January 23, 2020

Dentsply Sirona
Karl Nittinger
Vice President Corporate Regulatory Affairs
221 W Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K192530
Trade/Device Name: Surefil one™ Self-adhesive Composite Hybrid
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: December 24, 2019
Received: December 26, 2019

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 Srinivas “Nandu” Nandkumar, Ph.D.
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)*

K192530

Device Name

Surefil one™ Self-adhesive Composite Hybrid

Indications for Use *(Describe)*

Class I to Class V restorations
Core build up

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
For: K192530
Surefil one™ Self-adhesive Composite Hybrid

1. Submitter Information**:**

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

Contact Person: Karl Nittinger
Email: karl.nittinger@dentsplysirona.com
Telephone Number: 717-849-4424
Fax Number: 717-849-4343

Date Prepared: 20 December 2019

2. Device Name:

- Proprietary Name: Surefil one™ Self-adhesive Composite Hybrid
- Classification Name: Dental cement
- CFR Number: 872.3275
- Device Class: II
- Product Code: EMA

3. Predicate Device:

Predicate Device	**510(k)**	**Company Name**
Primary Predicate: Pulpdent RMGI FILL	K130223	Pulpdent Corporation
Reference Device	**510k)**	**Company Name**
Secondary Predicate: GC Fuji Direct	K172382	GC America Inc.

4. Description of Device:

The subject Surefil one™ Self-adhesive Composite Hybrid is an self- adhesive dental restorative material which is intended to be used as a restorative filling material for direct restorations. The “composite hybrid” composition of the subject device is based on resin-modified glass ionomer chemistry and is provided in a powder/liquid formulation in a mixing capsule.

The subject Surefil one™ Self-adhesive Composite Hybrid offers is available in multiple shades and exhibits the following features:

- Self-adhesiveness to enamel and dentin
- Fluoride release
- Bulk fill and dual-cure
- Radiopacity (equivalent to 2mm aluminum).

5. Indications for Use:

- Class I to Class V restorations
- Core build up

6. Substantial Equivalence:

Technological Characteristics

Proposed Device **Surefil one™** **Self-adhesive Composite Hybrid** **K192530**	**Primary Predicate Device** **Pulpdent RMGI FILL** **K130223**	**Reference Device** **GC Fuji Direct** **K172382**	**Differences**
Indications for Use: • Class I to Class V restorations • Core build up	Indications for Use: Resin-modified glass Ionomer preparation used by dental professionals as filling material in dental restorations	Indications for Use: 1. Class III and V restorations 2. Restoration of primary teeth 3. Core build-up 4. Cases where radiopacity is required 5. Base material for Class I and Class II cavities using a sandwich laminate technique	The verbiage describing the indications for Use of Surefil one™ Self-adhesive Composite Hybrid and the primary predicate, Pulpdent RMGI FILL is different. The wording used by the primary predicate (namely: "as filling material in dental restorations") describes a much broader field. The reference device indications when compared to the proposed Surefil one™ Self-adhesive Composite Hybrid lists the cavity classes and the core build-up, respectively.
Features:	**Features:**		
Self-adhesive composite hybrid restorative	Resin-modified glass ionomer (self-adhesive since no use of dental adhesive is required according to the Instructions for Use)	Resin-modified glass ionomer (No need for etchant and adhesive)	Composite hybrid restorative is based on resin-modified glass ionomer chemistry. By its chemistry, resin modified glass-ionomers exhibit self-adhesive properties to enamel and dentin.

Proposed Device **Surefil one™ Self-adhesive Composite Hybrid** **K192530**	**Primary Predicate Device** **Pulpdent RMGI FILL** **K130223**	**Reference Device** **GC Fuji Direct** **K172382**	**Differences**
Powder/liquid formulation in a mixing capsule	Paste/paste formulation in a double-chamber syringe	Paste/paste formulation in a double-chamber syringe.	The final delivery form of the proposed device into the teeth is a paste and therefore the same as the predicate devices.
Triple cure - Light-curing - Self-curing - Acid-base reaction	Triple cure - Light-curing - Self-curing - Acid-base	Acid-base reaction and polymerization of methacrylate monomers through dual cure	No difference between the proposed device and the primary predicate device. The reference only has dual cure feature.
Fluoride release	Release calcium, phosphate and fluoride	Bioactive material with high fluoride release	Release of calcium, release of phosphate ions and bioactive material are not a proposed feature for the subject device, Surefil one™ Self- adhesive Composite Hybrid device.
Sterility: Non-sterile when used.	Sterility: Non-sterile when used	Sterility: Non-sterile when used	Sterility of the proposed device is identical to the predicate and reference devices.
Storage Temp: 2°C - 24°C	Storage Temp: “Cool room temperature” *	Storage Temp: 4°C - 25°C	Storage temperature differs for the proposed device compared to the predicate and referenced devices. Test data is included to support that proposed device meets its identified requirements when stored within the identified temperature range.
Shelf Life: 10 months	Shelf Life: 2 years*	Shelf Life: 2 years	The initial shelf life of the proposed device is more limited than that of the predicate and reference devices. Shelf life data is included to verify that the proposed device meets its identified requirements throughout the proposed shelf life.
Available Shades: A1, A2, A3, A3.5, Bleach White	Available Shades*: A1, A2, A3, A3.5	Available Shades: A1, A2, A3	The proposed device is offered in identical shades as the predicate with the addition of bleach white.
Application System: Pre-dosed capsule and extruder.	Application System: Dual chamber syringe	Application System: Direct dispensed or manual application after mixing.	Proposed, predicate and reference devices can be direct dispensed.
* Obtained from publicly available labeling.			

7. Non-Clinical Performance Data:

In-vitro bench tests were performed on the Surefil one™ Self-adhesive Composite Hybrid according to the requirements in ISO 9917-2:2017 (Dentistry – Water based cements – part 2: Resin-modified cements) and internal Dentsply Sirona criteria.

Bench tests included in support of substantial equivalence of Surefil one™ Self-adhesive Composite Hybrid. Compartative tests were performed between the proposed Surefil one™ Self-adhesive Composite Hybrid and the predicate device (K130223). A summary list of testing conducted in support of substantial equivalence is as follows:

- Compressive strength
- Flexural strength
- Setting time
- Radio-opacity
- Shear bond strength to enamel
- Shear bond strength to dentin
- Shear bond strength to composite
- Enamel wear
- ACTA (Academic Center for Dentistry Amsterdam) wear test

The performance of the Surefil one™ Self-adhesive Composite Hybrid satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence.

Cytotoxicity testing was performed for Surefil one™ Self-adhesive Composite Hybrid as well as chemical analysis of leachable organic and inorganic compounds in compliance with the standard EN ISO 10993-1. The results of the biocompatibility testing and chemical analysis conducted relating to the subject Surefil one™ Self-adhesive Composite Hybrid support its substantial equivalence.

8. Clinical Performance Data

No data from human clinical studies has been included to support the substantial equivalence of the Surefil one™ Self-adhesive Composite Hybrid.

9. Conclusion Regarding Substantial Equivalence

The Surefil one™ Self-adhesive Composite Hybrid has the same intended use and has similar indications for use as the primary predicate Pulpdent RMGI FILL (K130223) and the secondary predicate GC Fuji Direct (K172382). Test data to verify the performance of the Surefil one™ Self-adhesive Composite Hybrid has been provided including: compressive and flexural strength, adhesion to enamel, dentin and composite, setting time, ACTA (Academic Center for Dentistry Amsterdam) wear, enamel wear and radio-opacity and the results of this testing, combined with the design and intended use comparison with the primary predicate device, support substantial equivalence.