August 28, 2024

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

Re: K241557
Trade/Device Name: Cercon® yo ML
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 31, 2024
Received: May 31, 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.

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241557

Device Name

Cercon® yo ML

Indications for Use *(Describe)*

Cercon® yo ML is indicated in the anterior and posterior segments for:
- Crowns
- Multi-unit bridges (with a maximum of two pontics between abutment crowns)
- 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.

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Dentsply Sirona
221 West Philadelphia Street Suite
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510(k) SUMMARY
for
Cercon® yo ML

K241557

1. Submitter Information:

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

Contact Person: Rebecca Sporer
Telephone Number: 717-849-4793
Email address: Rebecca.sporer@dentsplysirona.com

Date Prepared: 31 May 2024

2. Device Name:

Proprietary Name:	Cercon® yo ML
Classification Name:	Porcelain powder for clinical use
CFR Number:	21 CFR 872.6660
Device Class:	2
Product Code:	EIH

3. Predicate Device:

Primary Predicate Device Name	510(k)	Company Name
Cercon	K162888	Dentsply Sirona

Predicate Device Names	510(k)	Company Name
CELTRA Press	K161269	Dentsply Sirona
Cercon ht	K112152	Dentsply Sirona

Reference Device Name Technological Characteristics and Formulation	510(k)	Company Name
CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System	K234018	Dentsply Sirona

4. Description of Device:
   The proposed Cercon® yo ML is a partially sintered ceramic blank composed of yttrium oxide-(yttria-) stabilized zirconium oxide (zirconia) (Y-TZP). Cercon® yo ML is a multilayer disk built out of different shade layers and yttrium oxide contents which create a natural gradient of the restoration after sintering. The proposed device is supplied to dental professionals as a blank and then processed by machining and subsequent sintering to fabricate dental ceramic restorations.

5. Indications for Use:
   Cercon® yo ML is indicated in the anterior and posterior segments for:
   - Crowns
   - Multi-unit bridges (with a maximum of two pontics between abutment crowns)
   - Inlays, onlays and veneers

6. Comparison of Intended Use and Indications for Use and Technological Characteristics:
   The Indications for Use of the proposed device do not constitute a new intended use. The proposed Cercon® yo ML has the same intended use and similar Indications for Use compared to the primary predicate and predicate devices in that they are a ceramic intended for fixed dental prosthetic restorations. Table 6.1 compares the Intended Use and Indications for Use when cared to the predicate devices.

Table 6.1:Comparison of Intended Use and Indications for Use of the proposed and predicate devices					
	Proposed Device Cercon® yo ML (K241557)	**Primary Predicate Device Cercon® (K162888)**	**Predicate Devices**		**Discussion**
			CELTRA Press (K161269)	**Cercon® ht (K112152)**	
Intended Use	Cercon® yo ML blanks are a ceramic intended for fixed dental prosthetic restorations.	Cercon® are a ceramic intended for fixed dental prosthetic restorations.	CELTRA Press are a ceramic intended for fixed dental prosthetic restorations.	Cercon® ht are a ceramic intended for fixed dental prosthetic restorations.	Same
Indications for Use	Cercon® yo ML is indicated for in the anterior and posterior segments for: • Crowns • Multi-unit bridges (with a maximum of two pontics between abutment crowns) • Inlays, onlays and veneers	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: CELTRA Press is an all ceramic system for the creation of Occlusal veneers Thin veneers Veneers Inlays Onlays Crowns in the anterior and posterior region 3-unit bridges in the anterior and posterior region 3-unit bridges in the premolar region up to the second premolar as the terminal abutment Crown, splinted crown or 3 unit bridge up to the second premolar placed on top of an implant abutment.	Cercon® ht is indicated in the anterior and posterior segments for: • Crowns • telescopic primary crowns • multi-unit bridges (with no more the two pontics between abutment crowns)	The proposed, primary predicate, and predicate devices share the indication for crowns and bridges with applications in the anterior and posterior locations. The proposed, primary predicate and predicate devices share an indication for multi-unit bridges (e.g. 3-unit bridges). The proposed and predicate (Celtra Press [K161269]) devices are both indicated for inlays, onlays and veneers. The proposed device does not include an indication for telescopic primary crowns.

7. Comparison of Technological Characteristics:

The proposed Cercon® yo ML is similar in design, principles of operation and meet the requirements of ISO 6872 and ISO 9693 when compared to the primary predicate device, Cercon (K162888), and the predicate devices, CELTRA Press (K161269) and Cercon ht (K112152). When comparing the material, the proposed, primary predicate, predicate (Cercon ht [K112152]) and reference devices are all zirconia material whereas the predicate (Celtra Press [K161269]) device is a lithium silicate glass material. The proposed Cercon® yo ML is similar in composition to the primary predicate (Cercon [K162888]), the predicate (Cercon ht [K112152]) and the reference (CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System [K234018]) devices with the main difference in pigment used for esthetics (shade preference). Table 7.1 compares the technological characteristics of the proposed, Cercon® yo ML to the predicates and reference devices.

Table 7.1: Technological Characteristics Comparison between the proposed Cercon® yo ML, the primary predicate device Cercon® (K162888), predicates CELTRA Press (K161269) and Cercon® ht (K112152), and the reference device CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018)

Item of Comparison	Proposed Cercon® yo ML (K241557)	Primary Predicate Cercon® (K162888)	Predicate Devices		Reference Device	Similarities and Differences
			CELTRA Press (K161269)	Cercon® ht (K112152)	CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018)	
Product Code	EIH	EIH	EIH	EIH	NHA, PNP	Similar. The reference device, CEREC Cercon 4D Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018) is cleared under a different product code as it is marketed as a system. The block material within the system is processed and compatible with implant systems and TiBases.
Manufacturer	Dentsply Sirona	Dentsply Sirona	Dentsply Sirona	Dentsply Sirona	Dentsply Sirona	Same
Restoration	Single and multi-unit	Single and multi-unit	Single and multi-unit	Single and multi-unit	Single unit	Similar. The reference device, CEREC Cercon 4D Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018) is only used for single restorations.

Table 7.1:Technological Characteristics Comparison between the proposed Cercon® yo ML, the primary predicate device Cercon® (K162888), predicates CELTRA Press (K161269) and Cercon® ht (K112152), and the reference device CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018)						
Item of Comparison	**Proposed Cercon® yo ML (K241557)**	**Primary Predicate Cercon® (K162888)**	**Predicate Devices**		**Reference Device**	**Similarities and Differences**
			CELTRA Press (K161269)	**Cercon® ht (K112152)**	**CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018)**	
Material	Zirconia	Zirconia	Lithium silicate glass	Zirconia	Zirconia	Same except when compared to the predicate Celtra Press (K161269) which is a lithium silicate glass.
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Same
Biocompatibility	Meets ISO 10993 requirements	Meets ISO 10993 requirements	Meets ISO 10993 requirements	Meets ISO 10993 requirements	Meets ISO 10993 requirements	Same
Flexural Strength	>800 MPa per ISO 6872:2015 Type II Class 5	>500MPa per ISO 6872:2015 Type II Class 4	>500 MPa per ISO 6872:2015 Type II Class 4	>800MPa per ISO 6872:2008 Type II Class 6	>800 MPa per ISO 6872:2015 Type II Class 5	The proposed device has a higher flexural strength when compared to the primary predicate and the predicate device, Celtra Press (K161269) per the type and class defined in ISO 6872:2015. The proposed device is comparable in strength to the predicate, Cercon ht (K112152), and the reference device, CEREC Cercon 4D Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018).
Design	Disk	Disk	Ingot	Disk	Block	The proposed, primary predicate, and the predicate [Cercon ht (K112152)] devices are designed as a disk. The predicate, Celtra

Table 7.1:Technological Characteristics Comparison between the proposed Cercon® yo ML, the primary predicate device Cercon® (K162888), predicates CELTRA Press (K161269) and Cercon® ht (K112152), and the reference device CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018)						
Item of Comparison	**Proposed Cercon® yo ML (K241557)**	**Primary Predicate Cercon® (K162888)**	**Predicate Devices**		**Reference Device**	**Similarities and Differences**
			CELTRA Press (K161269)	**Cercon® ht (K112152)**	**CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018)**	
						press (K161269) is designed as an ingot and the refence device, CEREC Cercon 4D Abutment Blocks, CEREC Cercon 4D™ Abutment System (K234018) is a block.

8. Non-Clinical Performance Data:

Performance Bench Testing:
The proposed device 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**	**Acceptance Criteria**	**Results**
Flexural Strength	ISO 6872:2015 Amd 1. 2018 *Dentistry Ceramic Materials* Class 5 Type II material	≥800 MPa	Pass
CTE (Coefficient of Thermal Expansion)		The CTE of the ceramics shall not deviate by more than 0.5 x $10^{-6}K^{-1}$ from the value stated by the manufacturer.	Pass
Solubility		<100µg/cm^2 for each tested shade	Pass
Radioactivity		<1.0 Bq/g of ^{238}U	Pass
Shrinkage factor		Absolute Accuracy ± 0.002	Pass
Uniformity		Pigments shall be uniformly dispersed	Pass
Freedom from extraneous materials		Free from extraneous materials when assessed by visual inspection and radioactivity measurement	Pass

Table 8.2: Performance Bench Testing according to ISO 9693:2019			
Test Performed	**Test Method/Applicable Standard**	**Acceptance Criteria**	**Results**
De-bonding / crack-initiation	ISO 9693:2019 *Dentistry - Compatibility testing for metal-ceramic and ceramic-ceramic systems*	>20 MPa zirconia material with at least one specified dental veneering ceramic	Pass
Thermal shock resistance		Meet critical quenching temperature of at least 120 °C	Pass

Biocompatibility Testing:

A biological risk assessment was conducted on the proposed device, Cercon® yo ML. 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 and primary predicate devices were evaluated through performance bench testing. Minor differences in formulation between the proposed, primary predicate, predicate [Cercon ht (K112152)] and reference devices was evaluated through biocompatibility testing. Testing results demonstrated that the proposed device does not raise new questions regarding safety and effectiveness. Therefore, the nonclinical testing data supports the conclusion that the proposed device performs as well as the primary predicate, predicates and reference devices.

9. Clinical Performance Data:

   No data from human clinical studies has been included to support the substantial equivalence of the proposed Cercon® yo ML.

10. Conclusion Regarding Substantial Equivalence:

    Cercon® yo ML has the same intended use and similar Indications for Use as the primary predicate (Cercon [K162888]) and the predicates (Celtra Press [K161269] and Cercon ht [K112152]). Cercon® yo ML incorporates the same fundamental technology as the primary predicate (Cercon [K162888]) and the predicate (Cercon ht [K112152]) and the reference device (CEREC Cercon 4D™ Abutment Blocks, CEREC Cercon 4D™ Abutment System [K234018]). The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well or better than the legally marketed primary predicate, predicates and reference devices.