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
Helen Lewis
Director Corporate Regulatory Affairs
221 W Philadelphia St, Suite 60
York, Pennsylvania 17404

September 27, 2016

Re: K162107
Trade/Device Name: Tph Spectra+ Universal Composite Restorative
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: July 28, 2016
Received: July 29, 2016

Dear 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" (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,

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)*

Device Name
TPH Spectra® + Universal Composite Restorative

Indications for Use *(Describe)*
TPH Spectra® + Universal Composite Restorative is indicated for direct or indirect replacement of missing or deficient tooth structure in primary and permanent anterior and posterior teeth, e.g.,

1. Direct anterior and posterior restorations (including occlusal surfaces)
2. Core build-ups
3. Splinting
4. Indirect restorations including inlays, onlays

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 60
York, PA 17404

510(k) SUMMARY
for
TPH Spectra® + Universal Composite Restorative

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: July 28, 2016

Device Name:

- Proprietary Name: TPH Spectra® + Universal Composite Restorative
- Classification Name: Tooth Shade Resin Material
- CFR Number: 872.3690
- Device Class: II
- Product Code: EBF

Predicate Device:

Predicate Device Name	510(k)	Company Name
Filtek™ Supreme Ultra Universal Restorative	K083610	3M ESPE

Description of Device:

TPH Spectra® + Universal Composite Restorative is a visible light cured, radiopaque, composite restorative for anterior and posterior restorations and cosmetic and functional reshaping of primary and permanent teeth. The new device contains methacrylate-based resin, photo initiator, silanated inorganic filler and pigments. Available shades include opaque dentin shades, regular body shades and translucent enamel shades. This restorative provides high strength and low wear for durability.

TPH Spectra® + Universal Composite Restorative is applied to the tooth following use of a methacrylate-based dental adhesive and/or a cement, such as manufactured by DENSTPLY, which permanently bonds the restoration to the tooth structure.

TPH Spectra® + Universal Composite Restorative is packaged in traditional multi-use syringes, for outside-the-mouth dispensing onto a mixing pad, and in pre-dosed Compules® Tips for intraoral dispensing. The restorative composite in Compules® Tips is dispensed using a DENTSPLY Compules® Tips Gun.

Indications for Use:

TPH Spectra® + Universal Composite Restorative is indicated for direct or indirect replacement of missing or deficient tooth structure in primary and permanent anterior and posterior teeth, e.g.,

1. Direct anterior and posterior restorations (including occlusal surfaces)
2. Core build-ups
3. Splinting
4. Indirect restorations including inlays, onlays

Substantial Equivalence:

Technological Characteristics:

Information provided in this 510(k) submission shows that TPH Spectra® + Universal Composite Restorative supports substantial equivalence when compared to the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610) in terms of intended use, indications for use, composition, physical properties and technological characteristics.

Table 5.1 Similarities and Differences between the proposed and the predicate devices

Element	**Predicate Device** Filtek™ Supreme Ultra Universal Restorative	**Proposed Device** TPH Spectra® + Universal Composite Restorative	**Difference**
510(k)	K083610	To be assigned	
Indications for use	• Direct anterior and posterior restorations (including occlusal surfaces) • Core build-ups • Splinting • Indirect restorations including inlays, onlays and veneers	Direct or indirect replacement of missing or deficient tooth structure in primary and permanent anterior and posterior teeth, e.g. 1. Direct anterior and posterior restorations (including occlusal surfaces) 2. Core build-ups 3. Splinting 4. Indirect restorations including inlays, onlays and veneers	"Direct or indirect replacement of missing or deficient tooth structure in primary and permanent anterior and posterior teeth" is a description of the indications in general. Indications of the proposed device are the same as the predicate device. According to ISO 4049, the physical property data support that the proposed device meets the requirements primarily for the direct and indirect restorations.
Composition of Materials	Methacrylate-based resin, photo initiator, fillers and pigments.	Methacrylate-based resin, photo initiator, fillers and pigments.	Chemically similar to the predicate device.
Physical Properties	Radiopacity: 2.10 (0.0) mmAl Fracture Toughness: 1.64 (0.09) $MPa.m^{1/2}$ Fluorescence: similar to a natural tooth. Depth of Cure: 2.60 (0.02) mm Flexural Strength: 131 (14) MPa Flexural Modulus: 10.6 (0.6) MPa Water Sorption: 33.1 (2.1) $\mu g/mm^3$ Water Solubility: 1.0 (0.7) $\mu g/mm^3$ Localized Wear Loss: 0.87 (0.24) $x10^{-2}$ mm^3 Sensitivity to Ambient Light: 135 s Shade and Color Stability: Stable/Pass Stain Resistance: 3.30 (1.06)	Radiopacity: 2.23 (0.08) mmAl Fracture Toughness: 1.71 (0.16) $MPa.m^{1/2}$ Fluorescence: similar to a natural tooth. Depth of Cure: 2.12 (0.02) mm Flexural Strength: 117 (10) MPa Flexural Modulus: 11.6 (0.8) MPa Water Sorption: 19.3 (1.9) $\mu g/mm^3$ Water Solubility: 0 $\mu g/mm^3$ Localized Wear Loss: 0.47 (0.15) $x10^{-2}$ mm^3 Sensitivity to Ambient Light: 180 s Shade and Color Stability: Stable/Pass Stain Resistance: 1.69 (0.25)	Physical property data support substantial equivalence of the proposed device when compared to the predicate device.

Non-Clinical Performance Data:

Biocompatibility Testing:
An evaluation of biocompatibility was performed for the TPH Spectra® + Universal Composite Restorative in accordance with *ISO 10993-1(Biological Evaluation of Medical Devices- Part1: Evaluation and Testing)* and *ISO 7405 (Dentistry – Evaluation of Biocompatibility of Medical Devices used in Dentistry)*. TPH Spectra® + Universal Composite Restorative has been demonstrated as biocompatible for its intended use.

Physical Properties:
In-vitro bench tests were performed on the TPH Spectra® + Universal Composite Restorative including *Radiopacity, Fracture Toughness, Fluorescence, Depth of Cure, Flexural Strength, Flexural Modulus, Water Sorption and Solubility, Localized Wear Loss, and Sensitivity to Ambient Light*. The compressive strength was no evaluated due to the unbonded, free standing failure mode of the test which is clinically irrelevant under real clinical situations. The results indicated that the TPH Spectra® + Universal Composite Restorative meets or exceeds the requirements of *ISO 4049: 2009 (Dentistry -- Polymer-based restorative)* or DENTSPLY internal standards and supports substantial equivalence when compared to the predicate devices on physical properties.

Clinical Performance Data:
No clinical performance data was submitted.

Risk Analysis
The risk analysis of TPH Spectra® + Universal Composite Restorative was conducted by a design Failure Mode and Effects Analysis (FMEA).

As designed, the residual risk of the TPH Spectra® + Universal Composite Restorative is considered acceptable. The benefits of the product are considered to outweigh the risks outlined in the risk analysis.

Conclusion Regarding Substantial Equivalence:
TPH Spectra® + Universal Composite Restorative is a composite which is intended to be used for anterior and posterior restorations and cosmetic and functional reshaping of primary and permanent teeth. The TPH Spectra® + Universal Composite Restorative has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicate Filtek™ Supreme Ultra Universal Restorative cleared under premarket notification K083610. Test data to verify the performance of the TPH Spectra® + Universal Composite Restorative has been provided for Radiopacity, Fracture Toughness, Fluorescence, Depth of Cure, Flexural Strength, Flexural Modulus, Water Sorption and Solubility, Localized Wear Loss, and Sensitivity to Ambient Light.

Combined with the design and intended use comparison with the predicate device, we have determined that the proposed device TPH Spectra® + Universal Composite Restorative supports substantial equivalence when compared to predicate device Filtek™ Supreme Ultra Universal Restorative (K083610).