February 19, 2025

Institut Straumann AG
% Jennifer Jackson
Sr. Director, Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K243478
Trade/Device Name: Straumann InLab Validated Workflow
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: November 5, 2024
Received: January 24, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243478

Device Name

Straumann InLab Validated Workflow

Indications for Use *(Describe)*

Patient-specific abutment restorations, milled from Pre-milled Abutment Blanks (PMABs), are indicated for single tooth replacement and multiple tooth restorations. They are directly connected to various endosseous dental implant systems using a basal screw. Patient-specific abutment restorations milled from Pre-milled Abutment Blanks are to be digitally designed and milled using the Straumann InLab Validated Workflow. The Straumann InLab Validated Workflow is indicated for the design and fabrication of single or multiple-unit implant-borne prosthetics for the restoration of partially or fully edentulous mandibles and maxillae. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners or Extra-Oral Scanners, CAD software, CAM software, pre-milled abutment blanks, milling machines and associated tooling and accessories.

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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Traditional 510(k) Submission

Straumann InLab Validated Workflow

510(k) Summary

10 510(k) Summary

10.1 Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of : Institut Straumann AG Peter-Merian-Weg 12 4052 Basel, Switzerland And : JJGC Indústria e Comércio de Materiais Dentários AS (dba Neodent) Av. Juscelino Kubitschek de Oliveira, 3291 Curitiba, Paraná, Brazil 81270-200
Contact Person:	Jennifer M. Jackson, MS Director of Regulatory Affairs and Quality Phone Number : +1-978-747-2509 Fax Number : +1-978-747-0023
Prepared By & Alternate Contact:	Olivier Russo Associate Director Regulatory Affairs Institut Straumann AG Phone number: +41 61 965 1260
Date of Submission:	February 19, 2025

10.2 Name of the Device

Trade Names:	Straumann InLab Validated Workflow
Common Name:	Straumann InLab Validated Workflow
Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Device Classification :	II
Product Code(s):	NHA
Secondary Product Code:	PNP
Classification Panel:	Dental, dental abutment design software for dental laboratory
Proprietary Name:	Straumann InLab Validated Workflow

10.3 Predicate Device(s)

Primary Predicate:

- *K171649 - Straumann® CARES M-Series CADCAM System*

Reference Devices:

- *K150899 - Straumann CARES Titanium Alloy (TAN) Abutment*
- *K180536 - Neodent Implant System – GM Line (GM Exact Titanium Block for Medentika Holder)*
- *K233857 - Neodent Implant System – Custom Abutments*
- *K231072 - Anthogyr Flexibase for Axiom BL*
- *K200586 - Straumann TLX Implant System*
- *K190040 - Straumann BLX Line Extension - New Abutments*
- *K151455 - 3SHAPE ABUTMENT DESIGNER™ SOFTWARE.*
- *K190662 - MRI Compatibility for Existing Straumann Dental Implant Systems*
- *K182620 - MRI Compatibility for Existing Neodent Implant System*

10.4 Device Description

The Straumann InLab Validated Workflow is similar to the primary predicate K171649. It employs optical impression files that document the topographical characteristics of teeth, traditional dental impressions, or stone models. The 3Shape CAD software then allows the design of the desired restorations.

The CAM software converts the digital restoration design into the tooling and tool path commands needed to fabricate the restoration. When choosing the Straumann Validated workflow, the user will only see the available and cleared components which were tested and demonstrated as part of the validated workflow. The milling command file is encrypted prior to transfer to the Roland DWX-42W Plus milling System; this encryption ensures that files generated using other CAD or CAM software cannot be used with the Straumann InLab Validated Workflow. The user will then load the milling command file into the Roland DWX-42W Plus milling System where it is decoded. The user loads the appropriate dental material blank and initiates the milling operation.

Traditional 510(k) Submission

Straumann InLab Validated Workflow

510(k) Summary

This premarket notification includes restorations (one-piece metal patient-specific abutment restorations) manufactured from various Pre-milled Abutment Blanks (PMABs) from the Straumann Group companies : Institut Straumann AG and Neodent PMABs.

The digital workflow using the Straumann InLab Validated Workflow includes the use of the following products:

Dental Scan of the patient's situation

The Straumann InLab Validated Workflow can accept files created by scanners that generate STL files which represent the patient's mouth situation using the following Intra-oral or Desktop scanners : 3Shape Trios 5, 3Shape Trios 3, Allied Star SIRIOS, Medit T500. The dental scanner takes optical impressions that document the topographical characteristics of teeth or master models. This includes the location and orientation of dental implants or abutments when a Scanbody is employed during scan.

CAD Software

Under the Straumann InLab Validated Workflow, 3Shape Abutment Designer CAD Software is used as dental CAD applications that allows the user to digitally design dental restorations, based on information that was acquired by a dental scanner. As a result of the design process and the indication and material dependent dimensional limits, a three-dimensional geometry is created that is linked to the selected milling blank. The use of the Straumann Group manufacturers provided digital device models assures the accuracy of the interfaces between the designed restoration and the abutment or implant being restored.

CAM Module

The CAM interface software converts the three-dimensional geometry into milling machine control data. The CAM software uses the digital restoration geometry information and the material selection to define the tools to be used, the paths the tools are to follow to re-create the digital geometry in physical form and the speed and feed rates of the mill and the tooling. The completed CAM file is encrypted prior to being output for transfer to the milling machine. This encryption ensures that files generated using other CAD or CAM software cannot be used with the Straumann InLab Validated

Workflow. This is a means of assuring that only the validated product configuration is used.

Milling System

The Roland DWX-42W Plus milling machine receives the CAM file from the CAM software. The user will load the CAM file into the Roland machine where it is decoded. The user mounts the appropriate dental material blank, tools and burs. The user will also employ the recommended cutting fluid that acts as a lubricant and coolant for the milling operation. Once the machine is fully configured, the user initiates the milling operation.

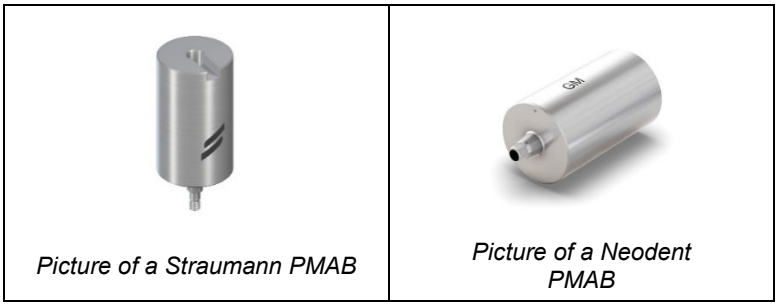
Abutment Milling Blanks

This submission also introduces a selection of milling blanks which are available for use with the Straumann InLab Validated Workflow. The materials and their design control limits are identified in Table 23.

Straumann Group Brand	Material	Minimum Post Height (mm)	Maximum Angulation	Minimum Wall Thickness (mm)	Gingiva Height (mm)	Abutment Diameter (mm)
Straumann PMABs	TAN (Ti-6Al-7Nb)	4.0	30˚	0.5	0.58 to 8.95	2.87 to 15.8
Neodent PMABs	Ti6Al4V-ELI - ASTM F136, Titanium Grade 5	4.0	30˚	0.5	0.6 to 8.6	2.52 to 15.8

Table 23 – Materials with design control limits for use under the Straumann InLab Validated Workflow

Note: The “Minimum Post Height” is the “length above the abutment collar / gingival height”.



Picture of a Straumann PMAB

Picture of a Neodent PMAB

Figure 16 – Example Images of Straumann Group's Available PMABs

10.5 Intended Use

The Straumann InLab Validated Workflow is intended for the design and manufacture of patient-specific dental restorations, for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement and screw retained restorations. Pre-milled Abutment Blanks are intended to be further processed by dental professionals with suitable expertise and milling systems to produce custom-made medical devices. Pre-milled Abutment Blank have a pre-fabricated connection that engages directly to the implant. The implant engaging part and screw-seat/channel of the Pre-Milled Abutment Blank is pre-manufactured and is not modified by the milling in the laboratory.

10.6 Indications for Use

Patient-specific abutment restorations, milled from Pre-milled Abutment Blanks (PMABs), are indicated for single tooth replacement and multiple tooth restorations. They are directly connected to various endosseous dental implant systems using a basal screw. Patient-specific abutment restorations milled from Pre-milled Abutment Blanks are to be digitally designed and milled using the Straumann InLab Validated Workflow. The Straumann InLab Validated Workflow is indicated for the design and fabrication of single or multiple-unit implant-borne prosthetics for the restoration of partially or fully edentulous mandibles and maxillae. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners or Extra-Oral Scanners, CAD software, CAM software, pre-milled abutment blanks, milling machines and associated tooling and accessories.

10.7 Technological Characteristics

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

Traditional 510(k) Submission

Straumann InLab Validated Workflow

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERNCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	**510(k) Number not yet know**	**K171649 - Straumann® CARES M-Series CADCAM System**	**K150899 - Straumann CARES Titanium Alloy (TAN) Abutment**	**K180536 - Neodent Implant System – GM Line (GM Exact Titanium Block for Medentika Holder)**	**K233857 - Neodent Implant System – Custom Abutments**
Indications for Use	Patient-specific abutment restorations, milled from Pre-milled Abutment Blanks (PMABs), are indicated for single tooth replacement and multiple tooth restorations. They are directly connected to various endosseous dental implant systems using a basal screw. Patient-specific abutment restorations milled from Pre-milled Abutment Blanks are to be digitally designed and milled using the Straumann InLab Validated Workflow. The Straumann InLab Validated Workflow is indicated for the design and fabrication of single or multiple-unit implant-borne prosthetics for the restoration of partially or fully edentulous mandibles and maxillae. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners or Extra-Oral Scanners, CAD software, CAM software, pre-milled abutment blanks, milling machines and associated tooling and accessories.	The Straumann CARES M-Series CAD/CAM System is indicated for the design and fabrication of single or multiple-unit implant-borne prosthetics for the restoration of partially or fully edentulous mandibles and maxillae. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners or Extra-Oral Scanners, CAD software, CAM software, restoration material blanks, milling machines and associated tooling and accessories. The system is used to design and fabricate CAD/CAM milled coping, crown and bridge restorations to be cemented onto Straumann® Variobase® Abutments, as well as milled abutments to be affixed to the endosseous dental implants of the Straumann® Dental Implant System using a basal screw.	The Straumann CARES® TAN abutments are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/ screw-retained.	The GM Exact Titanium Block for Medentika Holder is a titanium abutment used in fabricating a fully custom abutment, which is then placed onto Neodent dental implants to provide support for customized prosthetic restorations. The GM Exact Titanium Block for Medentika Holder abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. All digitally designed abutments for use with the GM Exact Titanium Block for Medentika Holder are intended to be sent to Straumann for manufacture at a validated milling center.	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 Abutment Ti with Screw are intended to be sent to Straumann for manufacturing at a validated milling center.
Source of Input Files	Intra-Oral Scanner Bench-top Scanners	Intra-Oral Scanner Bench-top Scanners	N/A	N/A	N/A
Bench Scanner Control	Yes	Yes	N/A	N/A	N/A
Implant Detection	Yes, using Scanbodies	Yes, using Scanbodies	N/A	N/A	N/A
Design Environment	3Shape Abutment Designer Software CAD Software: Closed CAD System facilitating the design of restorations used in conjunction with the devices of various Dental Implant Systems.	Straumann CARES Visual: Closed CAD System facilitating the design of restorations used in conjunction with the devices of the Straumann Dental Implant System (SDIS).	Straumann CARES Visual: Closed CAD System facilitating the design of restorations used in conjunction with the devices of the Straumann Dental Implant System (SDIS).	Straumann CARES Visual	Straumann CARES Visual
Restoration Types Supported	Device-borne: Solid Abutments for various Dental Implant Systems.	Device-borne: Copings and crowns for Variobase Abutments Copings, crowns, and bridges for Screw-Retained Abutments Bridges and bars for Variobase for Bridge/Bar Abutments Solid Abutments for Straumann Implants	Device-borne: Solid Abutments for Straumann Implants	Device-borne: Solid Abutments for Neodent Implants	Device-borne: Solid Abutments for Neodent dental implants having the Morse taper interface.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERNCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	**510(k) Number not yet know**	**K171649 - Straumann® CARES M-Series CADCAM System**	**K150899 - Straumann CARES Titanium Alloy (TAN) Abutment**	**K180536 - Neodent Implant System – GM Line (GM Exact Titanium Block for Medentika Holder)**	**K233857 - Neodent Implant System – Custom Abutments**
Compatible Implants	Straumann PMABs: • Straumann Tissue Level implants having the RN, WN, RT and WT implant-to-abutment interface geometries • Straumann Bone Level implants having the NC, RC, RB, WB implant-to-abutment interface geometries Neodent PMABs: • Neodent Implant having the GM and CM implant-to-abutment interface geometries.	Straumann Bone Level implants having the NC and RC implant-to-abutment interface geometries. Straumann Tissue Level implants having the NNC, RN, and WN, implant-to-abutment interface geometries.	Straumann Bone Level implants having the NC and RC implant-to-abutment interface geometries. Straumann Tissue Level implants having the RN, and WN, implant-to-abutment interface geometries	Neodent GM implants	Neodent GM implants Neodent NGM implants Neodent HS implants
Abutment Platform Diameters	3.3 - 7 mm	3.8 – 7.0 mm	3.8 – 7.0 mm	3.5 – 7 mm	3.5 – 4.5 mm
Abutment Material	Titanium alloy (Ti-6Al-7Nb, TAN) Ti6Al4V, medical grade 5, conforming ASTM F 136	Titanium alloy (Ti-6Al-7Nb, TAN)	Titanium alloy (Ti-6Al-7Nb, TAN)	Ti6Al4V, medical grade 5, conforming ASTM F 136	Ti6Al4V, medical grade 5, conforming ASTM F 136
Maximum Angulation	30° controlled in design software	30° controlled in design software	30° controlled in design software (Note : NC and RN Ø3.3 prosthetic platforms are not indicated for restorations requiring angulation correction)	30° controlled in design software	30° controlled in design software
Minimal wall thickness	**0.5mm**	0.4mm	0.4mm	0.4mm	0.4mm
Gingiva height	For Straumann RN, WN interface: n/a, tissue level implant system, GH is given by the implant design NC, RC interface: 0.87 – 8.87 mm NT, RT, WT interface: n/a, tissue level implant system, GH is given by the implant design RB/WB Interface: 0.95 – 8.95 mm WB Interface: 0.58 – 5.98 mm For Neodent NGM interface: 0.6 - 8.6 mm HS interface: n/a, tissue level implant system, GH is given by the implant design ** GM interface: 0.6 - 8.6 mm ***Helix Short (HS) Implant System, K223638, is a tissue level implant system*	Minimal Gingiva height 0.87mm Maximal Gingiva height 17.3 mm	No min/max Gingiva Height was defined as part of the submission	No min/max Gingiva Height was defined as part of the submission for the Titanium Block	NGM Customized abutment 0.6-5.8mm HS Customized abutment 0.2-5.4mm** GM Customized abutment 0.6-5.8mm GM Customized abutment with angled screw channel 0.6-5.6mm **Helix Short (HS) Implant System, K223638, is a tissue level implant system
Minimum Post Height	4 mm	N/A (not defined)	N/A (not defined)	N/A (not defined)	4 mm

Traditional 510(k) Submission

Straumann InLab Validated Workflow

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERNCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
K Number	**510(k) Number not yet know**	**K171649 - Straumann® CARES M-Series CADCAM System**	**K150899 - Straumann CARES Titanium Alloy (TAN) Abutment**	**K180536 - Neodent Implant System – GM Line (GM Exact Titanium Block for Medentika Holder)**	**K233857 - Neodent Implant System – Custom Abutments**
Abutment diameter range	For Straumann RN, WN interface: 5.13 – 15.8 mm NC, RC interface: 3.13 – 15.8 mm NT, RT, WT interface: 4.00 – 15.8 mm RB, WB Interface: 2.87 – 15.8 mm For Neodent NGM interface: 2.52 – 11.5 mm HS interface: 4.75 – 15.8 mm GM interface: 3.17 – 15.8 mm	No min/max abutment diameter was defined as part of the submission	No min/max abutment diameter was defined as part of the submission	Maximum body diameter is listed in the 510(k) summary 15.8mm	No min/max abutment diameter was defined as part of the submission
Restoration Sizes	Device-borne: One-piece patient-specific abutment restorations milled from PMAB Ø11.5 mm or Ø 16 mm.	Device-borne: Single crown up to 16-Unit Bridge	Device-borne: One-piece patient-specific abutment restorations milled from PMAB Ø11.5 mm or Ø 16 mm.	Device-borne: One-piece patient-specific abutment restorations milled from PMAB Ø11.5 mm or Ø 16 mm.	Device-borne: One-piece patient-specific abutment restorations milled from PMAB Ø11.5 mm or Ø 16 mm.
CAD to CAM Transfer	Seamless, same software interface	Seamless, same software interface	Seamless, same software interface	Seamless, same software interface	Seamless, same software interface
CAM Capability	Selection of tools, tool paths, speeds and feed rates that the mill uses to produce an accurate restoration. Encryption of milling file.	Nesting of multiple designs to maximize use of material disks. Selection of tools, tool paths, speeds and feed rates that the mill uses to produce an accurate restoration. Encryption of milling file.	Validated centralized milling center	Validated centralized milling center	Validated centralized milling center
CAM to Mill Transfer	The encrypted file format ensures that the milling equipment accepts files generated by the Straumann Validated workflow without allowing them to be altered.	Encrypted file format assures that the M-Series Mills can only accept files generated by the Straumann CARES Visual and CAM Module Software	Validated centralized milling center	Validated centralized milling center	Validated centralized milling center
Supported Milling System	Roland DWX-42W Plus milling System	Straumann CARES M-Series Mills	Validated centralized milling center	Validated centralized milling center	Validated centralized milling center
Fabrication Workflow	InLab Milling Workflow : Wet milling of Ti-6Al-7Nb and Titanium Grade 5 Pre-Milled Abutment Blanks	InLab Milling Workflow : Dry milling of partially crystallized ceramic blanks. Wet milling of Ti-6Al-7Nb Pre-Milled Abutment Blanks, Ivoclar IPS e.max CAD and n!ce Glass Ceramic using coolant.	Validated centralized milling center : Wet milling of Ti-6Al-7Nb Pre-Milled Abutment Blanks	Validated centralized milling center : Wet milling of Titanium Grade 5 Pre-Milled Abutment Blanks	Validated centralized milling center : Wet milling of Titanium Grade 5 Pre-Milled Abutment Blanks
Sterility	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.	Provided non-sterile – terminally sterilized via autoclave prior to implantation.

10.8 Performance Testing

10.8.1 Sterilization Validation and Shelf Life

The Pre-milled Abutment Blanks subject devices are provided non-sterile and need to be sterilized by moist heat (steam) after milling into the patient-specific shape by the end-user. The recommended sterilization method has been validated according to ISO 17665-1 and applicable recommendations in the FDA guidance document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015”. The sterilization methods and parameters are equivalent to the primary predicate and reference devices.

10.8.2 Biocompatibility Testing

Biological assessment has been performed according to ISO 10993-1 “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” and to the FDA Guidance document “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process’, Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016” for each of the subject devices.

The subject devices are equivalent in material and manufacturing processes to the primary predicate and reference devices, therefore, no new issues regarding biocompatibility were raised.

10.8.3 Electromagnetic Compatibility

There are no significant changes to the materials and dimensions from the currently marketed predicate devices. Therefore, no new issues of electromagnetic compatibility are raised for the subject devices, and they can be considered MR Conditional.

10.8.4 Performance Testing – Bench

<u>Dynamic Fatigue</u>

The device design and performance testing submitted or referenced in support of this premarket notification were conducted according to the FDA guidance document

"*Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*" and are representative of the design and performance of the subject devices.

Milling Accuracy

To mitigate the risk of inaccurate milling, a black-box validation confirming that the dimensions of the milled restoration are the same as the intended CAD design was performed. This test shows that the data sent from the CAD software to the CAM module, sent to the mill and then used to control the milling process results in accurately milled restorations that meet the design intent of the dental technician. The results of this report show that the accuracy requirement was met considering the tool's expected lifetime as specified by the Roland Milling Machine manufacturer.

Simulated Use Validation

A simulated use validation of the Straumann InLab Validated Workflow was conducted. The purpose of this validation is to confirm that the relevant pre-milled abutment blanks with Medentika Holder components, along with their respective design constraints and workflow restrictions, are correctly implemented (adequately written and locked into the compatible design software and available libraries) within the Straumann InLab Validated Workflow.

A simulated implant-abutment connection protection test was conducted to mitigate the potential risk of damaging the implant-abutment connection geometry during the milling of the patient-matched portions of the abutment blanks. This ensures that the safety and performance of the device are consistently maintained within the Straumann InLab Validated Workflow.

10.9 Conclusion

The conclusion drawn from the nonclinical tests submitted in this premarket notification demonstrates that the Straumann InLab Validated Workflow and submitted Pre-milled Abutment Blanks are substantially equivalent to the primary predicate and reference devices.