



Food and Drug Administration
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January 11, 2016

Straumann USA
Ms. Nandini Murthy
Regulatory Consultant
60 Minuteman Road
Andover, Massachusetts 01810

Re: K151328
Trade/Device Name: PURE Ceramic Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: December 8, 2015
Received: December 9, 2015

Dear Ms. Murthy:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina Kiang
-S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known)

K151328

Device Name

PURE Ceramic Implants

Indications for Use (Describe)

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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510(k) Summary

1.1 Submitter's Contact Information

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Andover, MA 01810

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Fax Number: 1-978-747-0023

Contact Person: Jennifer Jackson

Date of Submission: January 11, 2016

1.2 Name of the Device: PURE Ceramic Implants

Trade Name: Straumann® PURE Ceramic Implants

Common Name: Endosseous Dental Implant

Classification Name: Endosseous Dental Implant

Regulation Number: §872.3640

Classification: Class II

Product codes: DZE, NHA

1.2.1 Straumann® PURE Ceramic Protective Caps

Trade Name: Straumann® PURE Ceramic Protective Caps

Common Name: Endosseous Dental Implant Abutment

1.2.2 Straumann® PURE Ceramic Temporary Copings

Trade Name: Straumann® PURE Ceramic Temporary Copings

Common Name: Endosseous Dental Implant Abutment

1.3 Predicate Device

1.3.1 Primary Predicate Device

- K120793, Z-Look3 Evo SLM

1.3.2 Reference Predicate Device(s)

- K033922, Modification to ITI Dental Implant System
- K062129, P.004 Implants
- K123784, Straumann® Dental Implant System
- K111357, Narrow Neck CrossFit (NNC) Ø3.3 mm Dental Implant System
- K072071, Straumann P.004 Cementable Abutments
- K080286, Straumann P.004 NC Cementable Abutments

1.4 Device Description

1.4.1 PURE Ceramic Implants

The Straumann® PURE Ceramic Implant (Monotype) is made of 100% yttrium-stabilized zirconia. The endosteal region presents macro- and micro-roughness to support osseointegration (ZLA® surface). The implant has a 1.8 mm high machined neck. The implant features a monotype design where the ceramic abutment for final restoration is already built in. Straumann® PURE Ceramic Implant (Monotype) prosthetic components are identified with RD (Regular Diameter) corresponding to the neck diameter of 4.8 mm, and ND (Narrow Diameter) corresponding to the neck diameter of 3.5 mm.

The full range of size ranges of the PURE Ceramic implants are provided in Table 1 below.

K151328
Straumann® PURE Ceramic Implants

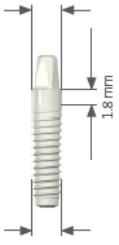
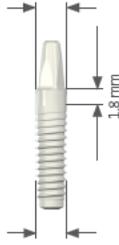
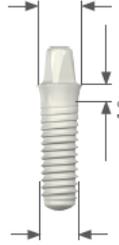
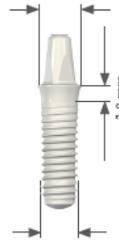
Implant Overview	Straumann® PURE Ceramic Implant Ø3.3 ND		Straumann® PURE Ceramic Implant Ø4.1 RD		
	ND	ND	RD	RD	
Prosthetic Platform	ND	ND	RD	RD	
Abutment height	AH 4 mm	AH 5.5 mm	AH 4 mm	AH 5.5 mm	
Shoulder diameter	Ø3.5 mm	Ø3.5 mm	Ø4.8 mm	Ø4.8 mm	
					
Endosteal diameter	Ø3.3 mm	Ø3.3 mm	Ø4.1 mm	Ø4.1 mm	
Length	8 mm	031.001S	031.011S	031.021S	031.031S
	10 mm	031.002S	031.012S	031.022S	031.032S
	12 mm	031.003S	031.013S	031.023S	031.033S
	14 mm	031.004S	031.014S	031.024S	031.034S

Table 1 – Full range of Straumann® PURE Ceramic Implants

1.4.2 Straumann® PURE Ceramic Protective Caps

The Protective Caps are manufactured from polyetheretherketone (PEEK Classix). The full range of Protective Caps is provided in Table 2.

Protective Cap Overview	AH 4 mm	AH 5.5 mm
		
For Ø3.3 (ND)	031.320	031.321
For Ø4.1 (RD)	031.330	031.331

Table 2 – Full range of Straumann® PURE Ceramic Implant Protective Caps

1.4.3 Straumann® PURE Ceramic Temporary Copings

The temporary copings are manufactured from polymethylmethacrylate (PMMA). The full range of temporary copings is provided in Table 3.

Temporary Coping Overview	For Crowns	For Bridges
		
For Ø3.3 (ND)	031.300	031.301
For Ø4.1 (RD)	031.310	031.311

Table 3 – Full range of Straumann® PURE Ceramic Implant temporary copings

1.5 Intended Use

1.5.1 Straumann® PURE Ceramic Implants

The Straumann® PURE Ceramic Implant (Monotype) is suitable for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients (unless specific indications and limitations are specified).

1.6 Indications for Use

1.6.1 Straumann® PURE Ceramic Implants

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.

1.6.2 Straumann® PURE Ceramic Protective Caps

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.

1.6.3 Straumann® PURE Ceramic Temporary Copings

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.

1.7 Technological Characteristics

The Straumann® PURE Ceramic Implant is a one-piece monotype implant and therefore does not have an internal connection. Table 4 below provides for a comparison of key technological characteristics and indications between the Straumann® PURE Ceramic Implant and the primary predicate device. The indications are substantially equivalent to the primary predicate, as any differences relate to placement limitation due to reduced diameter implant size and the addition of protective cap and temporary coping device components.

Features	Straumann® PURE Ceramic Implants (K151328)	Predicate Z-Look3 Evo SLM (K120793)
Indications for use	<p>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.</p> <p>The Ø3.3 mm reduced diameter implants are recommended for central and lateral incisors only.</p> <p>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.</p> <p>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.</p>	<p>Z-look3 evo slm implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. The z-look3 evo slm implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them.</p>
Material	Y-TZP	Y-TZP
Implant Design	Cylindrical Monotype	Cylindrical Monotype
Apical Diameter	Ø3.3 and Ø4.1 mm	Ø3.6, Ø4.0, and Ø5.0 mm
Length	8, 10, 12, and 14 mm	8, 10, 11.5, and 13 mm
Implant/Abutment connection	None (Monotype)	None (Monotype)

Table 4 – Comparison of Straumann® PURE Ceramic Implants to Predicate Z-Look3 Evo SLM

1.8 Performance Testing

Dynamic fatigue, static strength, insertion torque and surface characterization 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 Abutments*” and showed that the Straumann® PURE Ceramic implants were equivalent to the predicate devices. Specifically, the fatigue strength of the Ø3.3 mm Straumann® PURE ceramic implant was equivalent to the Ø3.6 mm predicate device’s fatigue strength. The insertion torque values of the Straumann® PURE Ceramic Ø3.3 mm implant were

measured and compared to the values of a predicate reference device (Straumann® NNC implant, K111357).

MRI testing was performed to support the MRI statements in Straumann® PURE Ceramic labeling.

The Straumann® PURE Ceramic Implants are manufactured from yttrium-stabilized zirconium oxide (Y-TZP). The material conforms to ISO 13356:2008, *Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*. In addition to prior proven biocompatibility of implant material used, including a toxicological evaluation report and conformance to ISO13356, the following testing was performed:

- Cytotoxicity according to ISO 10993-5:2009, *Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity*.
- Chemical Analysis (organic and inorganic) according to ISO 10993-18:2009, *Biological evaluation of medical devices – Part 18: Chemical characterization of materials*.
- A rabbit study comparing unaged ceramic implants with aged implants.

All of the testing above, along with a literature review, confirmed the biocompatibility of the Straumann® PURE Ceramic implants.

Sterilization validation of the Straumann® PURE Ceramic implants, in accordance with DIN EN 556-1:2002 (equivalent to ANSI AAMI ST67:2011), *Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: requirements for terminally sterilized devices*, was completed. The sterilization process for the provisional components as recommended in labeling was also validated according to applicable recommendations in the FDA Guidance document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015”. Straumann performed accelerated and real time aging testing to support the labeled shelf life.

Clinical study results support the equivalence of the Straumann® PURE Ceramic implants to predicate devices. Among the 41 ITT patients with complete follow-up through two years, 40 survived to at least two years (point estimate of 97.6%), which exceeded the acceptance criteria of 85% in the protocol.

1.9 Conclusion

The documentation submitted in this premarket notification demonstrates that the Straumann® PURE Ceramic Implants are substantially equivalent to the predicate devices.