GC America Inc.
Mark Heiss
Director, Regulatory Affairs
3737 W. 127th Street
Alsip, Illinois 60803

March 8, 2018

Re: K173500
Trade/Device Name: Nmf004a
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: December 19, 2017
Received: December 20, 2017

Dear Mark Heiss:

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.

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.

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 -S

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)*
K173500

Device Name
NMF004A

Indications for Use *(Describe)*
1. Liner or base
2. Blocking out undercuts
3. Repair of (in) direct aesthetic restorations, temporary crown & bridge, defect margins when margins are in enamel
4. Sealing hypersensitive areas
5. Fissure sealant
6. Direct restorative for Class I, II, III, IV, V cavities
7. 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.

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K173500

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Section 5 – 510(k) Summary

1. Submitter Information:

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Alternate Contact: Lori Rietman
Alternate Phone: (708) 926-3092

Date Prepared: November 9, 2017

2. Device Name:

Proprietary Name: NMF004A
Classification Name: Tooth shade resin material
Device Classification: Class II, 21 CFR 872.3690
Product Code: EBF

3. Predicate Devices:

Company	Device	Primary/ Reference	510(k) No.	Date Cleared
GC America Inc.	(GCUC-505) G-aenial Universal Flo	Primary	K091388	7/22/2009
GC America Inc.	(MFP-051) G-aenial Sculpt	Reference	K123631	7/23/2013
GC America Inc.	Kalore (GDLS-200)	Reference	K082434	11/14/2008

4. Description of Device:

NMF004A is a light cured nano-filled radiopaque composite resin filled in a syringe. The device is used for the restorations of both anterior and posterior teeth. The material is available in 30 shades.

5. Indications for Use:

1. Liner or base.
2. Blocking out undercuts.
3. Repair of (in) direct aesthetic restorations, temporary crown & bridge, defect margins when margins are in enamel.
4. Sealing hypersensitive areas.
5. Fissure sealant.
6. Direct restorative for Class I, II, III, IV, V cavities.
7. Core build-up

6. Performance Bench Tests:

It is confirmed that the device conforms to the required specifications and is suitable for its intended use. Performance testing includes:

- Sensitivity to ambient light
- Depth of cure
- Flexural strength
- Water sorption
- Solubility
- Color stability after irradiation and water sorption
- Radiopacity

7. Packaging:

1. Syringe 1.7g (1.0mL), 20 dispensing tips, 1 light protective cover

Dispensing tip package:

2. 30 dispensing tips, 2 light protective covers

9. Shelf Life Evaluation and Storage Conditions:

- Shelf Life 3 years
- Recommended for optimal performance, store in a cool and dark place. 4-25°C (39.2 - 77.0°F) away from high temperatures or direct sunlight.

Table 5.1 Substantial equivalence to the reference predicate devices

	Applicant device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device
Product category	Tooth shade resin material, Class II	Tooth shade resin material, Class II	Tooth shade resin material, Class II	Tooth shade resin material, Class II
Trade name	NMF004A	GCUC-505 (G-aenial Universal Flo) K091388	MFP-051 (G-aenial Sculpt) K123631	GDLS-200 (GC KALORE) K082434
Manufacturer	GC Corporation	GC Corporation	GC Corporation	GC Corporation
Indications for use	1. Liner or base 2. Blocking out undercuts. 3. Repair of (in) direct aesthetic restorations, temporary crown & bridge, defect margins when margins are in enamel. 4. Sealing hypersensitive areas. 5. Fissure sealant. 6. Direct restorative for Class I, II, III, IV, V cavities 7. Core build-up	1. Liner or base 2. Blocking out undercuts 3. Repair of (in) direct aesthetic restorations, temporary crown & bridge, defect margins when margins are in enamel 4. Sealing hypersensitive areas 5. Fissure sealant 6. Direct restorative for ~~small~~ Class I, II, III, IV, V cavities	1. Direct restorative for class I, II, III, IV, V cavities. 2. Direct restorative for wedge-shaped defects and root surface cavities. 3. Direct restorative for veneers and diastema closure.	1. Direct restorative for Class I, II, III, IV, V cavities. 2. Direct restorative for wedge-shaped defects and root surface cavities. 3. Direct restorative for veneers and diastema closure
Product description	NMF004A is a light-cured nano-filled radiopaque composite restorative resin filled in a syringe. For extrusion, a filling tip is attached to top of a syringe. The device is flowable composite resin formulated with high consistency.	G-aenial Universal Flo is a light-cured nano-filled radiopaque composite restorative resin filled in a syringe. For extrusion, a filling tip is attached to top of a syringe. The device is flowable composite resin formulated with high consistency.	MFP-051 is a light cured nano-filled radiopaque composite resin filled in a syringe and unitip. The device is used for the restorations of both anterior and posterior teeth	GDLS is a light-cured micro-filled radiopaque resin for the restoration of both anterior and posterior teeth. GDLS-200 consists of two delivery systems, Unitip (capsules for single dose) and Syringes. The GDLS-200 system is available in a variety of shades.
Instructions for Use	1. Preparations 2. Shade Selection 3. Cavity Preparation 4. Bonding treatment 5. Placement 6. Light Curing 7. Finishing and Polishing	1. Preparations 2. Shade Selection 3. Cavity Preparation 4. Bonding treatment 5. Placement 6. Light Curing 7. Finishing and Polishing	1. Shade Selection 2. Cavity Preparation 3. Bonding Treatment 4. Placement 5. Contouring before Light Curing 6. Light Curing 7. Finishing and Polishing	1. Shade Selection 2. Cavity Preparation 3. Bonding Treatment 4. Placement 5. Contouring before Light Curing 6. Light Curing 7. Finishing and Polishing
Technological Characteristics	All the compounds found in the applicant device, NMF004A, have already been used in the predicate devices except for methacryloxyoctyltrimethoxysilane. The curing mechanism of the predicates and NMF004A is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator system.	All the components of the applicant device, GCUC-505, have already been used in the predicate devices. The curing mechanism of the predicates and GCUC-505 is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator system.	All the components of the applicant device, MFP-051, have already been used in the predicate devices. PREMISE contains barium glass filler, which is one of the components in the proposed device. All the other components are included in GC KALORE (GDLS-200) and G-aenial Universal Flo (GCUC-505). The curing mechanism of the predicates is polymerization of uncured meth-acrylate ester monomers. This reaction is caused by photo initiator system.	The curing mechanism of the predicates and GCUC-505 is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator system.

8. Substantial equivalence:

The curing mechanism of the new and predicate devices is substantially equivalent in principle. Therefore, the new and predicate devices are the same in function, and similar in composition and intended use. This supports that the compatibility and safety of the applicant device are substantially equivalent to the predicate devices.

The applicant device complies with all the requirements of ISO 4049: 2009 (Dentistry - Polymer-based restorative materials) (see table below).

Property		Requirements
1	Sensitivity to ambient light	Remain physically homogeneous
2	Depth of cure	Opaque shade: > 1.5mm Other shade: > 2.0mm
3	Flexural strength	> 80 MPa
4	Water sorption	< 40 μg/mm^3
5	Solubility	< 7.5 μg/mm^3
6	Color stability after irradiation and water sorption	No more than slight change in color.
7	Radiopacity	Greater than the same thickness of aluminum

Differences

The following differences may be noted between the predicate devices and NMF004A:

- A coupling agent for NMF004A is different from that for predicate devices such as G-aenial Universal Flo, G-aenial Sculpt and Kalore (see section 12).

10. Conclusion:

Based on similarities in intended use, mode of action, chemical composition, and performance testing, NMF004A is substantially equivalent to the selected predicate devices.