October 24, 2024

Dentsply Sirona
Rebecca Sporer
Principal Regulatory Affairs Specialist
221 West Philadelphia Street
Suite 60W
York, Pennsylvania 17401

Re: K242462
Trade/Device Name: CEREC Cercon 4D CAD/CAM Blocks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: August 19, 2024
Received: August 19, 2024

Dear Rebecca Sporer:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242462

Device Name

CEREC Cercon 4D CAD/CAM Blocks

Indications for Use *(Describe)*

Indications for CEREC Cercon 4D CAD/CAM Blocks are:
-Crowns and bridges in the posterior and anterior tooth region
- Bridges with a maximum of two pontics
- Inlays, onlays and veneers

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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Dentsply Sirona
221 West Philadelphia Street Suite
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K242462 - 510(k) SUMMARY
for
CEREC Cercon 4D™ CAD/CAM Blocks

1. Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

Contact Person: Rebecca Sporer
Telephone Number: 717-849-4793
Email: rebecca.sporer@dentsplysirona.com
Date Prepared: 15 October 2024

2. Device Name:

- Trade Name: CEREC Cercon 4D™ CAD/CAM Blocks
- Common Name: Zirconia Blocks
- Classification Name: Porcelain powder for clinical use
- CFR Number: 872.6660
- Device Class: Class II
- Primary Product Code: EIH

3. Predicate/Reference Devices:

Primary Predicate Device	**510(k)**	**Company Name**
inCoris TZI	K123545	Dentsply Sirona
Predicate Device		
KATANA Zirconia Block	K190436	Kuraray Noritake Dental Inc.

Reference Device Name	**510(k)**	**Company Name**
CEREC Cercon 4D™ Abutment Block, CEREC Cercon 4D™ Abutment System	K234018	Dentsply Sirona
Cercon	K162888	Dentsply Sirona

4. Description of Device:

CEREC Cercon 4D™ CAD/CAM Block are pre-sintered zirconia blocks composed of yttria stabilized zirconia, which are designed for CAD/CAM milling. The proposed CEREC Cercon 4D™ CAD/CAM Blocks possess a 3-dimensional contour of dentine powder to mimic the natural tooth build-up. The aim of the 3D contour technology is to achieve more aesthetic restorations than with blocks based on the current multi-layer technology.

The CEREC Cercon 4D™ CAD/CAM Blocks are used for fabrication of a dental restoration. The CEREC Cercon 4D™ CAD/CAM Blocks are not provided as the finished, fully finished dental restoration. The blocks are single use, meaning that they can only be milled once and are not recommended for re-milling. The blocks are materials supplied to dental professionals that must be further processed/manufactured using CAD/CAM milling and subsequent sintering to fabricate all ceramic restorations and they are not intended to be reused as in the context of direct patient-applied devices and materials. Therefore, no reprocessing, cleaning or disinfection instructions apply because it is a dental material and not a finished dental restoration itself. After sintering of the restoration, the dental professional will finish the restoration via polishing or glazing, before insertion into the patient's mouth.

5. Indications for Use:

   Indications for CEREC Cercon 4D™ CAD/CAM Blocks are:

   - Crowns and bridges in the posterior and anterior tooth region.
   - Bridges with a maximum of two pontics
   - Inlays, onlay and veneers

6. Substantial Equivalence:

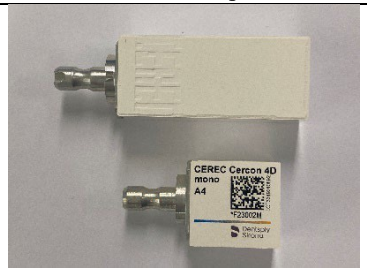
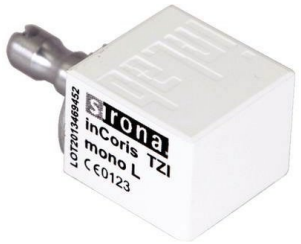
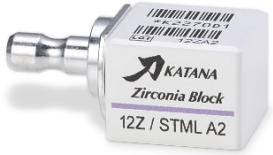
   The Indications for Use of the proposed device is similar to the primary predicate and predicate devices. Refer to Table 6.1 for a comparison.

Table 6.1-Comparison of Indications for Use			
Proposed Device CEREC Cercon 4D™ CAD/CAM Blocks	**Primary Predicate Device inCoris TZI (K123545)**	**Predicate Device KATANA Zirconia Blocks (K190436)**	**Discussion**
Indications for CEREC Cercon 4D™ CAD/CAM Blocks are: • Crowns and bridges in the posterior and anterior tooth region • Bridges with a maximum of two pontics • Inlays, onlays and veneers	Classic and Speed Sintering: Fully anatomic crowns and bridges in the posterior and anterior tooth regions. Bridges with maximum two pontics. Super Speed Sintering: Fully anatomic crowns.	KATANA Zirconia Blocks is used for the fabrication of the ceramic restorations (frameworks, FCZ crowns, FCZ bridges (14Z L), inlays, onlays and veneers).	The proposed and primary predicate have similar Indications for Use. They both are indicated for crowns and bridges in the posterior and anterior tooth regions and bridges with maximum of two pontics. The proposed and predicate have similar indications for crowns, bridges, inlay, onlays and veneers.

7. Technological Characteristics:

The proposed CEREC Cercon 4D™ CAD/CAM Blocks are similar in Indications for Use, design and principles of operation when compared to the primary predicate, inCoris TZi (K123545) and the predicate, KATANA Zirconia Block (K190436). Table 7.1 compares the technological characteristics of the proposed device compared to the primary predicate and predicate devices.

Table 7.1: Comparison between the proposed CEREC Cercon 4D™ CAD/CAM Blocks, the primary predicate device inCoris TZI (K123545) and predicate device KATANA Zirconia Block (K190436)

Item of Comparison	Proposed Device CEREC Cercon 4D™ CAD/CAM Blocks	Primary Predicate Device inCoris TZI (K123545)	Predicate Device KATANA Zirconia Block (K190436)	Similarities and Differences
Product Code	EIH	EIH	EIH	Same
Manufacturer	Dentsply Sirona	Dentsply Sirona	Kuraray Noritake Dental Inc.	The proposed and primary predicate devices are manufactured at different Dentsply Sirona (owner/ operator) facilities. The predicate device is a competitor product.
Restoration	Crowns, Bridges, Inlays, Onlays or Veneers	Crowns or Bridges	Crowns, Bridges, Inlays, Onlays or Veneers	Similar. The proposed and predicate device are indicated for the fabrication of the same type of restorations. The primary predicate is only indicated for crowns and bridges.
Material	Zirconia	Zirconia	Zirconia	Same. The proposed, primary predicate and predicate devices are all zirconia material.
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same
Biocompatibility	Meets ISO 10993 requirements	Meets ISO 10993 requirements	Meets ISO 10993 requirements	Same
Design				Same. The proposed and predicate devices are all shaped like a block

The reference devices, CEREC Cercon 4D™ Abutment Block, CEREC Cercon 4D™ Abutment System (K234018) and Cercon (K162888) are included to support the composition of the block material. The composition of the proposed device is similar to the composition of the reference devices, CEREC Cercon 4D™ Abutment Block, CEREC Cercon 4D™ Abutment System (K234018) and Cercon (K162888). The main difference in composition is the yttrium oxide ranges due to the 3-dimensional contour of dentine powder to mimic the natural tooth build-up which achieves a more aesthetic restorations based on the multi-layer technology. The proposed and reference devices both contain pigments for shading esthetics.

8. Non-Clinical Performance Data:

Performance Bench Testing:
The proposed CEREC Cercon 4D™ CAD/CAM Blocks was tested and conforms to:

- ISO 6872:2015 Amd 1. 2018 *Dentistry Ceramic Materials*
- ISO 9693:2019 *Dentistry - Compatibility testing for metal-ceramic and ceramic-ceramic systems*

Table 8.1 summarizes the bench testing conducted on the proposed device according to ISO 6872:2015 Amd 1. 2018. Table 8.2 summarizes the bench testing conducted on the proposed device according to ISO 9693:2019.

Table 8.1: Performance Bench Testing according to ISO 6872:2015 Amd. 1. 2018

Test Performed	Test Method/Applicable Standard	Results
Flexural Strength	ISO 6872:2015 Amd 1. 2018 *Dentistry Ceramic Materials* Class 5 Type II material	Pass
CTE (Coefficient of Thermal Expansion)		Pass
Solubility		Pass
Radioactivity		Pass
Shrinkage factor		Pass
Uniformity		Pass
Freedom from extraneous materials		Pass

Table 8.2: Performance Bench Testing according to ISO 9693:2019

Test Performed	Test Method/Applicable Standard	Results
De-bonding / crack-initiation	ISO 9693:2019 *Dentistry - Compatibility testing for metal-ceramic and ceramic-ceramic systems*	Pass
Thermal shock resistance		Pass

Biocompatibility Testing:

A biological risk assessment was conducted on the proposed device, CEREC Cercon 4D™ CAD/CAM Blocks. Review of available information on raw materials, manufacturing processes, chemical characterization tests and existing preclinical biological testing data concludes that the test results meet the requirements of the following ISO 10993 standard series.

The following biological tests were conducted:

- ISO 7405: 2018 *Dentistry-Evaluation of biocompatibility of medical device used in dentistry*
- ISO 10993-1:2018 *Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process*
- ISO 10993-5:2009 *Biological Evaluation of Medical Devices-Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-10:2021 *Biological Evaluation of Medical Devices-Part 10: Test for Skin Sensitization*
- ISO 10993-18:2020 *Biological Evaluation of Medical Devices-Part 18: Chemical Characterization of Medical Device Within a Risk Management Process*
- ISO 10993-23:2021 *Biological Evaluation of Medical Device-Part 23: Test for Irritation*
- USP <151> *Pyrogen Test (USP Rabbit Test)*

Conclusion:

Minor differences in the technological characteristics between the proposed, primary predicate, predicate and reference devices were evaluated through performance bench testing. Minor differences in formulation between the proposed and reference device, was evaluated through biocompatibility testing. Testing results demonstrated that the proposed CEREC Cercon 4D™ CAD/CAM Blocks does not raise new questions regarding safety and effectiveness. Therefore, the nonclinical testing data supports that the CEREC Cercon 4D™ CAD/CAM Block is substantially equivalent to the predicate devices.

9. Clinical Performance Data:

   No data from human clinical studies has been included to support the substantial equivalence of the proposed CEREC Cercon 4D™ CAD/CAM Blocks.

10. Conclusion Regarding Substantial Equivalence:

    CEREC Cercon 4D™ CAD/CAM Blocks have similar Indications for Use as the primary predicate and the predicate devices. CEREC Cercon 4D™ CAD/CAM Blocks incorporates the same fundamental technology as the primary predicate and predicate devices. The composition of the proposed CEREC Cercon 4D™ CAD/CAM Blocks is similar to the composition of the reference devices. Test data is included in this premarket notification to verify the safety and performance requirements of the proposed device and the results support a conclusion of substantial equivalence.