January 4, 2019

Institut Straumann AG
% Jennifer Jackson
Director, Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01801

Re: K180477
Trade/Device Name: Straumann PURE Ceramic Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: December 3, 2018
Received: December 4, 2018

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180477

Device Name
Straumann PURE Ceramic Implant System

Indications for Use *(Describe)*

Straumann PURE Ceramic Implant:
The Straumann PURE Ceramic Implant is indicated for the restoration of single-tooth gaps and in edentulous or partially edentulous jaws. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components.

Closure and healing caps:
Closure and Healing caps are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Closure and Healing caps should be used only with suitable implant connections. Do not use healing components for longer than 6 months.

Temporary Abutments:
The provisional components are intended to serve as a base for temporary crown or bridge restoration out of occlusion for the Straumann® PURE Ceramic Implant System. The Straumann® Temporary Abutment VITA CAD-Temp® for the Straumann® PURE Ceramic Implant is indicated for temporary usage of up to 180 days.

CI RD Straumann PUREbase Abutments:
CI RD Straumann PUREbase abutment is a titanium base placed onto Straumann ceramic dental implants to provide support for customized prosthetic restorations and is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase Abutment system are intended to be sent to Straumann for manufacture 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.

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5 510(k) Summary

5.1 Submitter

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

Phone Number: (978) 747-2509

Fax Number: (978) 747-0023

Contact Person: Jennifer M. Jackson, MS

Date of Submission: January 4, 2019

5.2 Device

Trade Name:	Straumann PURE Ceramic Implant System
Common Name:	Endosseous Dental Implant
	Endosseous Dental Implant Abutment
Classification Name:	21 CFR 872.3640
Regulatory Class:	II
Primary Product Code:	DZE
Secondary Product Code:	NHA

5.3 Predicate Device

Primary Predicate:	K171769 – Straumann PURE Ceramic Implants
Reference Devices:	K151328 – PURE Ceramic Implants
	K163043 – Zeramex P6 Dental Implant System
	K061277 – Straumann Computer Aided Restoration Services (CARES) Ceramic Coping
	K130808 – Straumann Healing Abutments, Healing Caps, and Closure Screws
	K122192 – Straumann Temporary Abutments VITA CAD-Temp

K142890 – Straumann Variobase Abutment NNC, Straumann Variobase Abutment RN, Straumann Variobase Abutment WN, Straumann Variobase Abutment NC, Straumann Variobase Abutment RC, IPS e.max CAD MO Coping, IPS e.max CAD LT Crown, IPS e.max CAD HT Crown, coron CoCr Single Unit

K170354 – Straumann Variobase Abutments

K170356 – Straumann Variobase Abutments

K173379 – Straumann Variobase for Crown AS

5.4 Device Description

The **Straumann PURE Ceramic Implant** is a dental implant made out of yttrium-stabilized zirconium dioxide (Y-TZP). The Straumann PURE Ceramic Implant is based on features of the Straumann PURE Ceramic implant Monotype. Straumann PURE Ceramic Implants can be placed using the existing instruments using the same osteotomy preparation protocol as for Bone Level implants. The subject implant is a two –piece implant and is available in Ø4.1 mm with lengths of 8, 10, 12, and 14 mm.

The **Closure and Healing caps** are screws machined as one piece and come in three gingival heights to accommodate individual gingival thickness. The material of the devices is titanium grade 4. The Closure caps are screwed into the implant to protect the inner configuration and shoulder of the implant during the healing phase in cases of submerged (submucosal) healing protocols and do not support a prosthetic restoration. Healing caps are screwed into the implant to protect the inner configuration in cases of transmucosal healing protocols and are placed out of occlusion and do not support a prosthetic restoration.

The **Temporary Abutments** are used to serve as a temporary crown or bridge restoration for the Straumann PURE Ceramic Implant System.

The **CI RD Straumann PUREbase Abutment** for Ceramic implant is a pre-manufactured (stock) abutment (the first piece of the two-piece abutment), sometimes referred to as “Tibase”, and is used as a base when fabricating a CAD/CAM customized restoration (the second piece of the two-piece abutment). The assembly of the two-

pieces becomes a finished medical device after cementation of the CAD/CAM customized restoration on the PURE base abutment.

5.5 Indications for Use

The **Straumann PURE Ceramic Implant** is indicated for the restoration of single-tooth gaps and in edentulous or partially edentulous jaws. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components.

The **Closure and Healing caps** are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Closure and Healing caps should be used only with suitable implant connections. Do not use healing components for longer than 6 months.

The provisional components are intended to serve as a base for temporary crown or bridge restoration out of occlusion for the Straumann® PURE Ceramic Implant System. The Straumann® **Temporary Abutment** VITA CAD-Temp® for the Straumann® PURE Ceramic Implant is indicated for temporary usage of up to 180 days.

The **CI RD Straumann PUREbase Abutment** is a titanium base placed onto Straumann ceramic dental implants to provide support for customized prosthetic restorations and is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.

5.6 Technological Characteristics

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

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICES	
	Subject **Straumann PURE Ceramic Implant System** **Straumann PURE Ceramic Implants**	**K171769** **Straumann PURE Ceramic Implants**	**K151328** **Straumann PURE Ceramic Implants**	**K163043** **Zeramex P6 Dental Implant System**
Indications for Use	The Straumann PURE Ceramic Implant is indicated for the restoration of single-tooth gaps and in edentulous or partially edentulous jaws. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components.	The Straumann® PURE Ceramic Implant (Monotype) is indicated for restoration in single tooth gaps and in an edentulous or partially edentulous jaw. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components. The ø3.3 mm reduced diameter implants are recommended for central and lateral incisors only.	The Straumann® PURE Ceramic Implant (Monotype) is indicated for restoration in single tooth gaps and in an edentulous or partially edentulous jaw. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components. The ø3.3 mm reduced diameter implants are recommended for central and lateral incisors only. The Straumann® PURE Ceramic Implant Protective Cap is intended to protect the Straumann® PURE Ceramic Implant (Monotype) during the healing phase after implant placement for up to 6 months. Temporary copings are intended to serve as a base for temporary crown or bridge restoration for the Straumann® PURE Ceramic Implant (Monotype) for up to 30 days.	The Zeramex® P6 Dental Implant System is intended to be surgically placed in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function. The Zeramex® P6 Dental Implant System can be used for single or multiple unit restorations. The Zeramex® P6 implants are intended for delayed loading. The Zeramex® P6 implants are specially indicated for patients with metal allergies/ intolerances and chronic illness due to metal allergies/intolerances. The Zeramex® P6 (Ø3.3mm SN) implant may only be used in the anterior teeth in the lower jaw and lateral incisor in the upper jaw.
Material	Y-TZP according to ISO 13356	Y-TZP according to ISO 13356	Y-TZP according to ISO 13356	Aluminum toughened zirconia
Surface Treatment	Sand-blasted, large-grit, acid etched (ZLA®)	Sand-blasted, large-grit, acid etched (ZLA®)	Sand-blasted, large-grit, acid etched (ZLA®)	N/A

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICES	
	Subject **Straumann PURE Ceramic Implant System** **Straumann PURE Ceramic Implants**	**K171769** **Straumann PURE Ceramic Implants**	**K151328** **Straumann PURE Ceramic Implants**	**K163043** **Zeramex P6 Dental Implant System**
Implant to Abutment Connection	2-piece Y-TZP dental implant	Integral coping superstructure	Integral coping superstructure	2-piece Y-TZP dental implant
Abutment to Implant Mode of Attachment	Screw-retained	Integral coping superstructure	Integral coping superstructure	Screw-retained or cement-retained
Restoration to Abutment Mode of Attachment	Cement-retained	Cement-retained	Cement-retained	Cement-retained
Endosteal Diameter	Ø4.1 mm	Ø3.3 and Ø4.1 mm	Ø3.3 and Ø4.1 mm	Ø3.3, Ø4.1, and Ø4.8 mm
Platform Diameter	Ø4.8 mm	Ø3.5 and Ø4.8 mm	Ø3.5 and Ø4.8 mm	N/A
Implant Length	8, 10, 12, and 14 mm	8, 10, 12, and 14 mm	8, 10, 12, and 14 mm	8, 10, and 12 mm
Implant Design	Straight cylindrical implant body	Straight cylindrical implant body	Straight cylindrical implant body	N/A
Thread Pitch	0.8 mm	0.8 mm	0.8 mm	N/A
Sterilization Method	End user receives product sterilized via Ethylene Oxide to an SAL of 10^{-6}	End user receives product sterilized via Ethylene Oxide to an SAL of 10^{-6}	End user receives product sterilized via Ethylene Oxide to an SAL of 10^{-6}	N/A

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES				
	Subject **Straumann PURE Ceramic Implant System** **CI RD Straumann PUREbase Abutments**	**K142890** **Straumann Variobase Abutments**	**K061277** **Straumann CARES Ceramic Coping**	**K170354** **Straumann Variobase Abutments**	**K170356** **Straumann Variobase Abutments**	**K173379** **Straumann Variobase Abutments for AS**
Indications for Use	The CI RD Straumann PUREbase Abutment is a titanium base placed onto Straumann ceramic dental implants to provide support for customized prosthetic restorations and is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase™ Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.	Copings are intended to provide support for prosthetic reconstructions such as crowns or bridges. The Straumann C.A.R.E.S. Ceramic Coping is indicated for cemented restorations. The coping can be used in single tooth replacements and multiple tooth restorations.	The Straumann® Variobase® Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase® Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.	The Straumann® Variobase® Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase® Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.	The Straumann® Variobase® for Crown AS is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for Crown AS are indicated for screw retained single tooth or cement-retained single tooth and bridge restorations. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. Temporary restorations are indicated to be placed out of occlusion. All digitally designed copings and/or crowns for use with the Straumann Variobase® for Crown AS are intended to be sent to Straumann for manufacture at a validated milling center.
Material	Ti-6Al-7Nb	Ti-6Al-7Nb	Y-TZP	Ti-6Al-7Nb	Ti-6Al-7Nb	Ti-6Al-7Nb
Implant to Abutment Connection	RD connection with a Y-TZP implant fixture and a Ti-6Al-7Nb Abutment	TiZr or Ti implant fixture and a Ti-6Al-7Nb Abutment	TiZr or Ti implant fixture and a Y-TZP abutment	TiZr or Ti implant fixture and a Ti-6Al-7Nb Abutment	TiZr or Ti implant fixture and a Ti-6Al-7Nb Abutment	TiZr or Ti implant fixture and a Ti-6Al-7Nb Abutment

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES				
	Subject **Straumann PURE Ceramic Implant System** **CI RD Straumann PUREbase Abutments**	**K142890** **Straumann Variobase Abutments**	**K061277** **Straumann CARES Ceramic Coping**	**K170354** **Straumann Variobase Abutments**	**K170356** **Straumann Variobase Abutments**	**K173379** **Straumann Variobase Abutments for AS**
Diameter	Ø3.6 mm	Ø3.8 – Ø7.0 mm	N/A	Ø3.8 – Ø7.0 mm	Ø3.8 – Ø7.0 mm	Ø3.8 – Ø7.0 mm
Overall Height	6.5 – 8.5 mm	5.9 – 8.9 mm	N/A	5.9 – 8.9 mm	5.9 – 8.9 mm	N/A
Coping/ Crown Material	Digital Workflow: polycon® ae (temporary) zerion® LT/HT (permanent) zerion® ML/UTML (permanent) IPS e.max CAD MO/LT/HT (permanent) n!ce (permanent)	Traditional Workflow: Type 4 Metals (ISO 22674) IPS e.max® Press Ceramic Digital Workflow: polycon® ae (temporary) zerion® (permanent) IPS e.max® CAD Ceramic (permanent) coron® (permanent)	N/A	Digital Workflow: n!ce (permanent)	Digital Workflow: zerion® ML/UTML (permanent)	Traditional Workflow: Type 4 Metals (ISO 22674) IPS e.max® Press Ceramic Digital Workflow: polycon® ae (temporary) zerion® (permanent) IPS e.max® CAD Ceramic (permanent) coron® (permanent) zerion ML/UTML (permanent) n!ce (permanent)
Maximum Angulation	30˚	30˚	30˚	30˚	30˚	30˚
Design Workflow	CAD with CARES Visual v.11	Wax-up or CAD	N/A	Wax-up or CAD	Wax-up or CAD	CAD with CARES Visual v.11

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES				
	Subject **Straumann PURE Ceramic Implant System** **CI RD Straumann PUREbase Abutments**	**K142890** **Straumann Variobase Abutments**	**K061277** **Straumann CARES Ceramic Coping**	**K170354** **Straumann Variobase Abutments**	**K170356** **Straumann Variobase Abutments**	**K173379** **Straumann Variobase Abutments for AS**
Manufacturing Workflow	Straumann Milling	Traditional casting or pressing or Straumann Milling	N/A	Straumann Milling	Straumann Milling	Traditional casting or pressing or Straumann Milling
Sterilization Method	Non-sterile – End user sterilized via autoclave	Non-sterile – End user sterilized via autoclave	N/A	Non-sterile – End user sterilized via autoclave	Non-sterile – End user sterilized via autoclave	Non-sterile – End user sterilized via autoclave
Mode of Attachment	Screw-retained or cement-retained	Screw-retained or cement-retained	N/A	Screw-retained or cement-retained	Screw-retained or cement-retained	Screw-retained or cement-retained

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES
	Subject **Straumann PURE Ceramic Implant System** **Closure and Healing Caps**	**K130808** **Straumann Healing Abutments, Healing Caps, and Closure Screws**
Indications for Use	The Closure and Healing caps are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Closure and Healing caps should be used only with suitable implant connections. Do not use healing components for longer than 6 months.	Closure Screws, healing caps, and healing abutments, are intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Customizable healing abutments made of PEEK are for use for up to 6 months.
Material	Titanium Grade 4	Titanium Grade 4
Implant to Cap Connection	RD with a Y-TZP implant fixture and a Ti Cap	RN/WN/NNC connections with TiZr or Ti Implant fixture and Ti Cap
Implant to Cap Mode of Attachment	Screw-retained	Screw-retained
Diameter	Closure Cap: Ø4.8 mm Healing Cap: Ø5.2 mm	Closure and Healing Caps: from Ø3.5 – Ø5.5 mm
Overall Height	Closure Cap: 4.6 mm Healing Cap: 6.2 and 7.2 mm	Closure Cap: 6.2 and 6.8 mm Healing Cap: 8.1 – 11.1 mm
Gingival Height	Closure Cap: 0.5 mm Healing Cap: 2.0 and 3.0 mm	Closure Cap: 0 and 0.5 mm Healing Cap: 2.0 and 3.0 mm
Sterilization Method	End user receives product sterilized via Irradiation to an SAL of 10^{-6}	End user receives product sterilized via Irradiation to an SAL of 10^{-6}

FEATURE	PROPOSED DEVICE	REFERENCE DEVICES
	Subject **Straumann PURE Ceramic Implant System** **Temporary Abutments**	**K122192** **Straumann Temporary Abutments VITA CAD-Temp**
Indications for Use	The provisional components are intended to serve as a base for temporary crown or bridge restoration out of occlusion for the Straumann® PURE Ceramic Implant System. The Straumann® Temporary Abutment VITA CAD-Temp® for the Straumann® PURE Ceramic Implant is indicated for temporary usage of up to 180 days.	Straumann Temporary Abutments VITA CAD-Temp are indicated for use with Straumann Bone Level and Tissue Level implants for temporary crown and bridge restorations, and to maintain, stabilize and shape the soft tissue during the healing phase for up to six months, and should be placed out of occlusion.
Material	Ti-6Al-7Nb and polymethyl methacrylate (PMMA)	Ti-6Al-7Nb and polymethyl methacrylate (PMMA)
Implant to Abutment Connection	RD connection with a Y-TZP implant fixture and a Ti-6Al-7Nb temporary abutment	RC/RN connection with TiZr or Ti implants and a Ti-6Al-7Nb temporary abutment
Diameter	Ø7.0 mm	Ø3.7 – Ø7.0 mm
Overall Height	12.3 mm	12.1 – 16.4 mm
Maximum Angulation	30˚	30˚
Manufacturing Workflow	Can be customized using common dental burs	Can be customized using common dental burs
Sterilization Method	Non-sterile End user sterilized via autoclave	Non-sterile End user sterilized via autoclave

5.7 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The subject device materials are identical to the predicate and reference device materials, therefore, no new issues regarding biocompatibility (according to ISO 10993-1:2009) were raised.

Sterilization

Sterilization validation performed per ISO 11135, *Sterilization of healthcare products – Ethylene Oxide – Requirements for development, validation and routine control of a sterilization process for medical devices*, using the Half Cycle Overkill Approach. The

validation demonstrates that the sterilization process and equipment is capable of reliably and consistently sterilizing the subject device to a minimum Sterility Assurance Level (SAL) of 10-6.

Pyrogenicity information provided is based on FDA Guidance on "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile, issued on 21 January 2016." The method used to determine the device meets pyrogen limit specifications is LAL Endotoxin Analysis with testing limit of 20 EU/device, based on a blood contacting and implanted device.

The sterilization process for the Straumann PURE temporary abutment and CI RD Straumann PUREbase abutments as recommended in the labeling was validated according to applicable recommnedations inf the FDA guidance document "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015*" and ISO 17665-1:2006 "*Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*".

Mechanical Testing

Dynamic fatigue tests 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 Implant Abutments*" and ISO 14801:2016 and demonstrated the Straumann PURE Ceramic Implant, Straumann PURE temporary abutments, and CI RD Straumann PUREbase abutments are equivalent to the predicate and reference devices.

Two additional bench tests were conducted after fatigue testing: Implant-to-abutment connection comparison to evaluate wear of the surfaces of the implant body, abutment and fixation screw and screw loosening comparison. Both data produced concluded of comparable behavior of the subject device to the reference devices in terms of wear on the implant-to-abutment connection and screw loosening.

A literature review was provided to evaluate the risk of screw loosening with ceramic abutments.

5.8 Conclusion

Based upon the assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate and/or reference devices.