DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Institut Straumann Ag
% Jennifer Jackson
Head Of Quality And Regulatory Affairs
Straumann Usa, LLC
60 Minuteman Road
Andover, Massachusetts 01810

September 16, 2016

Re: K160262
Trade/Device Name: N!ce Lt Glass Ceramic Blocks, N!ce Ht Glass Ceramic Blocks,
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: August 17, 2016
Received: August 18, 2016

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. 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,

Susan Runner DDS, MA

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: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*
K160262

Device Name

Straumann n!ce Glass-Ceramic Blocks

Indications for Use *(Describe)*

Once finalized into a suitable design, the n!ce™ glass-ceramic blocks are indicated for use as inlays, onlays, veneers, partial crowns and crowns.

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.

5. 510(k) Summary

Submission ID:	**K160262**
Submitter:	Straumann USA, LLC (on behalf of Institut Straumann AG) 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052
Contact Person:	Jennifer Jackson, MS Director of Regulatory Affairs and Quality Straumann USA, LLC +1 (978) 747-2509
Prepared By:	Christopher Klaczyk Head of North American Regulatory Affairs Institut Straumann AG +41 61 965 1260
Date Prepared:	July 1, 2016
Product Code(s):	EIH (21 CFR 872.6660)
Device Class:	II (21 CFR 872.6660)
Classification Panel:	Dental
Classification Name:	Porcelain powder for clinical use (21 CFR 872.6660)
Proprietary Name:	Straumann® n!ce™ Glass-Ceramic Blocks
Predicate Device::	K051705, IPS e.max CAD (Ivoclar Vivadent, Inc.)
Reference Device(s):	None
Device Description:	Straumann® n!ce™ glass ceramic is a proprietary lithium disilicate (Li_2O-SiO_2) glass ceramic material intended to be milled to produce prosthetic restorations for natural and endosseous dental implant abutment borne teeth. The material is suitable for use in inlays, onlays, veneers, copings and monolithic crown restorations.
Intended Use:	The n!ce™ glass ceramic is intended to be used to manufacture ceramic prostheses for the restoration of natural teeth or on top of abutments.

Indications For Use: Once finalized into a suitable design, the n!ce™ Glass-Ceramic Blocks are indicated for use as inlays, onlays, veneers, partial crowns and crowns.

Materials: Lithium Disilicate reinforced Lithium Aluminosilicate Glass-Ceramic

Technological Characteristics: A comparison of the relevant technological characteristics between the subject and primary predicate devices is provided in the table that follows.

Performance Data: Test data to support the evaluation of the subject n!ce™ Glass-Ceramic Blocks has been submitted as follows:

- Product performance testing per ISO 6872, *Dentistry—Ceramic materials* and
- Product performance testing per ISO 7991, *Glass—Determination of coefficient of mean linear thermal expansion.*
- Biocompatibility assessment per the ISO 10993 series standards:
  - Evaluation per ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*.
  - Cytotoxicity assessment per ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*.
  - Chemical characterization per ISO 10993-18, *Biological evaluation of medical devices—Part 18: Chemical characterization of materials*.
- Transport and package testing per ISTA 2A and the standards referenced therein.
- Evaluation of shelf life per ASTM F1980, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*.

Conclusions: Based upon our assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate devices.

Feature	Primary Predicate Device Ivoclar Vivadent IPS e.max CAD (K051705)	Subject Devices Straumann n!ce Glass Ceramic Blocks (K160262)	Comparison Discussion
Indications For Use	IPS e.max CAD is a CAD/CAM machinable glass ceramic based on lithium disilicate for the preparation of full ceramic crowns, inlays, onlays, and full ceramic 3-unit anterior bridges.	Once finalized into a suitable design, the n!ce™ Glass-Ceramic Blocks are indicated for use as inlays, onlays, veneers, partial crowns and crowns.	Equivalent The scope of indications for the subject material is within the scope of the indications for the predicate material. The subject device is not indicated for use in the fabrication of bridges.
Classification Reg.	21 CFR 872.6660	21 CFR 872.6660	Identical
FDA Product Code	EIH	EIH	Identical
Chemical Composition	Lithium disilicate glass	Lithium disilicate – lithium aluminosilicate glass	Equivalent Both the subject and predicate materials are based upon lithium disilicate chemistry.
Crystallization State as Supplied	Partially crystallized; final crystallization done by dental laboratory	Fully crystallized	Equivalent In both cases the final restoration is fully crystallized.
Flexural Strength **Chemical Solubility**	Meets ISO 6872 requirements for a Type II, Class 3 dental ceramic material: Monolithic ceramic for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration adhesively or non-adhesively cemented.	Meets ISO 6872 requirements for a Type II, Class 2 dental ceramic material: Monolithic ceramic for single-unit anterior or posterior prostheses adhesively cemented.	Equivalent The indications for the subject material are within the scope of indications for the predicate material.
Radioactivity	Meets ISO 6872 requirements	Meets ISO 6872 requirements	Identical
Type / Class per ISO 6872	Type II, Class 3	Type II, Class 2	Equivalent The indications for the subject material are within the scope of indications for the predicate material.

Feature	Primary Predicate Device Ivoclar Vivadent IPS e.max CAD (K051705)	Subject Devices Straumann n!ce Glass Ceramic Blocks (K160262)	Comparison Discussion
Coefficient of Thermal Expansion (CTE) 100-500°C	10.5 x 10^{-6}/K	HT: 7.1 x 10^{-6}/K LT: 7.2 x 10^{-6}/K	Equivalent CTE is a function of the chemical composition of the material and is particular importance for the compatibility of the stains and glazes to be used in conjunction with the material.
Glass Transition Temperature (T_g)	Not Reported	HT: 497°C LT: 491°C	Unknown
Esthetic Characteristics	Translucency: High Translucency (HT) Low Translucency (LT) Medium Opacity (MO) Shades: HT/LT: 16 A-D and 4 Bleach MO: 5 MO 0 – MO 4 Color Uniformity: Homogenous Fluorescence: Present	Translucency: High Translucency (HT) Low Translucency (LT) Shades: HT/LT: 6 A-D Color Uniformity: Homogenous Fluorescence: Present	Equivalent The range of translucencies and shades of the subject device are within the range offered for the predicate device.
Block Dimensions	C14 block (12.4 x 14.5 x 18.0 mm)	C14 block (12.4 x 14.5 x 18.0 mm)	Identical
Mandrel Design	The mandrel is compatible with material holders of Sirona CEREC and inLab mills.	The mandrel is compatible with material holders of Sirona CEREC and inLab mills and other third-party mills.	Identical
Minimum Wall Thickness	1.0 mm	1.0 mm	Identical