Greenway YW LLC
% Maritza Moncayo
VP Regulatory Affairs
Iris Global LLC
40931 W. Hopper Dr.
Maricopa, Arizona 85138

November 14, 2018

Re: K180463
Trade/Device Name: Apoller Flow Light Cure Flowable Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: August 23, 2018
Received: August 29, 2018

Dear Maritza Moncayo:

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

Digitally signed by Mary S. Runner -S3
Date: 2018.11.14 12:23:42 -05'00'

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

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)*

K180463

Device Name
APOLLER FLOW LIGHT CURE FLOWABLE COMPOSITE

Indications for Use *(Describe)*

Indications for use:
*Class III and V restorations
*Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations)
*Base/liner under direct restorations
*Repair of small defects in esthetic indirect restorations
*Pit and fissure sealant
*Undercut blockout
*Repair of resin and acrylic temporary materials

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.

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5. 510 (k) Summary

K180463 - Apoller Flow Light Cure Flowable Composite

Date prepared: November 09, 2018

5.1. Applicant, Contact and Manufacturer Information:

Applicant Information: GREENWAY YW LLC
21 N. Skokie Hwy, Suite 204
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Tel: 1(847) 525-5258
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Contact: Scott Yin
Email: yinradtech@gmail.com

Contact Person: Maritza Moncayo
Regulatory Affairs
IRIS GLOBAL, LLC
40931 W. Hopper Dr.
Maricopa, AZ 85138
Phone/Fax: 1 (847)-226-9176
Email: mmoncayo@irisgra.com

Manufacturer: SINO-DENTEX CO., LTD.
12357E Jinhu Road, High-Tech Development District,
Changchun, China 130103
Contact: Pengtao Yan
Email: dentex-ypt@163.com
Tel: (086) 431-87855156
Fax: (086) 431-87855157

5.2. General Device Information:

Greenway is providing general product information and classification per FDA guidelines, in Table 1.

Table 1.- Product Classification

Device Trade Name (Commercial):	Apoller Flow Light Cure Flowable Composite
Common Name:	Tooth Shade Resin Material
Classification:	21 CFR 872.3690
Regulation Name:	Tooth Shade Resin Material
Regulatory Class:	Class II
Product Code:	EBF

5.3. Primary Predicate Device Information to which Equivalence is Claimed:

The primary predicate device is Filtek™ Supreme Ultra Flowable Restorative, summary of the predicate device in Table 2:

Table 2- Summary Predicate Device

Device Trade Name	Filtek™ Supreme Ultra Flowable Restorative
Common Name	Tooth shade resin material
510 (k) Number	K100235
Decision Date	May 12, 2010
Manufacturer	3M Company
Classification	21 CFR 872.3690
Product Code	EBF
Class	II

5.4. Device Description:

Apoller Flow-Light Cure Flowable Composite is a low viscosity light activated flowable nanocomposite device. The device is comprised of a syringe with dispensing tips. It consists of methmethacrylate monomers, inorganic fillers and nanoparticles. Apoller Flow Light Cure Flowable Composite contains BisGMA, UDMA, TEGDMA, photo initiator, stabilizer and inorganic fillers including barium glass powder, strontium glass powder and nanosilica. The filler loading is about 56% by weight. The particle size varies from 0.03 to 1 micron. Apoller Flow Light Cure Flowable Composite series is packed in a plastic syringe with a bend metal injection needle heads for ease of usage, its model is Flowable and comes with Refill Syringe of 3.0g /syringe and 1.5 g /syringe. It is available in a variety of 15 tooth-colored shades.

5.5. Indications for Use:

- Class III and V restorations
- Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations)
- Base/liner under direct restorations
- Repair of small defects in esthetic indirect restorations
- Pit and fissure sealant
- Undercut blockout
- Repair of resin and acrylic temporary materials

5.6. Technological Characteristics:

The assessment of the technological characteristic of the Apoller Flow Light Cure Flowable Composite and of the predicate device "Filtek™ Supreme Ultra Flowable Restorative" are equivalent as the currently marketed predicate device manufactured by 3M Company-3M ESPE Dental Products, as described in Table 3.

Both Apoller Flow Light Cure Flowable Composite and primary predicate device are very similar in all comparison areas including chemical composition, intended use, method of polymerization, mechanical properties and application process and use. A slight difference is the filler loading which impact the flowability of the composite, doesn't influence the application and all physical properties.

Table 3.- Technological Characteristics

Technological Characteristics/ Properties	Apoller Flow Light Cure Flowable Composite	Filtek™ Supreme Ultra Flowable Restorative	Discussion
Intended use	*Class III and V restorations *Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations) *Base/liner under direct restorations *Repair of small defects in esthetic indirect restorations	*Class III and V restorations *Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations) *Base/liner under direct restorations *Repair of small defects in esthetic indirect restorations	Equivalent to primary predicate device

Technological Characteristics/ Properties	Apoller Flow Light Cure Flowable Composite	Filtek™ Supreme Ultra Flowable Restorative	Discussion
	*Pit and fissure sealant *Undercut blockout *Repair of resin and acrylic temporary materials	*Pit and fissure sealant *Undercut blockout *Repair of resin and acrylic temporary materials	
Method of Polymerization	Light Cured	Light Cured	Equivalent to primary predicate device
Chemical composition	Glass filled Methmethacrylate monomer resins Nanoparticle Filler loading-56 % by weight	Glass filled Methmethacrylate monomer resins Nanoparticle Filler loading-65 % by weight	Equivalent to primary predicate device
Mechanical/physical properties	Low viscosity Flowable	Low viscosity Flowable	Equivalent to primary predicate device
Application process and use	Similar	Similar	Equivalent to primary predicate device
Camphorquinone / amine photoinitiator system	Equivalent	Equivalent	
Methacrylate-based resin matrix	Equivalent	Equivalent	
Silane treated fillers	Equivalent	Equivalent	
Bonded with permanent dental adhesive	Equivalent	Equivalent	

5.7. Summary of Physical Properties:

The Physical properties of this 510(k) submission includes data of the comparison testing per ISO4049, performed to the Apoller Flow Light Cure Flowable Composite and the primary predicate device "Filtek™ Supreme Ultra Flowable Restorative". The properties evaluated included Sensitivity to ambient light, Depth of cure (mm), Flexural Strength (MPa), Water sorption (μg/mm^3), Water solubility(μg/mm^3), Shade Color stability after irradiation and water sorption, Radio-opacity (mm). Based on the tests performed the results demonstrate substantial equivalence to the primary predicate device.

5.8. Biocompatibility

Evaluation of biocompatibility was conducted using ISO7405, ISO 10993-1; ISO10993-3; ISO10993-5:2009 and ISO10993-11 to determine the biocompatibility of Apoller Flow Light Cure Flowable Composite. Based on the comparative test report it was concluded that Apoller Flow Light Cure Flowable Composite is substantial equivalent to the primary predicate device.

5.9. Non-Clinical Performance Testing:

Based on the technological characteristics, physical property and biocompatibility comparisons between Apoller Flow Light Cure Flowable Composite and the primary predicate device, it is demonstrated that Apoller Flow Light Cure Flowable Composite is equivalent to 3M Filtek™ Supreme Ultra Flowable Restorative.

5.10. Conclusion – Substantial Equivalence:

The information provided in the 510(k) submission shows that Apoller Flow Light Cure Flowable Composite is substantially equivalent to the primary predicate device Filtek™ Supreme Ultra Flowable Restorative, the two products have the same indications for use, are composed of similar materials, have the same intended use, physical properties and technological characteristics as well as a similar design.