



December 1, 2017

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

Re: K171773

Trade/Device Name: Straumann® n!ce Glass Ceramic A14 Blocks  
Regulation Number: 21 CFR 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: Class II  
Product Code: NHA  
Dated: November 2, 2017  
Received: November 3, 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.

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.

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](mailto: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

## Indications for Use

510(k) Number (if known)

K171773

Device Name

Straumann n!ce Glass-Ceramic A14 Blocks

Indications for Use (Describe) The Straumann n!ce Glass Ceramic A14 Blocks are intended to be ceramic mesostructures cemented to the Ti-base for a two-piece hybrid abutment for single tooth restorations or hybrid abutment crowns, used in conjunction with endosseous dental implant to restore chewing function. The following compatibilities apply:

| Ti-Base      |                         |           | Block          |
|--------------|-------------------------|-----------|----------------|
| manufacturer | system                  | Reference | interface size |
| Straumann    | RC Variobase® for CEREC | 022.0024  | L              |
|              | NC Variobase® for CEREC | 022.0025  | L              |
|              | RN Variobase® for CEREC | 022.0019  | L              |
|              | WN Variobase® for CEREC | 022.0020  | L              |

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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1. **510(k) Summary**

K171773

**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  
Head of Regulatory Affairs and Quality  
(978) 747-2509

**Prepared By:** Shokoufeh Khodabandeh  
Regulatory Affairs and Compliance Manager  
Institut Straumann AG  
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**Date Prepared:** December 1, 2017

**Product Code(s):** NHA (21 CFR 872.3630)

**Device Class:** II (21 CFR 872.3630)

**Classification Panel:** Dental

**Classification Name:** Endosseous Dental Implant Abutment (21 CFR 872.3630)

**Proprietary Name:** Straumann® n!ce Glass Ceramic A14 Blocks.

**Predicate Device:** K132209 IPS e.max CAD Abutment Solutions ( Ivoclar Vivadent, Inc.)

**Reference Device(s):** K160262 n!ce Glass Ceramic Blocks ( Institut Straumann AG)  
K151324, Variobase® for CEREC® (Institut Straumann AG)  
K170354, Variobase® with n!ce™ Restorations (Institut Straumann AG)

**Device Description:** Straumann® n!ce® glass ceramic is a proprietary lithium disilicate (Li<sub>2</sub>O-SiO<sub>2</sub>) dental glass ceramic material. The n!ce® glass-ceramic A14 blocks feature a pre milled interface that fits the Straumann® Variobase® for CEREC®. The blocks are further processed by the trained professional to make individually designed mesostructure that are milled into the desired shape of a hybrid abutment or hybrid abutment crown using the Sirona inLab (Version3.65) and CEREC® software (Version 4.2). n!ce® mesostructures can be ground, polished and fitted immediately without requiring

additional crystallization firing. Stain & glaze techniques can be applied.

n!ce® A14 blocks are available in two levels of translucency: HT (High Translucency) and LT (Low Translucency). Both translucencies are available in shades , A1, A2, A3, B2, B4 and C2 for flexibility and application variety to meet individual patient needs. n!ce® A14 blocks are available with one interface size large (L)”

**Intended Use:** The n!ce® glass-ceramic A14 blocks are intended to be used to manufacture mesostructure cemented to Ti-Bases as part of a two-piece abutment or abutment crown, which are placed onto dental implants.

**Indications For Use:** The Straumann n!ce Glass Ceramic A14 Blocks are intended to be ceramic mesostructures cemented to the Ti-base for a two-piece hybrid abutment for single tooth restorations or hybrid abutment crowns, used in conjunction with endosseous dental implant to restore chewing function. The following compatibilities apply:

| Ti-Base      |                         |           | Block          |
|--------------|-------------------------|-----------|----------------|
| manufacturer | system                  | Reference | interface size |
| Straumann    | RC Variobase® for CEREC | 022.0024  | L              |
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|              | RN Variobase® for CEREC | 022.0019  | L              |
|              | WN Variobase® for CEREC | 022.0020  | L              |

**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.

**Table 1 – Summary of the subject device and primary predicate device characteristic**

| Feature   | Primary Predicate Device<br>IPS e.max CAD Abutment Solutions (K132209)   | Subject Devices<br>Straumann® n!ce Glass Ceramic A14 Blocks   | Equivalence Discussion   |        |           |                      |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |  |  |  |  |   |
|---|--|---|--|--------|-----------|----------------------|-----------|-------------------------|----------|---|-------------------------|----------|---|-------------------------|----------|---|-------------------------|----------|---|--|--|--|--|---|
| <b>Indications For Use</b>                              | IPS e.max CAD Abutment Solutions is intended for use in partially or fully edentulous mandibles and maxillae in support of single cementretained restorations. The system comprises three parts: IPS e.max CAD ceramic structure, Ti base and CAD/CAM software. The IPS e.max CAD ceramic structure cemented to the Ti base is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants. | <p>The Straumann n!ce Glass Ceramic A14 Blocks are intended to be ceramic mesostructures cemented to the Ti-base for a two-piece hybrid abutment for single tooth restorations or hybrid abutment crowns, used in conjunction with endosseous dental implant to restore chewing function. The following compatibilities apply:</p> <table border="1" data-bbox="852 1024 1162 1163"> <thead> <tr> <th>Ti-Base manufacturer</th> <th>system</th> <th>Reference</th> <th>Block interface size</th> </tr> </thead> <tbody> <tr> <td rowspan="5">Straumann</td> <td>RC Variobase® for CEREC</td> <td>022.0024</td> <td>L</td> </tr> <tr> <td>NC Variobase® for CEREC</td> <td>022.0025</td> <td>L</td> </tr> <tr> <td>RN Variobase® for CEREC</td> <td>022.0019</td> <td>L</td> </tr> <tr> <td>WN Variobase® for CEREC</td> <td>022.0020</td> <td>L</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> | Ti-Base manufacturer   | system | Reference | Block interface size | Straumann | RC Variobase® for CEREC | 022.0024 | L | NC Variobase® for CEREC | 022.0025 | L | RN Variobase® for CEREC | 022.0019 | L | WN Variobase® for CEREC | 022.0020 | L |  |  |  |  | <p>Equivalent</p> <p>The indications for the n!ce Glass Ceramic A14 Blocks are within the indications of the IPS e.max CAD material.</p> <p>The Compatibility to NC and RC is covered directly by the predicate device.</p> <p>Compatibility to WN and RN is supported by the reference device per K151324, Variobase® for CEREC® (Institut Straumann AG)</p> |
| Ti-Base manufacturer                                    | system   | Reference   | Block interface size   |        |           |                      |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |  |  |  |  |   |
| Straumann   | RC Variobase® for CEREC  | 022.0024  | L  |        |           |                      |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |  |  |  |  |   |
|   | NC Variobase® for CEREC  | 022.0025  | L  |        |           |                      |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |  |  |  |  |   |
|   | RN Variobase® for CEREC  | 022.0019  | L  |        |           |                      |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |  |  |  |  |   |
|   | WN Variobase® for CEREC  | 022.0020  | L  |        |           |                      |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |  |  |  |  |   |
|   |  |   |  |        |           |                      |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |  |  |  |  |   |
| <b>Block Dimensions</b>                                 | A14 (12.4 x 14.5 x 18.0 mm)<br>A16 (17.8 x 15.8 x 18.0 mm )  | A14 (12.4 x 14.5 x 18.0 mm)   | <p>Equivalent</p> <p>The n!ce material is being offered in the A14 size which is also offered for IPS e.max CAD.</p> <p>n!ce material is not offered in A16 block size at this point.</p>              |        |           |                      |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |  |  |  |  |   |
| <b>Pre-milled TiBase interface (screw channel hole)</b> | Sizes: Large (L)<br>Small (S)  | Sizes: Large (L)  | <p>Equivalent</p> <p>The n!ce material is being offered with L screw channel size which is also offered for IPS e.max CAD</p> <p>n!ce material is not offered with (s) screw channel at this point</p> |        |           |                      |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |  |  |  |  |   |

| Feature                                  | Primary Predicate Device<br>IPS e.max CAD Abutment<br>Solutions (K132209)   | Subject Devices<br>Straumann® n!ce Glass<br>Ceramic A14 Blocks.   | Equivalence<br>Discussion  |
|--|---|---|--|
| <b>Chemical Composition</b>              | lithium disilicate glass Ceramic  | lithium disilicate – lithium aluminosilicate reinforced glass ceramic   | Equivalent<br>Both materials are in the family of lithium disilicate glasses   |
| <b>Crystallization State as Supplied</b> | Partially crystallized; final crystallization done by dental laboratory   | Fully Crystallized  | Equivalent<br>Both materials are fully crystallized when fitted in the patient’s mouth   |
| <b>Mandrel Design</b>                    | The mandrel is designed to be compatible with the material holders present on mills marketed by Sirona under the trade names CEREC and inLab and other third-party mills. | The mandrel is designed to be compatible with the material holders present on mills marketed by Sirona under the trade names CEREC and inLab and other third-party mills. | Equivalent<br>Both the subject and predicate designs can be effectively processed in mills designed to mate to the Sirona style mandrel.           |
| <b>Minimum Wall Thickness</b>            | 1.0 mm  | 1.0 mm  | Identical  |
| <b>Maximum Mesostructure Angulation</b>  | 20°   | 20°   | Identical  |
| <b>Design Workflow</b>                   | Per the Sirona CEREC InLab, software version 3.6 and Cerec SW (Version 4.2)   |   | Identical<br>Please note n!ce is NOT a new material added to software. We claim compatibility with the existing software cleared for IPS e.max CAD |
| <b>Manufacturing Workflow</b>            | Per the Sirona CEREC MC X and MC XL milling systems   |   | Identical  |

| <b>Feature</b>  | <b>Primary Predicate Device<br/>IPS e.max CAD Abutment<br/>Solutions (K132209)</b>  | <b>Subject Devices</b><br>Error! Reference source not<br>found.  | <b>Equivalence<br/>Discussion</b>   |
|---|---|--|---|
| <b>Compatible ti-<br/>bases</b>                       | NBRS 3.5<br>NBRS 4.3<br>NBRS 5.0<br>NBRS 6.0<br>NB A 4.5<br>NB A 5.0 S<br>BL 3.3 S<br>BL 4.1<br>B C 3.4<br>B C 4.1<br>B C 5.0 | RC Variobase® for CEREC<br>NC Variobase® for CEREC<br>RN Variobase® for CEREC<br>WN Variobase® for CEREC | Equivalent<br>Compatibility of<br>predicate device to<br>Straumann Variobase®<br>for CEREC is supported<br>by the reference device<br>per K151324,<br>Variobase® for CEREC®<br>(Institut Straumann AG)    |
| <b>Compatible ti-<br/>base platform<br/>diameters</b> | Not disclosed   | NC: 4.5 mm<br>RC: 4.6 mm<br>RN: 5.0 mm<br>WN: 7.0 mm   | Equivalent<br>Compatibility of predicate<br>device to<br>Straumann Variobase®<br>for CEREC is supported<br>by the reference device<br>per K151324,<br>Variobase® for<br>CEREC® (Institut<br>Straumann AG) |



**Table 2 – Substantial Equivalence Comparison with reference device Variobase for CEREC (K151324)**

| Feature                        | Reference Device<br>Variobase for CEREC<br>(K151324)  | Subject Devices<br>Straumann® n!ce Glass<br>Ceramic A14 Blocks  | Equivalence<br>Discussion  |  |       |  |              |        |           |                |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |   |
|--------------------------------|---|---|--|--|-------|--|--------------|--------|-----------|----------------|-----------|-------------------------|----------|---|-------------------------|----------|---|-------------------------|----------|---|-------------------------|----------|---|---|
| <b>Indications For Use</b>     | <p>The Straumann® Variobase® for CEREC® are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for CEREC® abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.</p> <p>All digitally designed copings and/or crowns for use with the Straumann® Variobase® for CEREC® abutments are to be designed using Sirona inLab software (Version 3.65) or Sirona CEREC Software (Version 4.2) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.</p> | <p>The Straumann n!ce Glass Ceramic A14 Blocks are intended to be ceramic mesostructures cemented to the Ti-base for a two-piece hybrid abutment for single tooth restorations or hybrid abutment crowns, used in conjunction with endosseous dental implant to restore chewing function. The following compatibilities apply:</p> <table border="1" data-bbox="857 850 1198 997"> <thead> <tr> <th colspan="2">Ti Base</th> <th colspan="2">Block</th> </tr> <tr> <th>manufacturer</th> <th>system</th> <th>Reference</th> <th>interface size</th> </tr> </thead> <tbody> <tr> <td rowspan="4">Straumann</td> <td>RC Variobase® for CEREC</td> <td>022.0024</td> <td>L</td> </tr> <tr> <td>NC Variobase® for CEREC</td> <td>022.0025</td> <td>L</td> </tr> <tr> <td>RN Variobase® for CEREC</td> <td>022.0019</td> <td>L</td> </tr> <tr> <td>WN Variobase® for CEREC</td> <td>022.0020</td> <td>L</td> </tr> </tbody> </table> | Ti Base  |  | Block |  | manufacturer | system | Reference | interface size | Straumann | RC Variobase® for CEREC | 022.0024 | L | NC Variobase® for CEREC | 022.0025 | L | RN Variobase® for CEREC | 022.0019 | L | WN Variobase® for CEREC | 022.0020 | L | <p><b>Equivalent</b></p> <p>Straumann n!ce glass ceramic was shown to be substantially equivalent to IPS e.max CAD per K170354 cleared on June 7, 2017.</p> |
| Ti Base                        |   | Block   |  |  |       |  |              |        |           |                |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |   |
| manufacturer                   | system  | Reference   | interface size   |  |       |  |              |        |           |                |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |   |
| Straumann                      | RC Variobase® for CEREC   | 022.0024  | L  |  |       |  |              |        |           |                |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |   |
|                                | NC Variobase® for CEREC   | 022.0025  | L  |  |       |  |              |        |           |                |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |   |
|                                | RN Variobase® for CEREC   | 022.0019  | L  |  |       |  |              |        |           |                |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |   |
|                                | WN Variobase® for CEREC   | 022.0020  | L  |  |       |  |              |        |           |                |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |   |
| <b>Ti-base Material</b>        | Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)  |   | <p><b>Identical</b></p> <p>Same Ti-base is used for subject device</p> |  |       |  |              |        |           |                |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |   |
| <b>Ti-base Diameter (base)</b> | NC: 4.5 mm<br>RC: 4.6 mm<br>RN: 5.0 mm<br>WN: 7.0 mm  |   | <p><b>Identical</b></p> <p>Same Ti-base is used for subject device</p> |  |       |  |              |        |           |                |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |   |
| <b>Ti-base post height</b>     | 4.7 mm  |   | <p><b>Identical</b></p> <p>Same Ti-base is used for subject device</p> |  |       |  |              |        |           |                |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |   |
| <b>Ti-base gingiva height</b>  | NC: 0.65 mm<br>RC: 0.85 mm<br>RN and WN: N/A - defined by the neck of the tissue level implant  |   | <p><b>Identical</b></p> <p>Same Ti-base is used for subject device</p> |  |       |  |              |        |           |                |           |                         |          |   |                         |          |   |                         |          |   |                         |          |   |   |

| Feature                        | Reference Device<br>Variobase for CEREC<br>(K151324)   | Subject Devices<br>Straumann® n!ce Glass<br>Ceramic A14 Blocks | Equivalence<br>Discussion  |
|--------------------------------|--|--|--|
| <b>Coping/ Crown Material</b>  | Compatible with any milling blanks cleared for use with the CEREC MC X and MC XL milling systems (i.e., containing the pre-machined mounting hole). Currently available:<br>inCoris ZI meso (K123664)<br>Ivoclar IPS e.max CAD(K132209)<br>Ivoclar Telio CAD (K093708) | Straumann n!ce Glass Ceramic                                   | <b>Equivalent</b><br><br>Straumann n!ce glass ceramic was shown to be substantially equivalent to IPS e.max CAD per K170354 cleared on June 7, 2017.<br><br>The compatibility of the n!ce glass blocks with the existing IPS e.max CAD milling program is validated as part of this submission |
| <b>Angulation</b>              | 20°  | 20°  | <b>Identical</b>   |
| <b>Compatible CAD software</b> | Sirona inLab software (Version 3.65) or Sirona CEREC Software (Version 4.2)  |  | <b>Identical</b>   |
| <b>Compatible milling unit</b> | Sirona CEREC or inLab MC X or MC XL milling unit.  |  | <b>Identical</b>   |

- Performance Data:** Test data to support the evaluation of the subject n!ce® Glass-Ceramic A14 Blocks has been submitted or referenced as follows:
- Product performance testing per ISO 6872, *Dentistry—Ceramic materials*, ISO 14801, *Dentistry—Implants—Dynamic fatigue test for endosseous dental implants*, FDA guidance *Root-form endosseous dental implants and endosseous dental implant abutments* and ISO 7991, *Glass—Determination of coefficient of mean linear thermal expansion*.
  - Transport and package testing per ISTA 2A and the standards referenced therein.
  - Effects of steam sterilization on product performance consistent with FDA guidance *Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff, Appendix C*.
  - Steam sterilization validation per ISO 17665 series standards
  - Biocompatibility assessment per the ISO 10993 series of standards.
  - Chemical characterization per ISO 10993-18, *Biological evaluation of medical devices—Part 18: Chemical characterization of materials*.
  - Evaluation of shelf life per ASTM F1980, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*.
  - Laboratory processing including Workflow validation, and Machinability of blocks

**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.