumann AG
K181703 Straumann BLX Line Extension (RB/WB), Institut Straumann AG
K110955 MegaGen AnyRidge Implant System, MegaGen Co., Ltd.

INDICATIONS FOR USE STATEMENT

PreFace abutment, TI-Forms abutment, Titanium base 2nd generation, and Titanium base ASC Flex are intended for use with dental implants as a support for single or multiple tooth protheses in the maxilla or mandible of a partially or fully edentulous patient. Abutment-level prosthetic components (Multi-unit Titanium Base, Multi-unit Titanium Cap, MedentiBASE Titanium Base) are intended for use as a support for multi-unit screw-retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient.

All digitally designed abutments for use with PreFace abutment, TI-Forms abutment, Titanium base 2nd generation, Titanium base ASC Flex, Multi-unit Titanium Base, Multi-unit Titanium Cap, and MedentiBASE Titanium Base are intended to be sent to an FDA-registered Medentika validated milling center for manufacture or to be manufactured according to the digital dentistry workflow, which integrates multiple components: Scans from desktop and intra oral scanners, CAD and CAM software and milling machine with associated accessories.

Medentika abutments for the Nobel Biocare Nobel Active® 3.0 mm, Dentsply Sirona Astra Tech OsseoSpeed EV® 3.0 mm and TX® 3.0 mm, Straumann Bone Level 2.9 implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

Implant System Compatibility Series

Series of the medical device	Manufacturer of the implant system	Compatible implant system	Implant Diameters (mm)	Platform Diameters (mm)
E-Series	Nobel Biocare	Replace™ Select	3.5, 4.3, 5.0, 6.0	3.5, 4.3, 5.0, 6.0
EV-Series	DENTSPLY Implants	ASTRA TECH OsseoSpeed® EV	3.0, 3.6, 4.2, 4.8, 5.4	3.0, 3.6, 4.2, 4.8, 5.4
F-Series	Nobel Biocare	NobelActive®	3.0, 3.5, 4.3, 5.0, 5.5	3.0, NP 3.5, RP 4.3/5.0, WP 5.5
GM-Series	Neodent	Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM
H-Series	ZimVie	Certain®/ T3® Certain	3.25, 4.0, 5.0	3.4, 4.1, 5.0
I-Series	ZimVie	External Hex/ T3® External Hex	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0
K-Series	Nobel Biocare	Brånemark System® NobelSpeedy®, Groovy®	3.3, 3.75, 4.0, 5.0	3.5, 4.1, 5.1
L-Series	Straumann	Bone Level	2.9, 3.3, 4.1, 4.8	SC, NC, RC

Series of the medical device	Manufacturer of the implant system	Compatible implant system	Implant Diameters (mm)	Platform Diameters (mm)
LX-Series	Straumann	BLX / BLC	3.3, 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB, WB
MG-Series	Megagen	AnyRidge	3.5, 4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4	3.5
N-Series	Straumann	Tissue Level	3.3, 4.1, 4.8	NNC, RN, WN
OT-Series	OSSTEM Implant HiOssen Implant®	TS-System ET-System	3.5, 4.0, 4.5, 5.0, 6.0, 7.0 3.5, 4.0, 4.5, 5.0, 6.0, 7.0	Mini, Regular
R-Series	ZimVie	Tapered Screw-Vent®	3.3, 3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7
S-Series	Dentsply Implants	ASTRA TECH OsseoSpeed® TX	3.0, 3.5, 4.0, 4.5, 5.0	3.0, 3.5/4.0, 4.5/5.0
T-Series	Dentsply Implants	XiVE® S	3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5, 5.5
Y-Series	Dentsply Implants	Ankylos C/X	3.5, 4.5, 5.5, 6.5	2.53

SUBJECT DEVICE DESCRIPTION

The principal purpose of this submission is to expand the options for the fabrication of patient-specific final abutments using Medentika CAD/CAM Abutments from a "validated milling center" to a digital dentistry workflow. The subject devices are to be manufactured via a digital dentistry workflow by using scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. The subject device abutments include Titanium Base abutments, Titanium base ASC Flex abutments, and PreFace and TI-Form (blanks) abutments, cleared under Product Code NHA in K150203, K170838, K191223, and K223113.

Additional purposes for this submission are

- to expand the Medentika CAD/CAM Abutment product line by adding new sizes of abutment designs previously cleared under Product Code NHA in K150203, K170838, K191123, and K223113, and
- to add new OEM compatibilities.

For subject device abutments that have been cleared previously under Product Code NHA, there are no changes to the abutment design, or implant compatibilities. All such part numbers have been cleared within previous submissions for manufacturing at a validated milling center. For these abutments, the sole purpose of this submission is to allow manufacturing via digital dentistry workflow.

The subject device Medentika CAD/CAM Abutments provide a range of prosthetic solutions for dental implant restoration. Medentika abutments are offered in a variety of connection types to enable compatibility with currently marketed dental implants. All abutments are provided non-sterile, and each abutment is supplied with the appropriate abutment screw (if applicable) for attachment to the corresponding implant.
All patient-specific custom abutment fabrication for Titanium base abutments, Titanium base ASC Flex abutments, PreFace and TI-Form is by prescription on the order of the clinician. Patient-specific abutments made from the subject device blanks (PreFace and TI-Forms) and all zirconia superstructures for use with the subject device Titanium base and Titanium base ASC Flex will be manufactured using a digital dentistry workflow by using scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

All subject device abutments are made of titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*, with the titanium base abutments including a zirconia superstructure. The materials specified in labeling for milling of superstructures are as follows:

Ivoclar Vivadent IPS e.max ZirCAD Prime, cleared under K152118
Ivoclar Vivadent IPS e.max ZirCAD Prime Esthetic, cleared under K152118
Amann Girrbach Zolid Bion, cleared under K171876
Amann Girrbach Zolid Gen-X, cleared under K171876
Institut Straumann AG n!ce Zirkonia HT, cleared under K222836.

The cement specified in labeling for bonding of superstructures is Multilink Hybrid Abutment Cement from Ivoclar Vivadent AG, cleared under K130436.

Titanium base abutments and Titanium base ASC Flex abutments are designed for retention of a CAD/CAM fabricated zirconia superstructure where the final two-piece abutment (base and cemented superstructure) is the finished device used for the prosthetic restoration. Each patient-specific superstructure is individually prescribed by the clinician.

Titanium base abutments, also identified as Titanium base 2nd Generation, were cleared in K150203 as TiBase Generation 2. (TiBase Generation 1 also was cleared in K150203.) The TiBase 2nd Generation design has a parallel walled coronal portion with a chimney height of 5.5 mm. It is provided in engaging and non-engaging versions with gingival heights ranging from 0.1 mm to 1.15 mm. The gingival height of the final abutment, which is the Titanium base abutment connected to the zirconia top half, is a minimum of 0.5 mm.

Titanium base ASC Flex is a titanium base abutment that permits an angled screw channel ("ASC") and allows for modification of the chimney height. It was developed for either a straight screw channel or to allow for moving the screw channel in an oral direction for esthetic purposes. It is manufactured with a chimney height of 6.5 mm, which can be modified to 5.5 mm, 4.5 mm or 3.5 mm. The design of the abutment was cleared in K223113.

Titanium base ASC Flex is provided in engaging and non-engaging versions with gingival heights ranging from 0.4 mm to 1.15 mm. The gingival height of the final abutment, which is the Titanium base ASC Flex connected to the zirconia top half, is a minimum of 0.5 mm. The engaging version is provided in two orientations. In Type SF, the screw channel is angled over the flat of the scanbody. Type SC is provided for implant systems that allow for only four or fewer positioning options between abutment and implant, with the screw channel angled over the corner of the scanbody. This ensures flexibility in aligning the screw channel in the desired direction.

Titanium base and Titanium base ASC Flex abutments, including the titanium alloy, were cleared with the Product Code NHA under K150203, K170838, and K223113. All designs are subject devices to be manufactured at a validated milling center or using a digital dentistry workflow.

The design parameters for the CAD/CAM zirconia superstructure to be used on Titanium base and Titanium base ASC Flex abutments are:

Minimum wall thickness – 0.5 mm
Minimum cementable post height (above the gingival collar) for single unit restorations – 4.0 mm
Maximum gingival margin height – 5.0 mm*
Minimum gingival margin height – 0.5 mm*
Maximum angulation of the final abutment - 30°

* Gingival margin height of superstructure is reduced by gingival margin height of Titanium base or Titanium Base ASC Flex.

PreFace and TI-Forms abutments (blanks) are to be used by a dental laboratory to fabricate a customized abutment made of titanium alloy. Each patient-specific superstructure is individually prescribed by the clinician.

PreFace abutments were cleared with the Product Code NHA under K150203, K170838, and K223113. TI-Forms abutments are similar in design to PreFace abutments but have an interface with the workpiece holder of Amann Girrbach milling machines. All designs are subject devices to be manufactured at a validated milling center or using a digital dentistry workflow. PreFace and TI-Forms abutments are provided in an engaging design and are made of titanium alloy (Ti-6Al-4V).

The design parameters for the PreFace and TI-Form abutments are:

Minimum wall thickness – 0.4 mm
Minimum cementable post height for single unit restorations – 4.0 mm
Maximum gingival margin height – 5.0 mm
Minimum gingival margin height – 0.5 mm
Maximum angulation of the final abutment – 30°

Prosthetic-level components are provided to be placed on previously cleared Medentika multi-unit abutments and MedentiBASE abutments. These prosthetic-level components are identical in design and material to components cleared in K191123 and K223113.

Each abutment is supplied with the appropriate abutment screw. The screws are designed to attach the abutment to the corresponding implant or the prosthesis to the abutment. For previously cleared compatibilities, the screws that were cleared in K150203, K170838, K191123, or K223113 for each compatibility are used.

While most of the abutment compatibilities with third party implants were cleared in previous submissions, this submission includes new compatibilities for the following implant/platforms: Neodent GM, Straumann Bone Level SC 2.9, Straumann BLX / BLC RB and WB, and MegaGen AnyRidge. For these new compatibilities, compatibility analysis reports and results of fatigue testing of worst-case constructs were provided.

The Medentika Digital Dentistry process uses 1) scan files from intraoral and desktop (laboratory) scanners such as 3Shape TRIOS4 Intraoral Scanner or 3Shape F8 Dental Lab Scanner, 2) CAD software, and 3) CAM software applicable to the milling machines with their associated tooling and accessories. These products are not subject devices of this submission.

Each restoration is custom designed using 3Shape Abutment Design (K200100) or Exocad AbutmentCAD (K193352) in order to meet the requirements of each patient. The Implant Library database is intended to ensure compliance with FDA-cleared design parameters for the subject device products in the use of 3Shape Abutment Design software and Exocad AbutmentCAD software. The software workflow has not been modified; design limitations have been put in place as shown in the documentation included in this submission.

The CAD designed outputs are imported into the existing CAM software such as Ivoclar PrograMill CAM, Hyperdent or vhf Dental CAM Application, and the respective designs in zirconia are nested and calculated with the selected milling strategy, imported into the milling machine to manufacture the outputs. The nesting of specific abutment component is automatically created in the validated CAM software, as the CAM software recognizes the existing output through the associated file. Milling machines include Versamill Ax200, Ivoclar Programill PM 7, vhf N4+, vhf R5, vhf S5 and vhf Z4, Amann Girrbach Motion 3, Amann Girrbach Matron.

PERFORMANCE DATA

Non-clinical data provided in this submission in support of substantial equivalence included:

- biocompatibility testing of final finished devices, including titanium alloy, zirconia, and cement, according to ISO 10993-1, ISO 10993-5, and ISO 10993-12;
- mechanical testing conducted according to ISO 14801 to demonstrate that the subject Medentika CAD/CAM Abutments, including titanium alloy, all specified zirconia superstructure materials, and cement, in combination with the compatible implants, have sufficient strength for the intended use;
- reverse engineering dimensional analysis for the OEM compatibilities that are new in this submission, analyzing OEM implant bodies, OEM abutments, and OEM abutment screws to demonstrate that the subject device abutments are compatible with the respective OEM implants;
- validation of CAD software to demonstrate that the maximum and minimum design parameters for the subject devices are locked into the design software and available libraries;
- validation of CAM software and milling machines to ensure the accuracy and reliability of the milling process, verified NC file imports, milling tools, materials, milling strategies and post-processing procedures;

- validation testing of CAM restriction zones to show avoidance of damage or modification of the connection geometry and locking of restriction zones from user editing in the CAM software, to address the potential risk of damage to the implant-abutment connection geometry during the milling of the patient-matched portions of the customized abutment.

Non-clinical data referenced from prior submissions in support of substantial equivalence included:

- referenced from K180564, non-clinical analysis and testing to evaluate the metallic subject devices and compatible dental implants in the MR environment;
- referenced from K170838, K223113 and K150203, moist heat sterilization for subject devices provided non-sterile to the end user, validated to a sterility assurance level of 10^{-6} by the overkill method according to ISO 17665-1 and ISO TR 17665-2;

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

Subject device abutments are substantially equivalent in intended use to the primary predicate device K221301 and reference devices K170838, K223113 and K150203. All are intended for use with endosseous dental implants to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. The IFUS for the subject device is substantially equivalent to that of the primary predicate device K221301 for manufacturing using a digital dentistry workflow. The digital dentistry workflow integrates multiple components, scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machines, and associated tooling and accessories. The IFUS for the subject device is substantially equivalent to that of the reference devices K170838, K223113 and K150203 for compatible OEM implants and manufacturing using a validated milling center.

The differences between the subject IFUS and primary predicate device K221301 do not raise different questions of substantial equivalence, as demonstrated by manufacturing software validation and workflow validation.

All subject device bases, blanks, prosthetic level devices, and screws that were cleared previously for manufacture of patient-specific abutments at a validated milling center (NHA) are identical in design, materials and technological characteristics to those of the reference devices K170838, K223113 and K150203. There are no changes to the abutment designs or implant compatibilities. The material of the abutments is Ti-6Al-4V ELI, identical to the material of the primary predicate device K221301 and reference devices K170838, K223113 and K150203. The material specified for superstructures is zirconia, equivalent to that used in the reference devices K170838, K223113 and K150203. The cement specified for bonding of superstructures is Multilink Hybrid Abutment Cement from Ivoclar Vivadent AG, cleared under K130436. The purpose of this submission is to allow manufacturing via digital dentistry workflow as well as to extend cleared designs to compatibilities that had been cleared previously for other components and to include new compatibilities.

The design of each subject device abutment that was not cleared previously under Product Code NHA is based on and is similar to that of previously cleared abutments for compatibilities other than that of the corresponding subject device abutment.

For TI-Forms Abutments, all designs are functionally equivalent to those of PreFace Abutments for the corresponding compatibilities. The only differences are in the design of the portion of the abutment that interfaces with the workpiece holder of the milling machine.

The implant/abutment interface is specific to each dental implant system. Except as noted, the subject device abutments have the same compatibilities as cleared in the reference devices K170838, K223113 and K150203.

The risks associated with the subject device abutment designs are mitigated by compatibility analysis and mechanical testing provided in submission. The mechanical testing data demonstrate that the subject device abutments in combination with the compatible implants have sufficient strength for their intended use.

Potential biocompatibility risk is mitigated by the fact the subject device titanium components in this submission are identical in formulation, processing, component interactions, and storage conditions to the Medentika

components previously cleared in K170838 and by the fact that biocompatibility testing has been performed on final finished devices.

The subject device abutments and abutment screws are provided non-sterile and are intended to be sterilized by the end-user using moist heat (steam) sterilization. This is the same sterilization method as used for the reference devices K170838, K223113 and K150203. Subject device abutments are packaged in the same packaging used for the reference devices K170838 and K223113.

Overall, the subject devices have the following similarities to the predicate devices:

- have the same intended use,
- use the same operating principles,
- incorporate the same basic designs,
- incorporate the same or very similar materials, and
- have similar packaging and are sterilized using the same materials and processes.

The basis for the belief of Medentika GmbH that the subject device is substantially equivalent to the predicate devices is summarized in the following Tables of Substantial Equivalence.

Table 1. Table of Substantial Equivalence – Indications for Use Statement

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td>Subject Device

K242542

Medentika CAD/CAM Abutments

Medentika GmbH</td><td>
PreFace abutment, TI-Forms abutment, Titanium base 2nd generation, and Titanium base ASC Flex are intended for use with dental implants as a support for single or multiple tooth protheses in the maxilla or mandible of a partially or fully edentulous patient. Abutment-level prosthetic components (Multi-unit Titanium Base, Multi-unit Titanium Cap, MedentiBASE Titanium Base) are intended for use as a support for multi-unit screw-retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient.

All digitally designed abutments for use with PreFace abutment, Ti-Forms abutment, Titanium base 2nd generation, Titanium base ASC Flex, Multi-unit Titanium Base, Multi-unit Titanium Cap, and MedentiBASE Titanium Base are intended to be sent to an FDA-registered Medentika validated milling center for manufacture or to be manufactured according to the digital dentistry workflow, which integrates multiple components: Scans from desktop and intra oral scanners, CAD and CAM software and milling machine with associated accessories.

Medentika abutments for the Nobel Biocare Nobel Active® 3.0 mm, Dentsply Sirona Astra Tech OsseoSpeed EV® 3.0 mm and TX® 3.0 mm, Straumann Bone Level 2.9 implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

Implant System Compatibility Series:
<table>
<tr><th>Series of the medical device</th><th>Manufacturer of the implant system</th><th>Compatible implant system</th><th>Implant Diameters (mm)</th><th>Platform Diameters (mm)</th></tr>
<tr><td>E-Series</td><td>Nobel Biocare</td><td>Replace™ Select</td><td>3.5, 4.3, 5.0, 6.0</td><td>3.5, 4.3, 5.0, 6.0</td></tr>
<tr><td>EV-Series</td><td>DENTSPLY Implants</td><td>ASTRA TECH OsseoSpeed® EV</td><td>3.0, 3.6, 4.2, 4.8, 5.4</td><td>3.0, 3.6, 4.2, 4.8, 5.4</td></tr>
<tr><td>F-Series</td><td>Nobel Biocare</td><td>NobelActive®</td><td>3.0, 3.5, 4.3, 5.0, 5.5</td><td>3.0, NP 3.5, RP 4.3/5.0, WP 5.5</td></tr>
<tr><td>GM-Series</td><td>Neodent</td><td>Grand Morse</td><td>3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0</td><td>GM</td></tr>
<tr><td>H-Series</td><td>ZimVie</td><td>Certain / T3® Certain</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>I-Series</td><td>ZimVie</td><td>External Hex / T3® External Hex</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>K-Series</td><td>Nobel Biocare</td><td>Brånemark System® NobelSpeedy®, Groovy®</td><td>3.3, 3.75, 4.0, 5.0</td><td>3.5, 4.1, 5.1</td></tr>
<tr><td>L-Series</td><td>Straumann</td><td>Bone Level</td><td>2.9, 3.3, 4.1, 4.8</td><td>SC, NC, RC</td></tr>
<tr><td>LX-Series</td><td>Straumann</td><td>BLX / BLC</td><td>3.3, 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5</td><td>RB, WB</td></tr>
<tr><td>MG-Series</td><td>Megagen</td><td>AnyRidge</td><td>3.5, 4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4</td><td>3.5</td></tr>
<tr><td>N-Series</td><td>Straumann</td><td>Tissue Level</td><td>3.3, 4.1, 4.8</td><td>NNC, RN, WN</td></tr>
<tr><td>OT-Series</td><td>OSSTEM Implant
HiOssen Implant®</td><td>TS-System
ET-System</td><td>3.5, 4.0, 4.5, 5.0, 6.0, 7.0
3.5, 4.0, 4.5, 5.0, 6.0, 7.0</td><td>Mini, Regular</td></tr>
<tr><td>R-Series</td><td>ZimVie</td><td>Tapered Screw-Vent®</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td>S-Series</td><td>Dentsply Implants</td><td>ASTRA TECH OsseoSpeed® TX</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>T-Series</td><td>Dentsply Implants</td><td>XiVE® S</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
<tr><td>Y-Series</td><td>Dentsply Implants</td><td>Ankylos C/X</td><td>3.5, 4.5, 5.5, 6.5</td><td>2.53</td></tr>
</table>
</td></tr>
</table>

	Indications for Use Statement
Primary Predicate Device K221301 DESS Dental Smart Solutions Terrats Medical SL	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with DESS Bases or Pre-milled Blanks are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories.

Compatible Implant Systems

Implant System Compatibility	Implant Diameter (mm)	Implant Platform Name
Ankylos C/X	3.5, 4.5, 5.5	3.5, 4.5, 5.5
Astra Tech EV	3.0	3.0
	3.6	3.6
	4.2	4.2
	4.8	4.8
	5.4	5.4
Astra Tech OsseoSpeed™	3.0	3.0
	3.5/4.0	3.5/4.0
	4.5/5.0	4.5/5.0
BioHorizons Internal	3.0, 3.4, 3.8	3.0
	3.8, 4.6	3.5
	4.6, 5.8	4.5
	5.8	5.7
Biomet 3i Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
Biomet 3i OSSEOTITE®	3.25	3.4
	3.75, 4.0	4.1
	5.0	5.0
Camlog	3.3	3.3
	3.8	3.8
	4.3	4.3
	5.0	5.0
Friadent XiVE®	3.4	3.4
	3.8	3.8
	4.5	4.5
	5.5	5.5
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)
NobelActive® NobelReplace/ NobelParallel Conical	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
	5.5	WP
NobelReplace® Trilobe	3.5	NP
	4.3	RP
	5.0	WP
	6.0	6.0
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
	5.0	WP
Osstem TS	3.5	Mini
	4.0, 4.5, 5.0, 6.0, 7.0	Regular
Straumann® BLX	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Straumann® Bone Level	3.3	NC
	4.1, 4.8	RC
Straumann® Tissue Level	3.3	NNC
	3.3, 4.1, 4.8	RN
	4.8	WN
Zimmer Screw-Vent® / Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td>Reference Device

K170838

Medentika CAD/CAM TiBases

Medentika GmbH</td><td>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>Dentsply® Implants/ASTRA TECH OsseoSpeed® EV</td><td>EV</td><td>3.6, 4.2, 4.8, 5.4</td><td>3.6, 4.2, 4.8, 5.4</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 Branemark</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 / Soft Tissue Level</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>
Medentika TiBase is intended for use with the Straumann® CARES® System.

All digitally designed copings and/or crowns are intended to be sent to Straumann for manufacture at a validated milling center.</td></tr>
</table>

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td>Reference Device

K223113

Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM TiBases, Medentika Multi-unit Abutments

(Portions relevant to current submission)

Medentika GmbH</td><td>
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. Medentika TiBase is intended for use with the Straumann® CARES® System. All digitally designed copings and/or crowns are intended to be sent to Straumann for manufacture at a validated milling center.

Medentika abutments for the Nobel Biocare Nobel Active® 3.0mm, Dentsply Sirona Astra Tech OsseoSpeed EV® 3.0mm and TX® 3.0mm implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

Implant System Compatibility Series
<table>
<tr><th>Medentika series of the medical device</th><th>Manufacturer of the implant system</th><th>Compatible implant system</th><th>Implant Diameters (mm)</th><th>Platform Diameters (mm)</th></tr>
<tr><td>EV-Series</td><td>DENTSPLY Implants</td><td>ASTRA TECH OsseoSpeed® EV</td><td>3.0</td><td>3.0</td></tr>
<tr><td>F-Series</td><td>Nobel Biocare</td><td>NobelActive® CC</td><td>3.0, 5.5</td><td>3.0, WP 5.5</td></tr>
<tr><td>OT-Series</td><td>OSSTEM Implant
HiOssen Implant®</td><td>TS-System
ET-System</td><td>3.5, 4.0, 4.5, 5.0, 6.0, 7.0
3.5, 4.0, 4.5, 5.0, 6.0, 7.0</td><td>Mini, Regular</td></tr>
<tr><td>S-Series</td><td>Dentsply Implants</td><td>ASTRA TECH OsseoSpeed® TX</td><td>3.0</td><td>3.0</td></tr>
</table>

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.

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. The final patient matched form is a MedentiCAD abutment.

Medentika abutments for the Dentsply Sirona Astra Tech OsseoSpeed EV 3.0mm and TX 3.0mm implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

Implant System Compatibility Series
<table>
<tr><th>Medentika series of the medical device</th><th>Manufacturer of the implant system</th><th>Compatible implant system</th><th>Implant Diameters (mm)</th><th>Platform Diameters (mm)</th></tr>
<tr><td>E-Series</td><td>Nobel Biocare</td><td>Replace™ Select</td><td>6.0</td><td>6.0</td></tr>
<tr><td>EV-Series</td><td>DENTSPLY Implants</td><td>ASTRA TECH OsseoSpeed® EV</td><td>3.0, 3.6, 4.2, 4.8, 5.4</td><td>3.0, 3.6, 4.2, 4.8, 5.4</td></tr>
<tr><td>F-Series</td><td>Nobel Biocare</td><td>NobelActive® CC</td><td>5.5</td><td>WP 5.5</td></tr>
<tr><td>OT-Series</td><td>OSSTEM Implant
HiOssen Implant®</td><td>TS-System
ET-System</td><td>3.5, 4.0, 4.5, 5.0, 6.0, 7.0
3.5, 4.0, 4.5, 5.0, 6.0, 7.0</td><td>Mini, Regular</td></tr>
</table>
</td></tr>
</table>

	Indications for Use Statement
Reference Device K150203 Medentika CAD/CAM Abutments Medentika GmbH	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.

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.

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.

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	3.0, 3.5, 4.3, 5.0	3.0, 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	3.0, 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.

Table 2. Table of Substantial Equivalence – Technological Characteristics

	Subject Device	Primary Predicate Device	Reference Devices			Equivalence
	K242542 **Medentika CAD/CAM Abutments** **Medentika GmbH**	**K221301** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K170838** **Medentika CAD/CAM TiBases** **Medentika GmbH**	**K223113** **Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM TiBases, Medentika Multi-unit Abutments (Relevant portions)** **Medentika GmbH**	**K150203** **Medentika CAD/CAM Abutments** **Medentika GmbH**	
Reason for Predicate / Reference Devices	Not applicable	Digital workflow	Titanium base abutment designs; materials; biocompatibility; sterilization; shelf life	Indications for Use Statement; Titanium base and PreFace abutment designs	Titanium base and PreFace abutment designs, fatigue test results	
Product Codes	NHA, PNP	NHA, PNP	NHA	NHA	NHA	Equivalent
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Equivalent
Subject Abutment Designs Included	Titanium base (2nd Generation), Titanium base ASC Flex PreFace (blank) TI-Forms (blank)	Titanium base, Premill (blank)	Titanium base 2nd Generation	Titanium base 2nd Generation, Titanium base ASC Flex, PreFace (blank)	Titanium base 2nd Generation, Titanium base 1st Generation, PreFace (blank)	Equivalent
Titanium base, Titanium base ASC Flex						
Prosthesis Attachment	Cement retained	Cement retained	Cement retained	Cement retained	Cement retained	Equivalent
Abutment material (Bases)	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Equivalent

	Subject Device	Primary Predicate Device	Reference Devices			Equivalence
	K242542 **Medentika CAD/CAM Abutments** **Medentika GmbH**	**K221301** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K170838** **Medentika CAD/CAM TiBases** **Medentika GmbH**	**K223113** **Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM TiBases, Medentika Multi-unit Abutments (Relevant portions)** **Medentika GmbH**	**K150203** **Medentika CAD/CAM Abutments** **Medentika GmbH**	
Superstructure/restoration material	Ivoclar Vivadent IPS e.max ZirCAD Prime (K152118) Ivoclar Vivadent IPS e.max ZirCAD Prime Esthetic (K152118) Amann Girrbach Zolid Bion (K171876) Amann Girrbach Zolid Gen-X (K171876) Institut Straumann AG n!ce Zirkonia HT (K222830)	VITA YZ ST and VITA YZ XT (K180703)	Ivoclar Vivadent IPS e.max CAD (K152118)	Zirconia (not specified)	Zirconia (not specified)	Equivalent
Compatible implant body diameter, mm	3.0 – 8.0	2.52 – 6.5	3.3 – 6.0	3.0 – 7.0	3.3 – 6.0	Equivalent. Addition of 8.0 mm diameter implant does not raise different questions of safety and effectiveness. Mechanical testing of worst-case implants in new compatible systems demonstrates equivalence.
Gingival height of Ti base, mm	0.1-1.15	(From catalog) 0.3 – 3.5	0.1-1.15	0.65-1.2	0.1-1.15	Equivalent
Cement	Multilink Hybrid Abutment Cement (K130436)	Multilink Hybrid Abutment Cement (K130436)	Multilink Hybrid Abutment Cement (K130436)	Multilink Hybrid Abutment Cement (K130436)	Multilink Hybrid Abutment Cement (K130436)	Equivalent
Superstructure minimum wall thickness	0.5	0.45	0.4, (0.9 for IPS e.max CAD)	0.5	0.4	Equivalent
Minimum cementable post height for single unit restorations, mm	4.0	4.0 – 4.7	4.0	4.0	4.0	Equivalent

	Subject Device	Primary Predicate Device	Reference Devices			Equivalence
	K242542 **Medentika CAD/CAM Abutments** **Medentika GmbH**	**K221301** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K170838** **Medentika CAD/CAM TiBases** **Medentika GmbH**	**K223113** **Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM TiBases, Medentika Multi-unit Abutments (Relevant portions)** **Medentika GmbH**	**K150203** **Medentika CAD/CAM Abutments** **Medentika GmbH**	
Superstructure maximum gingival height, mm	5	6.0	5	5	5	Equivalent
Gingival height of final abutment, mm	0.5 – 5.0	0.3 – 9.5	0.5 – 5.0	0.65 – 5.65	0.5 – 5.0	Equivalent
Superstructure maximum angulation	30°	Straight only	30°	30°	30°	Equivalent
CAD/CAM System	Digital dentistry workflow, Validated Milling Center	Digital dentistry workflow, Validated Milling Center	Straumann CARES System, Validated Milling Center	Straumann CARES System, Validated Milling Center	Straumann CARES System	Equivalent
Sterility	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user	Equivalent
Sterilization by end user	Moist heat	Moist heat	Moist heat	Moist heat	Moist heat	Equivalent
PreFace, TI-Forms						
Abutment Designs	Titanium Blank, Ø 11.5 and 11.8 mm	(From catalog) Titanium Blank, Ø 10 and 14 mm		Titanium Blank, Ø 11.5 and 16 mm	Titanium Blank, Ø 11.5 and 16 mm	Equivalent
Prosthesis Attachment	Cemented	Cemented		Cemented	Cemented	Equivalent
Compatible implant body diameter, mm	3.0 – 8.0	2.52 – 6.5		3.0 – 7.0	3.0 – 6.5 0	Equivalent. Addition of 8.0 mm diameter implant does not raise different questions of safety and effectiveness. Mechanical testing of worst-case implants in new compatible systems demonstrates equivalence.
Abutment Material	Ti-6Al-4V	Ti-6Al-4V		Ti-6Al-4V	Ti-6Al-4V	Equivalent
Patient-specific Abutment Design Limits						
Minimum wall thickness, mm	0.4	0.4, 0.45		0.4	0.4	Equivalent

	Subject Device	Primary Predicate Device	Reference Devices			Equivalence
	K242542 **Medentika CAD/CAM Abutments** **Medentika GmbH**	**K221301** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K170838** **Medentika CAD/CAM TiBases** **Medentika GmbH**	**K223113** **Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM TiBases, Medentika Multi-unit Abutments (Relevant portions)** **Medentika GmbH**	**K150203** **Medentika CAD/CAM Abutments** **Medentika GmbH**	
Maximum gingival height, mm	5.0	6.0		5.0	5.0	Equivalent
Minimum gingival height, mm	0.5	0.3		0.1	0.0	Equivalent
Minimum cementable post height for single unit restorations, mm	4.0	4.0		4.0	4.0	Equivalent
Maximum angulation	30°	Straight, 30°		30°	30°	Equivalent
Prosthetic Level Components						
Abutment Designs	Multi-unit Titanium Base Multi-unit Titanium Cap MedentiBASE Titanium Base			Multi-unit Titanium Base Multi-unit Titanium Cap MedentiBASE Titanium Base		Equivalent
Internal conical interface	43°, 60°			43°, 60°		Equivalent
Prosthetic diameter, mm	4.8			4.8		Equivalent
Height	4.5, 14.5			4.5, 14.5		Equivalent