December 23, 2025

MEDENTiKA GmbH
% Jennifer Jackson
Sr Dir, Regulatory & Quality NAM
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K253341
Trade/Device Name: Custom Abutment AS
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 30, 2025
Received: September 30, 2025

Dear Jennifer Jackson:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253341

Device Name
Custom Abutments AS

Indications for Use *(Describe)*
Medentika Custom Abutments AS (Angulated Screw Channel) 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. Medentika Custom Abutments AS are intended for use with the Straumann® CARES® System. All digitally designed Medentika Custom Abutments AS are intended to be manufactured at a Straumann® validated milling center. The final patient matched form is a Custom Abutment AS.
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, and Straumann Bone Level 2.9 implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

Implant System Compatibility Series (Series / Implant System / Implant diameter / Platform Diameters or Implant Connection):

Medentika Series of the medical device	**Manufacturer of the implant system**	**Compatible implant system**	**Implant Diameter (mm)**	**Platform Diameter (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® CC	3.0, 3.5, 4.3, 5.0, 5.5	3.0, 3.5, 4.3/5.0, 5.5
H-Series	ZimVie	Biomet 3i Certain® Internal Connection	3.25, 4.0, 5.0	3.4, 4.1, 5.0
I-Series	ZimVie	Biomet 3i External Hex	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0
K-Series	Nobel Biocare	Branemark 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
N-Series	Straumann	Tissue Level	3.3, 4.1, 4.8	NNC, RN, WN
OT-Series	OSSTEM Implants HiOssen Implants®	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

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 On behalf of: MEDENTiKA GmbH, Hammweg 8-10, 76549 Hügelsheim, Germany
Contact Person:	Jennifer M. Jackson, MS Director of Regulatory Affairs Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023
Prepared By:	Laura Bleyendaal Sr. Regulatory Affairs Specialist
Date of Submission:	December 17, 2025

Name of the Device

Trade Names:	Custom Abutments AS
Common Name:	Endosseous dental implant abutment
Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Device Classification:	II
Product Code(s):	NHA
Classification Panel:	Dental

Predicate Device(s)

Primary Predicate:

- K223113 – Medentika CAD/CAM Abutments
    - Custom Abutments Series E, EV, F, and OT with a straight screw channel

Reference Devices:

- K150203- Medentika CAD/CAM Abutments
    - Custom Abutments Series E, F, H, I, K, L, N, R, S and T with a straight screw channel
- K242542- Medentika CAD/CAM Abutments
    - Custom Abutment Series L (SC) with a straight screw channel
- K242542- Medentika CAD/CAM Abutments
    - TiBases CAD/CAM ASC Flex to support angulated screw channel feature and Abutment screws
- K223113- Medentika CAD/CAM Abutments
    - TiBases CAD/CAM ASC Flex to support angulated screw channel feature and Abutment screws
- K180564 – Medentika MRI Compatibility
    - To support MRI compatibility

Device Description

Medentika GmbH Custom Abutments

The Custom Abutments (previously named MedentiCAD and PreFace abutments) can be used in combination with cemented prosthetics, e.g., crowns and superstructures, to reconstruct the function and esthetics of lost teeth. The Custom Abutment is a one-piece abutment, which is a customized abutment that is digitally designed by the customer with Straumann® CARES® Visual and can be only milled and ordered from the Straumann validated milling center. The abutments have an implant-specific connection interface for the respective compatible implant. The previously cleared Custom Abutments feature a straight screw channel for the abutment screw which fixes the abutment to the respective implant. The purpose of this submission is to add Custom Abutments AS (Angulated Screw Channel) to the Medentika Custom Abutment Portfolio. The subject Medentika

K253341 Traditional 510(k) Submission

Custom Abutments AS

510(k) Summary

Custom Abutments AS can be designed and manufactured with an angled screw channel (as opposed to the predicate straight screw-channel), so that the screw-exit is located in a favorable position (away from the incisal/occlusal edge and tooth cusps) for esthetic and functional results. The screw channel can be angulated to allow screwdriver access at an angle up to 25°.

Each of the abutment to implant connection geometries (in terms of Series and implant diameter) currently exists for the existing marketed Medentika Custom Abutments (with straight screw channel). No new compatible implant is added, in terms of series, implant diameter, and implant platform diameter within this submission.

Indications for Use

Medentika Custom Abutments AS (Angulated Screw Channel) 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. Medentika Custom Abutments AS are intended for use with the Straumann® CARES® System. All digitally designed Medentika Custom Abutments AS are intended to be manufactured at a Straumann® validated milling center. The final patient matched form is a Custom Abutment AS.

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, and Straumann Bone Level 2.9 implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

Implant System Compatibility Series (Series / Implant System / Implant diameter / Platform Diameters or Implant Connection):

Medentika Series of the medical device	**Manufacturer of the implant system**	**Compatible implant system**	**Implant Diameter (mm)**	**Platform Diameter (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

Medentika Series of the medical device	Manufacturer of the implant system	Compatible implant system	Implant Diameter (mm)	Platform Diameter (mm)
F-Series	Nobel Biocare	NobelActive® CC	3.0, 3.5, 4.3, 5.0, 5.5	3.0, 3.5, 4.3/5.0, 5.5
H-Series	ZimVie	Biomet 3i Certain® Internal Connection	3.25, 4.0, 5.0	3.4, 4.1, 5.0
I-Series	ZimVie	Biomet 3i External Hex	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0
K-Series	Nobel Biocare	Branemark 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
N-Series	Straumann	Tissue Level	3.3, 4.1, 4.8	NNC, RN, WN
OT-Series	OSSTEM Implants HiOssen Implants®	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

Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in the following table:

Table.1 Substantial Equivalence – Indications for Use Statement.

<table>
<tr><th></th><th colspan="6">Indications for Use Statement</th></tr>
<tr><td>Subject Device

Medentika Custom Abutments AS

Medentika GmbH</td><td colspan="6">Medentika Custom Abutments AS (Angulated Screw Channel) 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. Medentika Custom Abutments AS are intended for use with the Straumann® CARES® System. All digitally designed Medentika Custom Abutments AS are intended to be manufactured at a Straumann® validated milling center. The final patient matched form is a Custom Abutment AS. 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, and Straumann Bone Level 2.9 implant bodies are indicated for maxillary lateral and mandibular central/lateral incisors only.

Implant System Compatibility Series (Series / Implant System / Implant diameter / Platform Diameters or Implant Connection):

<table>
<tr><th>Medentika Series of the medical device</th><th>Manufacturer of the implant system</th><th>Compatible implant system</th><th>Implant Diameter (mm)</th><th>Platform Diameter (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® CC</td><td>3.0, 3.5, 4.3, 5.0, 5.5</td><td>3.0, 3.5, 4.3/5.0, 5.5</td></tr>
<tr><td>H-Series</td><td>ZimVie</td><td>Biomet 3i Certain®
Internal Connection</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>Biomet 3i
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>Branemark 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>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 Implants

HiOssen Implants®</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>
</table>
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<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td>Primary Predicate Device

K223113

Medentika CAD/CAM Abutments

(Portions relevant to current submission)

Medentika GmbH</td><td>
Medentika Preface CAD/CAM Abutments 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.

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 (Series / Implant System / Implant diameter / Platform Diameters or Implant Connection):
<table>
<tr><th>Medentika Series of the medical device</th><th>Manufacturer of the implant system</th><th>Compatible implant system</th><th>Implant Diameter (mm)</th><th>Platform Diameter (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 Implants
HiOssen Implants</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 **K242542** **Medentika CAD/CAM Abutments** **Medentika GmbH**	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 Diameter (mm)**	**Platform Diameter (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	Biomet 3i Certain® Internal Connection	3.25, 4.0, 5.0	3.4, 4.1, 5.0
I-Series	ZimVie	Biomet 3i External Hex	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0
K-Series	Nobel Biocare	Branemark 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 Implants HiOssen Implants®	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

Table 2. Comparative Summary of Technological Characteristics.

Comparison	Medentika Custom Abutments AS	K223113 Medentika Preface CAD/CAM abutments	K242542 Medentika CAD/CAM Abutments (PreFace, TI-Forms)	K150203 Medentika Preface Abutments	K223113 Medentika CAD/CAM TiBases ASC Flex	K242542 Medentika CAD/CAM Abutments TiBases ASC Flex	Equivalence
FDA product code	NHA	NHA	NHA, PNP	NHA	NHA	NHA, PNP	Identical
Series	E, EV, F, H, I, K, L, N, OT, R, S, T	E, EV, F, OT	E, EV, F,GM, H, I, K, L, LX, MG, N, OT, R, S, T, Y	E, F, H, I, K, L, N, R, S, T	Titanium base EV, S, F, OT	Titanium base E, EV, F, H, I, K, L, N, R, S, T	Equivalent. No new series is added. No new compatible implant system is introduced, in terms of series, implant diameter and platform diameter with this submission.
Abutment Designs	Titanium blank Ø13 with pre-manufactured implant-interface Customized at validated milling center	Titanium blank Ø11.5 and 16mm with pre-manufactured implant-interface Customized at validated milling center	Titanium Blank, Ø 11.5 and 11.8 mm with pre-manufactured implant-interface Customized at validated milling center or to be manufactured according to the digital dentistry workflow	Titanium blank Ø11.5 and 16mm with pre-manufactured implant-interface Customized at validated milling center	Titanium base Angled Screw Channel (ASC) Flex	Titanium base Angled Screw Channel (ASC) Flex	Equivalent
Prosthesis Attachment	Cement retained	Cement retained	Cement retained	Cement retained	Cement retained	Cement retained	Equivalent
Compatible Implant Body Diameter (mm)	2.9 - 7.0	3.0-7.0	2.9 – 8.0	3.0-6.5	3.0-7.0	2.9 – 8.0	Equivalent
Abutment & Abutment Screw Materials	Ti6Al4V, medical grade 5, conforming to ASTM F136	Ti6Al4V, medical grade 5, conforming to ASTM F136	Ti6Al4V, medical grade 5, conforming to ASTM F136	Ti6Al4V, medical grade 5, conforming to ASTM F136	Ti6Al4V, medical grade 5, conforming to ASTM F136	Ti6Al4V, medical grade 5, conforming to ASTM F136	Equivalent
Sterilization	**Supplied non-sterile** Moist heat sterilized by end user	**Supplied non-sterile** Moist heat sterilized by end user	**Supplied non-sterile** Moist heat sterilized by end user	**Supplied non-sterile** Moist heat sterilized by end user	**Supplied non-sterile** Moist heat sterilized by end user	**Supplied non-sterile** Moist heat sterilized by end user	Identical
Usage- All components	**Single-patient, single-use**	**Single-patient, single-use**	**Single-patient, single-use**	**Single-patient, single-use**	**Single-patient, single-use**	**Single-patient, single-use**	Identical
Design Limits							
Minimum wall thickness to screw channel (mm)	0.5	0.4	0.4	0.4	Not applicable; Titanium base	Not applicable; Titanium base	Equivalent
Minimum gingival height in stock component (mm)	0.1 (for N series abutments for use with tissue level implant systems, gingival height is given by the implant design)	0.1-0.25	Not supplied in 510(k) summary	0.00-0.23	Not applicable; Titanium base	Not applicable; Titanium base	Equivalent Labeling includes specific warnings for gingival heights less than 0.5mm
Maximum gingival height (mm)	8.3	5	5	6	Not applicable; Titanium base	Not applicable; Titanium base	An engineering rationale supports the maximum gingival height.
Max angulation of abutment body to implant axis (degrees)	30°	30°	30°	30°	30°	30°	Equivalent

Comparison	Medentika Custom Abutments AS	K223113 Medentika Preface CAD/CAM abutments	K242542 Medentika CAD/CAM Abutments (PreFace, TI-Forms)	K150203 Medentika Preface Abutments	K223113 Medentika CAD/CAM TiBases ASC Flex	K242542 Medentika CAD/CAM Abutments TiBases ASC Flex	Equivalence
Minimum abutment post height (mm) (height above the abutment collar/gingival height) (for single unit restorations)	4.0	4.0	4.0	4.0	Not applicable; Titanium base	Not applicable; Titanium base	Equivalent
Max screw channel angulation	up to 25° from the implant axis	Straight	Straight	Straight	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.	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.	Equivalent
Design workflow	Computer aided design (CAD)	Computer aided design (CAD)	Computer aided design (CAD)	Computer aided design (CAD)	N/A; Titanium base	N/A; Titanium base	Equivalent
Manufacturing workflow	Milled at Straumann validated milling center	Milled at Straumann CARES validated milling center	Milled at an FDA registered Medentika validated milling center or at point-of-care	Milled at Straumann CARES validated milling center	N/A; Titanium base	N/A; Titanium base	Equivalent

Materials

Medentika Custom Abutments AS

The Custom abutment AS (Angulated Screw Channel) and abutment screws are manufactured from titanium alloy conforming to *ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.*

Performance data

Nonclinical testing data submitted, referenced or relied upon to demonstrate substantial equivalence in this 510(k) includes:

- Dynamic fatigue testing according to Root-form endosseous dental implants and endosseous dental abutments- class II special controls guidance document for industry and FDA staff and Guidance for industry and ISO 14801: 2016 Dentistry — implants — dynamic loading test for endosseous dental implant.
- Referenced from K223113, K242542, K150203 and K170838 (Medentika GmbH) was dimensional analysis and reverse engineering of the implant-to-abutment connection platform, including an assessment of maximum and minimum dimensions of critical design aspects, tolerances, and cross-sectional images of the submission device and compatible OEM implant body, OEM abutment, and OEM fixation screw.
- Referenced from K223113 and K242542 (Medentika GmbH) Medentika TiBases CAD/CAM ASC Flex was compared to support angulated screw channel feature.
- Referenced from K223113 (Medentika GmbH) was steam sterilization validations according to ISO 17665-1: Sterilization of health care products- Moist heat- Part 1: Development, validation and routine control of a sterilization process for medical devices and ISO/TS 17665-2: Sterilization of health care products- Moist heat- Part 2: Guidance on the application of ISO 17665-1.
- Referenced from K180564 (Medentika GmbH) was MR testing in accordance with ASTM F2052-15, ASTM F2213-06 (2011), ASTM F2182-11a and ASTM F2119-13.
- Referenced from K223113 (Medentika GmbH) was biocompatibility comparisons in accordance with ISO 10993-1, Biological evaluation report Custom Abutments Titanium,

which covers biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Conclusion

The data included in this submission demonstrates substantial equivalence to the predicate device listed above. Performance testing and comparison to previous clearances show that the subject devices are substantially equivalent.