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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner-S3

For 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
Indications for Use

Device Name
TPH Spectra® ST Flowable Composite Restorative

Indications for Use (Describe)
TPH Spectra® ST Flowable Composite Restorative is indicated for:

- Direct restoration of cavities and lesions
- Filling of defects and undercuts in crowns, inlays, and onlays
- Blockouts
- Repair of defects
- Pit and fissure sealants
- Cementation of light transmissible indirect restorations

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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K182288
510(k) SUMMARY
TPH Spectra® ST Flowable Composite Restorative

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

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

Date Prepared: August 21, 2018

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

Predicate Device:

<table>
<thead>
<tr>
<th>Company</th>
<th>Device</th>
<th>Predicate / Reference</th>
<th>510(k)</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shofu Dental Corporation</td>
<td>Beautiful Flow Plus</td>
<td>Predicate</td>
<td>K101603</td>
<td>EBF</td>
</tr>
<tr>
<td>Dentsply International</td>
<td>Flowable Composite</td>
<td>Reference</td>
<td>K981965</td>
<td>EMA</td>
</tr>
</tbody>
</table>

Description of Device:

TPH Spectra® ST Flowable Composite Restorative is a visible light cured, radiopaque composite resin restorative material with flow characteristics that make it ideal for use in anterior and posterior 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.
TPH Spectra® ST Flowable Composite Restorative is applied to the tooth following use of a methacrylate-based dental adhesive and/or a cement, which bonds the restoration to the tooth structure.

TPH Spectra® ST Flowable Composite Restorative is packaged in multi-use dispensing packages and pre-dosed Compula® Tips for intraoral dispensing.

Indications for Use:
TPH Spectra® ST Flowable Composite Restorative is indicated for:

- Direct restoration of cavities and lesions
- Filling of defects and undercuts in crowns, inlays, and onlays
- Blockouts
- Repair of defects
- Pit and fissure sealants
- Cementation of light transmissible indirect restorations

Substantial Equivalence:

Technological Characteristics:
Information provided in this 510(k) submission supports the substantial equivalence of TPH Spectra® ST Flowable Composite Restorative when compared to the predicate device, Beautifil Flow Plus (K101603), and the reference device, Flowable Composite (K981965), in terms of intended use, indications for use, composition, physical properties and technological characteristics. The subject device has similar indications for use as those cleared for the predicate device (K101603). Both are indicated for direct restoration of cavities and lesions, as well as, repairs. The reference device (K981965), which, like the subject device, is also a methacrylate-based flowable composite material, is included in support of substantial equivalence as it is cleared for the; filling of defects and undercuts in crowns, inlays, and onlays; blockouts; and pit and fissures sealant indications as are included in the indications for use of the subject TPH Spectra® ST Flowable Composite Restorative.

As a tooth shade resin material classified under 21 CFR 872.3690, the subject TPH Spectra® ST Flowable Composite Restorative has the same intended use as the predicate Beautiful Flow Plus (K101603). The subject TPH Spectra® ST Flowable Composite Restorative incorporates the same fundamental technology (low-viscosity, methacrylate-based composite resin) and its physical properties conform to the same recognized consensus standard as do the properties of the predicate device (K101603).

Tables 5.1 and 5.2 are presented in the following pages to summarize the indications for use and technical comparison of the subject TPH Spectra® ST Flowable Composite Restorative to the predicate and reference devices.
Table 5.1-Comparison of the proposed TPH Spectra® ST Flowable Composite Restorative and the Predicate Device, Beautifil Flow Plus (K101603)

<table>
<thead>
<tr>
<th>Proposed Device</th>
<th>Predicate Device</th>
<th>Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for Use:</strong></td>
<td><strong>Indications for Use:</strong></td>
<td>The Indications for Use of the proposed device are similar to the predicate device.</td>
</tr>
<tr>
<td>• Direct restoration of cavities and lesions</td>
<td>• Beautifil Flow Plus is a light-curing dental filling material having low viscosity intended to directly restore cavities and lesions (except for root canal filling), and to repair fractured artificial crowns.</td>
<td></td>
</tr>
<tr>
<td>• Filling of defects and undercuts in crowns, inlays, and onlays</td>
<td>&quot;Filling of defects and undercuts in crowns, inlays, and onlays&quot; and &quot;Blockouts&quot; are not specific indications for use of the primary predicate device. However, the reference device is included in support of substantial equivalence, incorporates the same technology as the subject device, and includes these indications.</td>
<td></td>
</tr>
<tr>
<td>• Blockouts</td>
<td>“Repair of defects” is a general description of all direct or indirect repairs, e.g. repair of fractured artificial crowns in the predicate device.</td>
<td></td>
</tr>
<tr>
<td>• Repair of defects</td>
<td>&quot;Pit and fissure sealants&quot; and &quot;Cementation of light transmissible indirect restorations&quot; are not the indications of this predicate device.</td>
<td></td>
</tr>
<tr>
<td>• Pit and fissure sealants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Cementation of light transmissible indirect restorations</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Composition of Materials:</th>
<th>Composition of Materials:</th>
<th>Chemically similar to the predicate device.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methacrylate-based resins, photo initiators, fillers and pigments.</td>
<td>Methacrylate-based resins, photo initiators, fillers and pigments.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physical Properties:</th>
<th>Physical Properties:</th>
<th>Physical Property data similar to the predicate device.</th>
</tr>
</thead>
</table>
## Table 5.2-Comparison of the proposed TPH Spectra® ST Flowable Composite Restorative and the reference device, Flowable Composite (K981965)

<table>
<thead>
<tr>
<th>Proposed Device</th>
<th>Reference Device</th>
<th>Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>TPH Spectra® ST Flowable Composite Restorative</td>
<td>Flowable Composite (K981965)</td>
<td></td>
</tr>
</tbody>
</table>

### Indications for Use:

**Proposed Device**
- Direct restoration of cavities and lesions
- Filling of defects and undercuts in crowns, inlays, and onlays
- Blockouts
- Repair of defects
- Pit and fissure sealants
- Cementation of light transmissible indirect restorations

**Reference Device**
- Filling of defects and undercuts in crowns, inlays and onlays
- Liner under direct restorative materials and under inlay restorations – Class II box liner
- Tunnel preparations
- Pit and fissure sealants
- Amalgam margin repair
- Improving margins of acrylic temporaries
- Small Class IV repairs
- Intracoral porcelain repair
- Cementing porcelain veneers, crowns, inlays/onlays
- Refacing acrylic temporaries
- Blockouts
- Covering incisal edge stains
- Repair of small enamel defects
- Provisional occlusal changes
- Class III, V restorations
- Conservative Class I restorations
- Margin correction / adjustment of composite crowns for indirect laboratory use

The Indications for Use of the proposed device is similar to the reference device.

“Direct restoration of cavities and lesions” is a general description of all direct restoration indications of the reference device. Class I, Class II and Class IV restorations are not the indications of this reference device.

“Repair of defects” is a general description of all direct or indirect repair indications of the reference device.

### Composition of Materials:

**Proposed Device**
Methacrylate-based resins, photo initiators, fillers and pigments.

**Reference Device**
Methacrylate-based resins, photo initiators, fillers and pigments.

Chemically similar to the reference device.

### Physical Properties:

**Proposed Device**
Meet ISO 4049:2009 requirements.

**Reference Device**
Meet ISO 4049:2009 requirements.

Physical Property data similar to the reference device.
Non-Clinical Performance Data:

Biocompatibility Testing:
An evaluation of biocompatibility was performed for the TPH Spectra® ST Flowable Composite Restorative in accordance with ISO 10993-1 (Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing), ISO 7405 (Dentistry – Evaluation of Biocompatibility of Medical Devices used in Dentistry) and FDA Guidance for Industry and Food and Drug Administration Staff “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". In support of substantial equivalence, biocompatibility test data on the TPH Spectra® ST Flowable Composite Restorative have been included. The biocompatibility data support a conclusion that the TPH Spectra® ST Flowable Composite Restorative met the requirements of the following biological evaluations:

- Cytotoxicity Using the Colony Assay
- ISO Intracutaneous Study
- ISO Maximization Sensitization Test
- Genotoxicity: Bacterial Reverse Mutation Study
- Genotoxicity: Mouse Lymphoma Assay

Physical Properties:
In-vitro bench tests were performed on the TPH Spectra® ST Flowable Composite Restorative according to the requirements in ISO 4049: 2009 (Dentistry – Polymer-based restorative) and internal Dentsply Sirona internal criteria.

Bench tests included in support of the substantial equivalence of TPH Spectra® Flowable Composite Restorative are:

- Compressive Strength
- Flexural Strength
- Surface Hardness
- Radiopacity
- Water Sorption
- Water Solubility
- Sensitivity to Ambient Light
- Fracture Toughness
- Localized Wear Volume Loss
- Fluoride Ion Release Characterization
- Shade and Color Stability
- Film Thickness

The results from bench tests included in this premarket notification support the substantial equivalence of the TPH Spectra® ST Flowable Composite Restorative.
Clinical Performance Data:

No data from human clinical studies has been included to support the substantial equivalence of the proposed device TPH Spectra® ST Flowable Composite Restorative.

Conclusion Regarding Substantial Equivalence:

The similarities in technology and indications for use, together with results of non-clinical performance testing and biocompatibility testing, support that TPH Spectra® ST Flowable Composite is substantially equivalent to the predicate devices.