DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Dentsply Sirona
Helen Lewis
Director Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

August 16, 2016

Re: K161269
Trade/Device Name: CELTRA Press
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: Class II
Product Code: EIH
Dated: July 5, 2016
Received: July 6, 2016

Dear Ms. Helen Lewis:

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" (21CFR 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

Tina Kiang, Ph.D.
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
CELTRA Press

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

SECTION 5. 510(k) SUMMARY
for
CELTRA Press

Submitter Information**:**

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

Contact Person: Helen Lewis
Telephone Number: 717-487-1332
Fax Number: 717-849-4343

Date Prepared: 24 June 2016

Device Name:

- Proprietary Name: CELTRA Press
- Common Name: All-ceramic system
- Classification Name: Porcelain powder for clinical use
- CFR Number: 21 C.F.R. 872.6660
- Device Class: II
- Product Code: EIH

Predicate Device:

Predicate Device Name	510(k)	Company Name
IPS e.max Press and IPS e.max Press Multi	K120134	Ivoclar Vivadent AG
Reference Device for Biocompatibility Quattro Porcelain System	K091706	DENTSPLY Prosthetics

Description of Device:

CELTRA Press is a high-strength zirconia-reinforced lithium silicate glass ceramic material that can be used for the fabrication of highly aesthetic all-ceramic restorations by using the hot-pressing technique in dental labs. The homogeneous, industrially produced ingots are available in both high and low translucency for full-contour application. They are pressed in pressing furnaces using press investments material which do not form surface reaction layer to obtain tooth-colored, highly aesthetic, all-ceramic restorations. Subsequently, CELTRA Press may be veneered, stained and/or glazed with compatible CELTRA Press veneering porcelains.

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.

Substantial Equivalence:

The proposed CELTRA Press has the similar indications for use as the predicate IPS e.max Press and IPS e.max Press Multi (K120134) with the exception of an indication for 3-unit bridges in the posterior region. The proposed CELTRA Press meets the requirement of flexural strength for this indication in accordance with ISO 6872:2015 (Dentistry – Ceramic materials).

Proposed Device CELTRA Press system	**Predicate Device IPS e.max Press and IPS e.max Press Multi, K120134**	**Differences**
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.	Indications for Use: IPS e.max Press and IPS e.max Press Multi 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 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.	The proposed device CELTRA Press is indicated for 3-unit posterior bridges while the predicate IPS e.max Press and IPS e.max Press Multi, K120134 is not indicated for this use based on its ISO 6872 standard classification.

Technological Characteristics:

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

Type II: All other forms of ceramic products
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

Physical Properties ISO 6872	Proposed Device CELTRA Press	Predicate Device IPS e.max Press and IPS e.max Press Multi, K120134	Differences
Type and Classification	Conforms to ISO 6872	Conforms to ISO 6872	The proposed device CELTRA Press is a Type II class 4 device which requires a minimum mean flexural strength of 500MPa while the predicate IPS e.max Press and IPS e.max Press Multi, K120134 is a Type II class 3 devices based on its ISO 6872 standard classification.
Flexural Strength			
Chemical Solubility			
Coefficient of Thermal Expansion, CTE			
Radioactivity			

The strength of the proposed CELTRA Press meets the requirement for Type II Class 4 (materials with a minimum mean flexural strength of 500 MPa), which by definition includes three unit prostheses.

Non-Clinical Performance Data:

Physical Properties:
In accordance with ISO 6872:2015 (Dentistry – Ceramic materials), the product must meet the requirements for flexural strength, chemical solubility, coefficient of thermal expansion, and radioactivity. Both CELTRA Press and predicate IPS e.max Press and IPS e.max Press Multi (K120134) meet the requirements of the applicable Class, as detailed in Table under Technological Characteristics. The performance of CELTRA Press meets the requirements of the non-clinical bench testing conducted to support substantial equivalence.

Toxicological Testing;
Testing according to ISO 10993-1, 10993-5 and 10993-18 (Biological evaluation of medical devices) was completed to characterize the biocompatibility of CELTRA Press. Results of the testing conducted in accordance with ISO standard support the biocompatibility of CELTRA Press. CELTRA Press veneering porcelains (accessory) were compared to reference device, Quattro Porcelain System (K091706) for biocompatibility purposes.

Clinical Performance Data.

Not applicable. No data from human clinical studies has been included to support the substantial equivalence of the CELTRA Press.

Conclusion Regarding Substantial Equivalence

CELTRA Press supports substantial equivalence to the predicate IPS e.max Press and IPS e.max Press Multi cleared under premarket notification K120134 because:

- It has the similar intended use as the predicate
- Has similar technological characteristics as the predicate, with the exception of flexural strength. CELTRA Press meets the requirement of flexural strength for Type II, Class 4 materials.