January 20, 2021

Dentsply Sirona
Karl Nittinger
Director, Regulatory Affairs
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

Re: K202629
Trade/Device Name: Dentsply Sirona Universal Spray Glazes
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: October 21, 2020
Received: October 22, 2020

Dear 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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

For Michael Adjodha
Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202629

Device Name
Dentsply Sirona Universal Spray Glazes

Indications for Use *(Describe)*
Dentsply Sirona Universal Spray Glazes are aerosol glazing porcelains used to glaze high-strength glass ceramic and zirconia dental restorations. The glaze sprays are applied to restorations and fired.

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 60W
York, PA 17401

510(k) SUMMARY
K202629
Dentsply Sirona Universal Spray Glazes

1. Submitter Information**:**

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

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

Date Prepared: January 6, 2021

2. Device Name:
   - Proprietary Name: Dentsply Sirona Universal Spray Glazes
   - Classification Name: Porcelain powder for clinical use
   - CFR Number: 21 C.F.R. 872.6660
   - Device Class: II
   - Product Code: EIH

3. Predicate Device:

Primary Predicate Device	510(k)	Company Name
CEREC SpeedGlaze	K160099	Sirona Dental Systems GmbH

Reference Devices:

(Reference devices are included to support the biocompatibility of the proposed devices.)

Reference Devices	510(k)	Company Name
Quattro Porcelain System	K091706	Dentsply Sirona
Celtra Press	K161269	Dentsply Sirona
PFZ Porcelain System	K033553	Dentsply Sirona
Cercon Ceram S	K022796	Dentsply Sirona
Duceram Plus Ceramic System	K040420	DeguDent GmbH

4. Description of Device:
The proposed devices, Dentsply Sirona Universal Spray Glazes are sprayable glazing porcelains, intended for glazing the surface of dental restorations. The glazes are supplied to dental professionals in an aerosol can. Different variations of glazes are available to meet the aesthetic preferences of dental professionals and patients. Variations with or without fluorescing agent come in a ready-to-use spray can. Variations are distinguished by the names, “Fluo” or “No Fluo” to designate the presence or absence of fluorescing agents in the product.

No mixing is required by dental professionals as different glaze options (with or without fluorescing agent) are supplied to dental professionals in a ready-to-use form. The addition of the fluorescing agent contributes to a more aesthetic natural looking restoration.

The proposed devices, Dentsply Sirona Universal Spray Glazes, are applied on the surface of the dental restoration (example: fixed dental prostheses such as crown or bridge) in a thin-uniform layer. After initial application, the restoration is then fired in a furnace for further processing. An additional layer of the proposed Dentsply Sirona Universal Spray Glazes can be applied after first firing, if necessary. If additional layer is applied, the dental restoration is placed again in the dental furnace for final firing.

5. Indications for Use:
Dentsply Sirona Universal Spray Glazes are aerosol glazing porcelains used to glaze high-strength glass ceramic and zirconia dental restorations. The glaze sprays are applied to restorations and fired.

6. Substantial Equivalence:
For the purpose of substantial equivalence, the proposed device, Dentsply Sirona Universal Spray Glazes is compared to the legally marketed predicate device CEREC SpeedGlaze (K160099) manufactured by Sirona Dental Systems GmbH.

The proposed device Dentsply Sirona Universal Spray Glazes are intended for glazing the surface of dental restorations and thereby have the same intended use as the predicate device CEREC SpeedGlaze (K160099).

Both the predicate and proposed devices have been tested to applicable requirements of ISO 6872 - Dentistry – Ceramic materials.

Table 5.1. details the similarities and differences between the proposed and predicate devices

Table 5. 1 Element	Proposed Device Dentsply Sirona Universal Spray Glazes	Primary Predicate Device CEREC SpeedGlaze	Similarities and Differences
510(k)	**K202629**	**K160099**	**N/A**
Indications for use	Dentsply Sirona Universal Spray Glazes are aerosol glazing porcelains used to glaze high-strength glass ceramic and zirconia dental restorations. The glaze sprays are applied to restorations and fired.	Glazing of individually designed dental restorations from dental ceramics. The CEREC SpeedGlaze Spray is used for coating dental restorations made from Sirona CAD/CAM materials. It is administered extra-orally and is indicated for crowns, inlays, onlays, partial crowns and bridges in the anterior and posterior tooth region.	Both the proposed device Dentsply Sirona Universal Spray Glazes and predicate device CEREC SpeedGlaze (K160099) have similar indications for use and identical intended use as glazing materials. Both devices are aerosol sprays designed for glazing dental restorations. The predicate device CEREC SpeedGlaze further details the use by including the types of dental restorations that can be glazed such as crowns, inlays, etc. The proposed device Dentsply Sirona Universal Spray Glazes have the same use but is worded differently for simplification purposes. The proposed Dentsply Sirona Universal Spray Glazes are marketed to dental professionals. Types of dental restorations are covered under ISO 6872:2015 for Type I Class 1 materials. This is well-known within the dental industry and does not need to be explicitly stated within the indications statement.

Table 5. 1 Element	Proposed Device Dentsply Sirona Universal Spray Glazes	Primary Predicate Device CEREC SpeedGlaze	Similarities and Differences
510(k)	**K202629**	**K160099**	**N/A**
Composition	Major components: oxides Device contains organic components and propellent that is burned-off during the firing process and is not included in the final device.	Major components: oxides Device contains organic components and propellent that is burned-off during the firing process and is not included in the final device.	• Both devices have similar composition for major components. • The organic components and propellent gas are not relevant as they burn-off without residue during firing process. • Minor changes in components have been made to the proposed device Dentsply Sirona Universal Spray Glazes to offer different variations (with and without fluorescing agent).
Application	The glaze is applied by spraying on to the surface of the dental restorations and a firing process is carried out in a dental furnace.	The glaze is applied by spraying on to the surface of the dental restorations and a firing process is carried out in a dental furnace.	Same.
Physical properties	ISO 6872 – Dentistry – Ceramic materials Type 1 Class 1 materials	ISO 6872 – Dentistry – Ceramic materials Type 1, Class 1A materials	Both devices have similar physical properties as glazing materials. Note: there are no specification differences between class 1A and Class 1 (A and B) materials per ISO 6872 standard.
Packaging components	Packaged in a spray can with cap.	Packaged in a spray can with cap.	All packaging components are the same.
Shelf life / Storage	3.5 years Avoid exposure to temperatures exceeding 50°C / 122 °F.	3.5 years Avoid exposure to temperatures exceeding 50°C / 122 °F.	Same.

7. Non-Clinical Performance Data

Physical Properties:

The proposed device, Dentsply Sirona Universal Spray Glazes, and the predicate device, CEREC SpeedGlaze (K160099), have been tested per ISO 6872 – Dentistry
– Ceramic materials.

The test samples used for performance testing included highest possible % of the components. The test samples contained fluorescing agent at the highest possible % despite not having any effect on the performance testing. Data derived from testing is included to support the conclusion that the proposed device Dentsply Sirona Universal Spray Glaze is equivalent to the predicate device CEREC SpeedGlaze (K160099).

Table 5.2. Summary of similarities and differences between the proposed and predicate devices

Table 5.2 ISO 6872 Test Requirement of the proposed and predicate devices

ISO 6872 Test Requirement	Proposed Device Dentsply Sirona Universal Spray Glazes	Predicate Device CEREC SpeedGlaze K160099*	Specification limit ISO 6872:2015 Type I Class 1
Uniformity	Meets criteria	Not reported	Visual inspection
Freedom from extraneous material	Meets criteria	Not reported	Visual inspection
Linear Thermal Expansion Coefficient, CTE	Meets criteria	$7.5 \times 10^{-6} K^{-1} \pm 0.5 \times 10^{-6} K^{-1}$	No specification limit Acceptance criteria is defined as: The coefficient of thermal expansion shall not deviate by more than $0.5 \times 10^{-6} K^{-1}$ from the value stated by the manufacturer
Glass Transition Temperature	Meets criteria	490° C ± 10°C	No specification limit Acceptance criteria is defined as: The glass transition temperature shall not deviate by more than 20°C from the value stated by the manufacturer
Flexural Strength	Meets criteria >50 MPa	>50 MPa	50 MPa min.
Chemical Solubility	Meets criteria $<100 \mu g/cm^2$	$<100 \mu g/cm^2$	$< 100 \mu g/cm^2$ min
Radioactivity	Meets criteria <1 Bq/g U^{238}	<1 Bq/g U^{238}	<1 Bq/g U^{238}

Biocompatibility:

An analysis is included to support the biocompatibility of the proposed device Dentsply Sirona Universal Spray Glazes and its equivalency to the predicate device CEREC SpeedGlaze (K160099). Additional support for biocompatibility included reference to formulation components comprising the reference devices listed in Section 3 of this 510(k) Summary. Confirmatory cytotoxicity test results further support the biocompatibility of the proposed device Dentsply Sirona Universal Spray Glazes conducted in accordance with ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity. The test samples used for the biocompatibility testing included highest possible % of the components inclusive of fluorescing agents.

8. Clinical Performance Data

No data from human clinical studies has been included to support the substantial equivalence of the proposed device, Dentsply Sirona Universal Spray Glazes.

9. Conclusion Regarding Substantial Equivalence

The proposed device Dentsply Sirona Universal Spray Glazes and the predicate device CEREC SpeedGlaze are intended for use as glazing materials. The proposed device has the same intended use as a glazing materials, incorporates the same fundamental technology and has similar major components as the predicate device CEREC SpeedGlaze, K160099.

Both the predicate and proposed devices have similar technological characteristics and were tested to the same ISO 6872:2015 (Dentistry-Ceramic materials) standard and met the same specification requirements of Type I Class 1 materials.

Both the predicate and proposed devices have same packaging components. Spray can / cap are composed of the same materials and packaged in an identical way.

The comparative information, combined with the design and intended use comparison with the predicate device, support substantial equivalence to the proposed device Dentsply Sirona Universal Spray Glazes.