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
Director of Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

March 2, 2017

Re: K170420
Trade/Device Name: N!ce Glass Ceramic Blocks For Amann Girrbach
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: February 9, 2017
Received: February 13, 2017

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,

Susan Runner DDS, MA

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

510(k) Number *(if known)*

Device Name

Straumann n!ce Blocks for Amann Girrbach

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.

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5. 510(k) Summary

Submitter:	Straumann USA, LLC (on behalf of Institut Straumann AG) 60 Minuteman Road Andover, MA 01810
Contact Person:	Jennifer M. Jackson, MS Head of Regulatory Affairs and Quality Straumann USA
Prepared By & Secondary Contact:	Christopher Klaczyk Head of Regulatory Affairs & Compliance Institut Straumann AG
Date Prepared:	February 9, 2017
Product Code(s):	EIH (21 CFR 872.6660)
Device Class:	II (21 CFR 872.6660)
Classification Panel:	Dental
Classification Name:	Powder, porcelain for clinical use (21 CFR 872.6660)
Proprietary Name:	Straumann® n!ce™ Blocks for Amann Girrbach
Predicate Device::	K160262, Straumann® n!ce™ Glass Ceramic Blocks (Institut Straumann AG)
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. The mandrel bonded to the blocks is compatible with Amann Girrbach milling equipment.
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.

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

Feature	Subject Device n!ce Blocks for Amann Girrbach	Primary Predicate Devices Straumann n!ce Glass Ceramic Blocks (K160262)
Block Chemical Composition	lithium disilicate – lithium aluminosilicate glass	
Crystallization State as Supplied	Fully crystallized	
Esthetic Characteristics	Translucency: High Translucency (HT) Low Translucency (LT) Shades: HT/LT: 6 A-D Color Uniformity: Homogenous Fluorescence: Present	
Block Dimensions	C14 (12.4 x 14.5 x 18.0 mm)	
Mandrel Design	The mandrel is compatible with material holders of Amann Girrbach mills.	The mandrel is compatible with material holders of Sirona CEREC and inLab mills and other third-party mills.
Mandrel Material	AlMgSiSn Alloy with Alodine 1500 anti-corrosive coating	AlSi1Sn1MgBi Alloy
Minimum Wall Thickness	1.0 mm	
Flexural Strength	Meets ISO 6872 requirements for a Type II, Class 2 dental ceramic material.	
Radioactivity	Meets ISO 6872 requirements for a Type II, Class 2 dental ceramic material	
Chemical Solubility	Meets ISO 6872 requirements for a Type II, Class 2 dental ceramic material.	
Coefficient of Thermal Expansion (CTE) 100-500°C	HT: 7.1 x 10^{-6}/K LT: 7.2 x 10^{-6}/K	
Glass Transition Temperature (T_g)	HT: 497°C LT: 491°C	

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

- Product performance testing per ISO 6872, *Dentistry—Ceramic materials*
- ISO 7991, *Glass—Determination of coefficient of mean linear thermal expansion*.
- Biocompatibility assessment as follows:
  - 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.