May 7, 2026

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

Re: K260460
Trade/Device Name: Neodent Gold Hue Custom Abutments, Medentika Custom Abutments Gold Hue
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 11, 2026
Received: February 11, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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)*

K260460

Device Name

Neodent Gold Hue Custom Abutments

Indications for Use *(Describe)*

The Gold Hue Custom Abutment is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations. All abutments are only intended to be digitally designed and manufactured using specifics CAD/CAM software according to digital dentistry workflow. Gold Hue Custom Abutments are indicated for screw-retained single restorations or cemented-retained single or multiple restorations. All digitally designed abutments for use with the Gold Hue Custom Abutment are intended to be sent to Straumann for manufacturing at a validated milling center.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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."

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)*

K260460

Device Name

Medentika Custom Abutments Gold Hue

Indications for Use *(Describe)*

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

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PRAStaff@fda.hhs.gov

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K260460 510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052
Prepared By:	On behalf of: Institut Straumann AG, Peter Merian-Weg 12 Basal 4002 Switzerland Laura Bleyendaal Sr. Regulatory Affairs Specialist
Contact Person:	Jennifer M. Jackson, MS Director of Regulatory Affairs Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023
Date of Submission:	May 7, 2026

Name of the Device

Trade Names:	Neodent Gold Hue Custom Abutments, Medentika Custom Abutments Gold Hue
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:

- K250614 – Neodent Implant System – Custom Abutments
    - Custom Abutments AS (angulated screw channel) for NGM and HS and ASC screws

Reference Devices:

Neodent

- K233857 – Neodent Implant System – Custom Abutments
    - Custom Abutments AS for GM, Custom Abutments for NGM and HS
- K162848 – Straumann CARES Golden Ti/TiN Abutments
    - Custom Abutments with same titanium nitride coating via same process

Medentika

- K253341 – Medentika Custom Abutments Angulated Screw Channel (AS)
    - Custom Abutments AS Series E, EV, F, H, I, K, L, N, OT, R, S and T
- K223113 – Medentika Abutment System, Medentika CAD/CAM Abutments
    - Custom Abutments Series E, EV, F, and OT with a straight screw channel
- 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
- K162848 – Straumann CARES Golden Ti/TiN Abutments
    - Custom Abutments with same titanium nitride coating via same process

Device Description

The Neodent Gold Hue Custom Abutments, Medentika Custom Abutments Gold Hue can be used in combination with cemented prosthetics, e.g., crowns and superstructures, to reconstruct the function and esthetics of lost teeth. The Neodent Gold Hue Custom Abutments, Medentika Custom Abutments Gold Hue are one-piece abutments, which are customized abutments that are digitally designed and can only be milled and ordered from the Straumann validated milling center. The Neodent Gold Hue Custom Abutments, Medentika Custom Abutments Gold Hue have an implant-specific connection geometry for the respective compatible implant. The predicate devices are made from titanium

alloy (titanium 6-aluminum 4-vanadium) conforming to ASTM F136. The purpose of this submission is to add Neodent Gold Hue Custom Abutments, Medentika Custom Abutments Gold Hue. The subject Neodent Gold Hue Custom Abutments, Medentika Custom Abutments Gold Hue feature a titanium nitride (TiN) coating on the emergence profile and coronal aspect of the abutment. The TiN coating results in the abutment having a gold color. The TiN coating serves to produce a more natural looking restoration; the gold color makes the presence of the abutment less noticeable, particularly in patients with thin gingival tissue.

Indications for Use

Neodent Gold Hue Custom Abutments

The Gold Hue Custom Abutment is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations. All abutments are only intended to be digitally designed and manufactured using specifics CAD/CAM software according to digital dentistry workflow. Gold Hue Custom Abutments are indicated for screw-retained single restorations or cemented-retained single or multiple restorations. All digitally designed abutments for use with the Gold Hue Custom Abutment are intended to be sent to Straumann for manufacturing at a validated milling center.

Medentika Custom Abutments Gold Hue

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

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

Technological Characteristics

Neodent Comparison

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

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

	Indications for Use Statement
Subject Device **Neodent Custom Abutments Gold Hue**	The Gold Hue Custom Abutment is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations. All abutments are only intended to be digitally designed and manufactured using specifics CAD/CAM software according to digital dentistry workflow. Gold Hue Custom Abutments are indicated for screw-retained single restorations or cemented-retained single or multiple restorations. All digitally designed abutments for use with the Gold Hue Custom Abutment are intended to be sent to Straumann for manufacturing at a validated milling center.
Primary Predicate device **K250614 Neodent Implant System – Custom Abutments** **JJGC Indústria e Comércio de Materiais Dentários S.A.**	Custom Abutment AS: The Custom Abutment with Angled Screw Channel is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations. All abutments are only intended to be digitally designed and manufactured using specifics CAD/CAM software according to digital dentistry workflow. Custom Abutments with Angled Screw Channel are indicated for screw-retained single restorations or cemented-retained single or multiple restorations. All digitally designed abutments for use with the Custom Abutment Ti with Angled Screw Channel are intended to be sent to Straumann for manufacturing at a validated milling center.
Reference device **K233857 Neodent Implant System –**	The Custom Abutment Ti with Screw is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations. All abutments are only intended to be digitally designed and manufactured using specifics CAD/CAM software according to digital dentistry workflow. Custom Abutments Ti with Screw are indicated for screw-retained single restorations or cemented-retained single or multiple restorations. All digitally designed abutments for use with the Custom

	Indications for Use Statement
Custom Abutments **JJGC Indústria e Comércio de Materiais Dentários S.A.**	Abutment Ti with Screw are intended to be sent to Straumann for manufacturing at a validated milling center. The Custom Abutment with Angled Screw Channel is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations. All abutments are only intended to be digitally designed and manufactured using specifics CAD/CAM software according to digital dentistry workflow. Custom Abutments with Angled Screw Channel are indicated for screw-retained single restorations or cemented-retained single or multiple restorations. All digitally designed abutments for use with the Custom Abutment Ti with Angled Screw Channel are intended to be sent to Straumann for manufacturing at a validated milling center.
Reference device **K162848** **Straumann® CARES® Golden Ti/TiN Abutments** **Institut Straumann AG**	Straumann® CARES® Golden Ti/TiN Abutments Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges or overdentures. The Straumann CARES Golden Ti/TiN Abutments are indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration is cement-retained.

Table.2 Substantial Equivalence – Neodent Comparative Summary of Technological Characteristics.

Comparison	Neodent Gold Hue Custom Abutments	K250614 Neodent Implant System – Custom Abutments	K233857 Neodent Implant System – Custom Abutments	K162848 Straumann CARES Golden Ti/TiN Abutments	Equivalence
FDA product code	NHA	NHA	NHA	NHA	Identical
Implant-Abutment Connection	Grand Morse (GM) Narrow Grand Morse (NGM) Helix Short (HS)	NGM HS	GM NGM HS	CrossFit (NC, RC) SynOcta (NN, RN, WN)	Equivalent. No new compatible implant system is introduced with this submission.
Channel Solution	Straight and angulated	Angulated (NGM, HS)	Straight (GM, NGM, HS) Angulated (GM)	Straight	Equivalent. No new channel solution for a new implant abutment connection is introduced.
Abutment Designs	Titanium blank with pre-manufactured implant-interface Customized at validated milling center	Titanium blank with pre-manufactured implant-interface Customized at validated milling center	Titanium blank with pre-manufactured implant-interface Customized at validated milling center	Titanium blank with pre-manufactured implant-interface Customized at validated milling center	Equivalent
Prosthesis Attachment[1]	Cement retained	Cement retained	Cement retained	Cement retained	Equivalent
Abutment & Abutment Screw Materials	Ti6Al4V ELI, medical grade 5, conforming to ASTM F136 Titanium nitride coating on abutments	Ti6Al4V ELI, medical grade 5, conforming to ASTM F136	Ti6Al4V ELI, medical grade 5, conforming to ASTM F136	Commercially pure Titanium (grade 4) conforming to ISO 5832-2 Titanium nitride coating on abutments	Equivalent; the addition of a titanium nitride coating is supported by the predicate Straumann CARES Golden Ti/TiN Abutments as well as coating testing.
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	Identical
Usage- All components	**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)	0.4	0.4	0.4	Not specified in 510(k) summary	Equivalent
Gingival Height (mm)	Straight screw channel: GM: 0.6 - 8.6 mm NGM: 0.6 - 8.6 mm	Angulated screw channel NGM: 0.6 - 8.6mm	The maximum gingiva height that the blank allows milling to considering the 4mm	Not specified in 510(k) summary	Equivalent

[1] Note: The devices are indicated for screw-retained single restorations- however this application still requires cement. The “screw-retained” terminology refers to extra oral cementation of the prosthesis (designed with screw hole) to the abutment followed by intraoral fixation of the abutment/prosthesis construct to the implant with the abutment screw.

Comparison	Neodent Gold Hue Custom Abutments	K250614 Neodent Implant System – Custom Abutments	K233857 Neodent Implant System – Custom Abutments	K162848 Straumann CARES Golden Ti/TiN Abutments	Equivalence
	HS for use with tissue level implant system, gingival height is given by the implant design Angulated screw channel GM: 0.6 – 8.6 mm NGM: 0.6 - 8.6 mm HS: for use with tissue level implant system, gingival height is given by the implant design	HS: for use with tissue level implant system, gingival height is given by the implant design	minimum abutment post height is the following: Straight screw channel: GM: 0.6 - 8.6 mm NGM: 0.6 - 8.6 mm HS for use with tissue level implant system, gingival height is given by the implant design Angulated screw channel GM: 0.6 – 8.6 mm		
Max angulation of abutment body to implant axis (degrees)	30°	30°	30°	30°	Equivalent
Minimum abutment post height (mm) (height above the abutment collar/gingival height) (for single unit restorations)	4.0	4.0	4.0	Not specified in 510(k) summary	Equivalent
Max screw channel angulation	Straight Angulated up to 25° from the implant axis	Angulated up to 25° from the implant axis	Straight Angulated up to 25° from the implant axis	Straight	Equivalent
Design workflow	Computer aided design (CAD)	Computer aided design (CAD)	Computer aided design (CAD)	Computer aided design (CAD)	Equivalent
Manufacturing workflow	Milled at Straumann validated milling center	Milled at Straumann validated milling center	Milled at Straumann validated milling center	Milled at Straumann validated milling center	Equivalent

Medentika Comparison

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

Table 3. Table of Substantial Equivalence – Medentika Indications for Use Statement.

	Indications for Use Statement
Subject Device **Medentika Custom Abutments Gold Hue**	Medentika Custom Abutments Gold Hue 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 Gold Hue are intended for use with the Straumann® CARES® System. All digitally designed Medentika Custom Abutments Gold Hue are intended to be manufactured at a Straumann® validated milling center. The final patient matched form is a Custom Abutment Gold Hue. 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):

	Indications for Use Statement

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® ET System	TS 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

	Indications for Use Statement

Predicate Device

K223113

Medentika CAD/CAM Abutments

(Portions relevant to current submission)

Medentika GmbH

Medentika CAD/CAM Abutments

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):

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	6.0	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	5.5	WP 5.5
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

	Indications for Use Statement
Reference device **K162848** **Straumann® CARES® Golden Ti/TiN Abutments** **Institut Straumann AG**	Straumann® CARES® Golden Ti/TiN Abutments Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges or overdentures. The Straumann CARES Golden Ti/TiN Abutments are indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration is cement-retained.

Table 4. Medentika Comparative Summary of Technological Characteristics.

Comparison	**Medentika Custom Abutments Gold Hue**	**K253341 Medentika Custom Abutments AS**	**K223113 Medentika Preface CAD/CAM abutments**	**K242542 Medentika CAD/CAM Abutments (PreFace, TI-Forms)**	**K150203 Medentika Preface Abutments**	**K162848 Straumann CARES Golden Ti/TiN Abutments**	**Equivalence**
FDA product code	NHA	NHA	NHA	NHA, PNP	NHA	NHA	Identical
Series	E, EV, F, H, I, K, L, N, OT, R, S, T	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	CrossFit (NC, RC) SynOcta (NN, RN, WN)	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	Straight screw channel Titanium blank Ø11.5 and 16mm with pre-manufactured implant-interface Customized at validated milling center Angulated screw channel Titanium blank Ø13 with pre-manufactured implant-interface	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 blank with pre-manufactured implant-interface Customized at validated milling center	Equivalent

Comparison	Medentika Custom Abutments Gold Hue	K253341 Medentika Custom Abutments AS	K223113 Medentika Preface CAD/CAM abutments	K242542 Medentika CAD/CAM Abutments (PreFace, TI-Forms)	K150203 Medentika Preface Abutments	K162848 Straumann CARES Golden Ti/TiN Abutments	Equivalence
	Customized at validated milling center						
Prosthesis Attachment	Cement retained	Cement retained	Cement retained	Cement retained	Cement retained	Cement retained	Equivalent
Compatible Implant Body Diameter (mm)	2.9-7.0	2.9-7.0	3.0-7.0	2.9 – 8.0	3.0-6.5	3.3-4.8	Equivalent
Abutment & Abutment Screw Materials	Ti6Al4V ELI, medical grade 5, conforming to ASTM F136 Titanium nitride coating on abutments	Ti6Al4V ELI, medical grade 5, conforming to ASTM F136	Ti6Al4V ELI, medical grade 5, conforming to ASTM F136	Ti6Al4V ELI, medical grade 5, conforming to ASTM F136	Ti6Al4V ELI, medical grade 5, conforming to ASTM F136	Commercially pure Titanium (grade 4) conforming to ISO 5832-2 Titanium nitride coating on abutments	Equivalent; the addition of a titanium nitride coating is supported by the predicate Straumann CARES Golden Ti/TiN Abutments as well as coating testing.
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)	0.4 Straight screw channel 0.5 Angulated Screw channel	0.5	0.4	0.4	0.4	Not specified in 510(k) summary	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 (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 specified in 510(k) summary	Equivalent Labeling includes specific warnings for gingival heights less than 0.5mm
Maximum gingival height (mm)	8.3	8.3	5	5	6	Not specified in 510(k) summary	Equivalent

Comparison	Medentika Custom Abutments Gold Hue	K253341 Medentika Custom Abutments AS	K223113 Medentika Preface CAD/CAM abutments	K242542 Medentika CAD/CAM Abutments (PreFace, TI-Forms)	K150203 Medentika Preface Abutments	K162848 Straumann CARES Golden Ti/TiN Abutments	Equivalence
Max angulation of abutment body to implant axis (degrees)	30°	30°	30°	30°	30°	30°	Equivalent
Minimum abutment post height (mm) (height above the abutment collar/gingival height) (for single unit restorations)	4.0	4.0	4.0	4.0	4.0	Not specified in 510(k) summary	Equivalent
Max screw channel angulation	Straight Angulated up to 25° from the implant axis	up to 25° from the implant axis	Straight	Straight	Straight	Straight	Equivalent
Design workflow	Computer aided design (CAD)	Computer aided design (CAD)	Computer aided design (CAD)	Computer aided design (CAD)	Computer aided design (CAD)	Computer aided design (CAD)	Equivalent
Manufacturing workflow	Milled at Straumann validated milling center	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	Milled at Straumann validated milling center	Equivalent

Materials

The Neodent Gold Hue Custom Abutments, Medentika Custom Abutments Gold Hue are made of Titanium alloy (titanium 6-aluminum 4-vanadium) conforming to ASTM F136 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401). The emergence profile and coronal aspect of the Neodent Gold Hue Custom Abutments, Medentika Custom Abutments Gold Hue are titanium nitride coated.

Performance data

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

- The surface treatment evaluation has been performed in accordance with 'Section 11 of Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment'. The Titanium Nitride coating information such as chemical composition analysis, coating thickness, SEM imaging, surface roughness, scratch test data, static shear and tension testing was provided. Shear testing of the TiN coating was performed per ASTM F1044 Standard Test Method for Shear Testing of Calcium Phosphate and Metallic Coatings. Dynamic shear testing of the TiN coating was performed per ASTM F1160 Standard Test Method for Shear and Bending Fatigue of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/ Metallic Coatings.
- Referenced from K253341, K223113, K242542, K150203 (Medentika GmbH) and K233857, K163194, K223638, K220251 (JJGC) 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 (Medentika GmbH) and K250614 (JJGC) 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 K162848 (Institut Straumann AG) was titanium nitride coating process and supporting data (cytotoxicity, chemical characterization, coating composition, coating thickness, coating porosity, coating mean volume percent voids, coating surface roughness and coating wear against dental tips)

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.