November 30, 2020

GENOSS Co., Ltd.
Hong Jeon
Manager
1F, Gyeonggi R&DB Center, 105 Gwanggyo-ro,
Yeongtong-gu, Suwon-si
Suwon-si, 16229 KOREA

Re: K200155
Trade/Device Name: Bright High Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBC
Dated: October 22, 2020
Received: October 22, 2020

Dear Hong Jeon:

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

GENOSS

Indication for use

510(k) Number: K200155

Device Name: Bright High Flow

Indication for use:

1) Base/liner
2) Pit & Fissure sealant

Prescription Use __√__ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K200155

510(k) Summary

12/20/2019

1. Company

	Submitter
Name	GENOSS Co., Ltd.
Address	1F, Gyeonggi R&DB Center / 226, 2F, GSBC, 105 Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea
Phone/Fax	+82-70-7098-7541/ +82-31-888-5105
Contact person	HongJun Jeon / RA hjjeon@genoss.com
Summary Date	12/20/2019

2. Device Name

Proprietary name: Bright High Flow

Regulation description : Light-cured Flowable Composite Resin

Classification name: Tooth shade resin material

3. Predicate Device

K091388 G-aenial Universal Flo

4. Description

Bright Flow is a light-cured flowable composite resin. It comprises two different types of flowability (Low Flow and High Flow) and 9 shades depending on the intended use, which enables aesthetic and durable outcomes for anterior and posterior composite restorations.

5. Indication for use

1) Base/liner

2) Pit & Fissure sealant

6. Technological Characteristics

Bright High Flow has the similar technological characteristics as the predicate device; main material, indication for use and design. Technological characteristics of Bright High Flow, G-aenial Universal Flo are as following.

Device name		Bright High Flow	G-aenial Universal Flo
Manufacturer		Genoss Co., Ltd.	GC America, Inc.
510(k) Number		New Device	K091388
Clinical	Target population	Human tooth	Human tooth
	Purpose	Direct restoration	Direct restoration
	Site of application	Dentin, Enamel	Dentin, Enamel
	Clinical Performance	High flexural strength and strong bonding	High flexural strength and strong bonding
Biological	Materials	Methacrylate resins, Fillers (Barium glass, Silica)	Methacrylate resins, Fillers (Barium glass, Silica)
	Chemical Safety	Biocompatible	Biocompatible
	Sterilization	Non-sterile	Non-sterile
	Shelf-Life	2 years	3 years
Technical	Form	Paste	Paste
	Indication for use	1) Base / liner 2) Pit & Fissure sealant	1) Direct restorative for Class I, IV, III, II and V cavities. 2) Fissure sealant 3) Sealing hypersensitive areas 4) Repair of (in) direct aesthetic restorations, temporary crown & bridge, defect margins when margins

			are in enamel 5) Blocking out undercuts 6) Liner or base
	Use	Prescription	Prescription
	Depth of cure	ISO 4049:2009 7.10 (More than 1.5 mm)	
	Water Sorption	ISO 4049:2009 7.12 (Less than 40 ㎍/㎟)	
	Solubility	ISO 4049:2009 7.12 (Less than 7.5 ㎍/㎟)	
	Flexural Strength	ISO 4049:2009 7.11 (More than 80 MPa)	
	Radio-opacity	ISO 4049:2009 7.14 (More than the same thickness of aluminum)	

7. Performance Data

Biocompatibility testing on the proposed Bright High Flow has been completed. Requirements for biological evaluation of the proposed device were based on FDA recognized concensus standard of ISO10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing." The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological bone and tissues with its intended use. The following biocompatibility tests were completed:

(P: Pass, F: Fail)

No.	Test	Method	Acceptance criteria	P/F	Report No.
1	Cytotoxicity	ISO 10993-5	None cytotoxicity	P	CDM-18-0061-12
2	Irritation	ISO 10993-10	None oral irritation	P	MTK-2018-000707
3	Sensitization	ISO 10993-10	None sensitization	P	MTK-2018-000706
4	Acute systemic toxicity	ISO 10993-11	None systemic toxicity	P	MTK-2018-000706
5	Genotoxocity	ISO 10993-3	None genotoxicity	P	MTK-2018-000705

6	Implantation	ISO 10993-6	Biocompatible	P	BER-18-028
7	Chronic toxicity	ISO 10993-11	No chronic toxicity	P	BER-18-028

The proposed Bright High Flow was evaluated using the following performance bench testing to confirm the performance characteristics:

No.	Items	Method	Acceptance Criteria	P/F	File No.
1	Visual	ISO 4049	No impurities and No specific changes	P	CDM-18-0061-01
2	Capacity	ISO 4049	Capacity error of; Standard Capacity < ±5%	P	CDM-18-0061-02
3	Package	ISO 4049	No damage	P	CDM-18-0061-03
4	Sensitivity to Ambient Light	ISO 4049	Must be physically uniform	P	CDM-18-0061-04
5	Depth of Cure	ISO 4049	More than 1.5 mm	P	CDM-18-0061-05
6	Shade	ISO 4049	Must be shade uniform	P	CDM-18-0061-06
7	Color Stability	ISO 4049	Color should be stable	P	CDM-18-0061-07
8	Flexural Strength	ISO 4049	More than 80 MPa	P	CDM-18-0061-08
9	Water Sorption	ISO 4049	Less than 40 μg/mm3	P	CDM-18-0061-09
10	Solubility	ISO 4049	Less than 7.5 μg/mm3	P	CDM-18-0061-10
11	Radio-opacity	ISO 4049	More than Al	P	CDM-18-0061-11

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the Bright High Flow met the established specifications necessary for consistent performance according to its intended use.

8. Conclusion

Based on the information provided in this premarket notification of GENOSS Co., Ltd. Concludes that Bright High Flow is acceptable and safe, substantially equivalent to predicate devices.