DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Dentsply Sirona
Mr. Karl Nittinger
Senior Manager, Regulatory Affairs
221 West Philadelphia Street
Suite 60
York, Pennsylvania 17404

February 24, 2017

Re: K162888
Trade/Device Name: Cercon
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: January 25, 2017
Received: January 26, 2017

Dear Mr. Karl Nittinger:

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)*
K162888

Device Name
Cercon®

Indications for Use *(Describe)*
Cercon® is indicated for all ceramic restorations for anterior and posterior locations, including crowns and 3-unit bridges in anterior and posterior regions.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**SECTION 5. 510(k) SUMMARY**
**for**
Cercon® (K162888)

1. Submitter Information**:**

Dentsply Sirona
221 West Philadelphia Street
Suite 60
York, PA 17404

Contact Person: Karl Nittinger
Telephone Number: 717-849-4424
Fax Number: 717-849-4343

Date Prepared: February 22, 2017

2. Device Name:

- Proprietary Name: Cercon®
- Common Name: zirconia based millable blank
- Classification Name: Porcelain powder for clinical use
- CFR Number: 21 C.F.R. 872.6660
- Device Class: II
- Product Code: EIH

**1.** Predicate Device:

| Predicate Device Name | 510(k) | Company Name |
|---|---|---|
| BruxZir™ Anterior | K143330 | Prismatik Dentalcraft, Inc |

| Reference Device for Biocompatibility and composition | 510(k) | Company Name |
|---|---|---|
| Cercon® Base | K051462 | DeguDent GmbH |
| Cercon® ht | K112152 | DeguDent GmbH |

| Reference Device for specific indications for use statement | 510(k) | Company Name |
|---|---|---|
| CELTRA Press | K161269 | DeguDent GmbH |

4. Description of Device:

The subject device, Cercon® is a partially sintered ceramic blank composed of yttria stabilized zirconium oxide, (yttria stabilized tetragonal zirconia particle, Y-TZP). The subject device, Cercon® is supplied to dental professionals as a blank and then processed by machining and subsequent sintering to fabricate all ceramic restorations. Cercon® blanks are zirconia based millable blanks (yttrium oxide- (yttria-) stabilized zirconium oxide (zirconia) (Y-TZP)) that are used for all ceramic restorations for anterior and posterior locations. Specifically, Cercon® is indicated for all ceramic restorations for anterior and posterior locations, including crowns and 3-unit bridges in anterior and posterior regions.

The subject device, Cercon® is available in various shades (colors) for esthetics. Specifically, the subject Cercon® material is offered in the following shades: A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4 and white.

The sintered restorations which are fabricated using the subject Cercon® material may be veneered with compatible veneering porcelains.

5. Indications for Use:

Cercon® is indicated for all ceramic restorations for anterior and posterior locations, including crowns and 3-unit bridges in anterior and posterior regions.

6. Substantial Equivalence:

The proposed Cercon® has similar indications for use as the predicate BruxZir™ Anterior, K143330. The indications are specifically defined as crowns and 3-unit bridges in anterior and posterior regions. The proposed Cercon® meets the requirement of flexural strength for this indication in accordance with ISO 6872:2015 (Dentistry – Ceramic materials) Type II Class 4 material. See Technological Characteristics for more details.

**Table 5.1 Indications for Use Comparison**

| **Proposed Device Cercon® K162888** | **Primary Predicate Device BruxZir™ Anterior K143330** | **Secondary Predicate Device CELTRA Press K161269** | **Differences** |
|---|---|---|---|
| Indications for Use: Cercon® is indicated for all ceramic restorations for anterior and posterior locations, including crowns and 3-unit bridges in anterior and posterior regions. | Indications for Use: The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location. | Indications for Use: CELTRA Press is an all-ceramic system for the creation of<br>Occlusal veneers<br>Thin veneers<br>Veneers<br>Inlays<br>Onlays<br>Crowns in the anterior and posterior region<br>3-unit bridges in the anterior and posterior region<br>3-unit bridges in the premolar region up to the second premolar as the terminal abutment<br>Crown, splinted crown or 3 unit bridge up to the second premolar placed on top of an implant abutment. | The Indications for Use for the proposed device, Cercon® includes additional clarity and are specifically defined as intended for use in the fabrication of crowns and 3-unit bridges in anterior and posterior regions. |

**Composition comparison**

The proposed device, Cercon® is primarily composed of Zirconium Oxide ($ZrO_2$). Though the exact composition of the predicate BruxZir™ Anterior, K143330 is not available; the 510(k) Summary for the BruxZir™ Anterior 510(k) K143330 describes the predicate as zirconia milling blanks which are the same as the proposed device, Cercon®.

The proposed device, Cercon® consists of the same base (primary) composition as previously cleared devices, Cercon® Base (K051462) and Cercon® ht (K112152). Base composition for the proposed device Cercon® as well as reference devices Cercon® Base (K051462) and Cercon® ht (K112152) is Zirconium Oxide ($ZrO_2$).

Technological Characteristics:

The proposed device, Cercon® was classified and tested in accordance with ISO 6872:2015 (Dentistry – Ceramic materials). Cercon® classification and clinical usage is noted below:

Type II: All other forms of ceramic products

Class 4:

Class 4a: Monolithic ceramic for three-unit prostheses involving molar restoration

Class 4b: Partially or fully covered substructure for three-unit prostheses involving molar restoration

**Table 5.3 Physical Properties per ISO 6872 standard**

| Physical Properties ISO 6872 | Proposed Device Cercon® K162888 | Predicate Device BruxZir™ Anterior K143330 | ISO 6872:2015 Type II Class 4 | Differences |
|---|---|---|---|---|
| Flexural strength | Meets requirements per ISO 6872:2015 | Meets requirements, per ISO 6872:2008 | Meets requirements per ISO 6872:2015 | The proposed device Cercon® is a Type II class 4 device in accordance with ISO 6872:2015 standard while the primary predicate BruxZir™ Anterior, K143330 is a Type II class 6 (per 510(k) summary) in accordance with ISO 6872:2008 standard. Both the proposed device Cercon® and the predicate device, BruxZir™ Anterior (K143330) meet the requirements for the appropriate type and class for its clinical usage. The secondary predicate, CELTRA Press (K161269) is a type II class 4 material per ISO 6872:2015 and meets the requirements for its indications for use same as the proposed device, Cercon®. |
| Chemical solubility | Meets requirements per ISO 6872:2015 | Not listed | Meets requirements per ISO 6872:2015 | |
| Coefficient of thermal expansion, CTE | A4<br>$10.1x10^{-6}\,K^{-1}$ (25-500°C)<br>$10.2x10^{-6}K^{-1}$ (25-600°C)<br>C4<br>$10.0x10^{-6}\,K^{-1}$ (25-500°C)<br>$10.1x10^{-6}K^{-1}$ (25-600°C) | $11 \times 10^{-6}$ / K<br>(100-500°C) | $9.80\pm0.06 \times 10^{-6}\,K^{-1}$<br>(25°C-500°C) | |
| Radioactivity | Meets requirements per ISO 6872:2015 | Not listed | Meets requirements per ISO 6872:2015 | |
| Uniformity | Meets requirements per ISO 6872:2015 | Not listed | Not listed | |
| Mixing and Condensation Properties of type I ceramics | Not applicable | Not listed | Not listed | |
| Shrinkage factor | Meets requirements per ISO 6872:2015 | Not listed | Not listed | |
| Glass transition temperature | Not applicable | Not listed | Not listed | |
| Freedom from extraneous materials | Meets requirements per ISO 6872:2015 | Not listed | Not listed | |
| Fracture Toughness | Meets requirements per ISO 6872:2015 | Not listed | Not listed | |

Both the proposed device Cercon® and the predicate device, BruxZir™ Anterior (K143330) meet the requirements for the appropriate type and class for its clinical usage. The secondary predicate, CELTRA Press (K161269) is a type II class 4 material per ISO 6872:2015 and meets the requirements for its indications for use same as the proposed device, Cercon®. The strength of the proposed Cercon® meets the requirement for ISO 6872:2015 for the defined indications for use.

7. Non-Clinical Performance Data:

Physical properties

In accordance with ISO 6872:2015 (Dentistry – Ceramic materials), the product must meet the requirements for the appropriate type and class for its clinical usage. Both the proposed device, Cercon®, and the predicate device, BruxZir™ Anterior (K143330), meet the requirements of the applicable type and class for its clinical usage (Table 5.3).

In addition to ISO testing, verification testing on finished restorations fabricated with the Cercon material was conducted.. All restorations were milled and sintered in accordance with the directions instructions for use and visual inspection for cracks was performed. All finished dental restorations were found to be crack-free.

Comparative evaluation of finished restorations fabricated using the subject Cercon® material and the predicate Cercon ht (K112152) material was also conducted. The restorations were evaluated for fit, margin, surface quality, and overall impression of dental objects (dental restorations). Results of the evaluation met the predetermined acceptance criteria.

The performance of the proposed device, Cercon® satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence.

Biocompatibility Testing

Cytotoxicity testing according to ISO 10993-5 (Biological evaluation of medical devices) was completed to characterize the biocompatibility of the proposed device Cercon®. In addition, previously cleared devices (Cercon® Base, K051462 and Cercon® ht, K112152) were utilized to support biocompatibility for the proposed device Cercon®. Results of the testing support the biocompatibility of proposed device, Cercon®.

8. Clinical Performance Data:

Not applicable. No data from human clinical studies has been included to support the substantial equivalence of the proposed device, Cercon®.

9. Conclusion Regarding Substantial Equivalence:

The comparative information included in this section regarding the proposed device, Cercon®, supports substantial equivalence to the predicate device, BruxZir™ Anterior cleared under premarket notification K143330 . Substantial equivalence of the subject Cercon device is supported by the following determinative factors:

- It has the same intended use and incorporates the same fundamental technology as the primary predicate device (BruxZir™ Anterior, K143330).
- It has the same specific indications for use as secondary predicate device (CELTRA Press, K161269).
- It has the same base (primary) composition Zirconium Oxide ($ZrO_2$) as the reference devices Cercon® Base (K051462) and Cercon® ht (K112152).
- It has similar technological characteristics as the predicate. The proposed device, Cercon® as well the predicate device, BruxZir™ Anterior, K143330 meet the requirement of the related type and class for its usage.