October 28, 2020

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

Re: K200153
Trade/Device Name: Bright Bond Universal
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin tooth bonding agent
Regulatory Class: Class II
Product Code: KLE
Dated: August 3, 2020
Received: August 3, 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

Indication for use

510(k) Number: K200153

Device Name: Bright Bond Universal

Indication for use:

1) Direct bonding for light-cured composites to tooth surface
2) Bonding of dual-cured core build up composites to tooth surface
3) Intraoral repair of composite, PFM and ceramic restoration using cements
4) Sealing of tooth preparation for indirect restoration

Prescription Use __√__ **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary K200153

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 Bond Universal

Regulation description : Resin tooth bonding agent

Classification name: Agent, Tooth Bonding, Resin

3. Predicate Device

K110302 Scotchbond Universal

4. Description

Bright Bond Universal is a light-cured dental adhesive that combines etching, priming, and bonding functions in a single bottle solution. It provides strong and durable bonds between dentin/enamel and light-curable direct/indirect restorative materials.

5. Indication for use

1) Direct bonding for light-cured composites to tooth surface
2) Bonding of dual-cured core build up composites to tooth surface
3) Intraoral repair of composite, PFM and ceramic restoration using cements
4) Sealing of tooth preparation for indirect restoration

6. Technological Characteristics

Bright Bond Universal has the similar technological characteristics as the predicate device; main material, indication for use and design. Technological characteristics of Bright Bond Universal, Scotchbond Universal are as following

Device name		Bright Bond Universal	Scotchbond Universal
Manufacturer		Genoss Co., Ltd.	3M ESPE
510(k) Number		New Device	K110302
Clinical	**Target population**	Human tooth (Dentin, Enamel)	Human tooth (Dentin, Enamel)
	Purpose	Restoration	Restoration
	Site of application	Dentin, Enamel	Dentin, Enamel
	Clinical Performance	Strong bonding with composite resin	Strong bonding with composite resin
Biological	**Materials**	Multifunctional methacrylate resins (HEMA, 10-MDP)	Multifunctional methacrylate resins (HEMA, 10-MDP)
	Chemical Safety	Biocompatible	Biocompatible
	Sterilization	Non-sterile	Non-sterile
	Shelf-Life	2 years	2 years
Technical	**Form**	Liquid	Liquid
	Indication for use	1) Direct bonding for light-cured composites to tooth surface 2) Bonding of dual-cured core build up composites to tooth surface 3) Intraoral repair of composite, PFM	1) Bonding light-cured composite or compomer for all classes of direct restorations 2) Bonding of dual-cure cements and core build-up materials 3) Bonding of self-cure composites 4) Root surface desensitization

		and ceramic restoration using cements 4) Sealing of tooth preparation for indirect restoration	5) Sealing of dentin prior to amalgam restorations 6) Protective varnish for glass ionomer restorative materials 7) Repair of composite or compomer restorations 8) Bonding sealants 9) Bonding veneers in combination with 3M™ RelyX™ Veneer Cement
	Use	Prescription	Prescription
	pH	2.1	2.7
	Film thickness	2.0 ㎛	10.6 ㎛
	Depth of cure	3.0 mm	2.8 mm
	Bonding Strength	24.5 Mpa	22.0 MPa

7. Performance Data

Biocompatibility testing on the proposed Bright Bond Universal 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-18-0161-11
2	Irritation	ISO 10993-10	None oral irritation	P	CDM-18-0161-12
3	Sensitization	ISO 10993-10	None sensitization	P	MTK-2019-000014
4	Acute systemic toxicity	ISO 10993-11	None systemic toxicity	P	CDM-18-0161-13

5	Genotoxocity	ISO 10993-3	None genotoxicity	P	BER-18-056
6	Implantation	ISO 10993-6	Biocompatible	P	BER-18-056
7	Chronic toxicity	ISO 10993-11	No chronic toxicity	P	BER-18-056

The proposed Bright Bond Universal was evaluated using the following performance bench testing to confirm the performance characteristics:

No.	Items	Method	Acceptance Criteria	Result	File No.
1	Visual test	Bare eyes	No impurities and No specific changes	No impurities and No specific changes	CDM-18-0161-01
2	Capacity test	Weight difference	Capacity error of; Standard Capacity < ±5 %	2.75 %	CDM-18-0161-02
3	Package test	Bare eyes	No damage	No damages, cracks	CDM-18-0161-03
4	Film Thickness	ISO 4049:2009 7.5	≤ 50 ㎛	2 ㎛	CDM-18-0161-04
5	Sensitivity to Ambient Light	ISO 4049:2009 7.9	Must be physically uniform	Homogeneous	CDM-18-0161-05
6	Depth of Cure	ISO 4049:2009 7.10	≥ 1.5 mm	3.0 mm	CDM-18-0161-06
7	Bonding Strength (Dentin)	ISO 29022:2013 7	≥ 8 MPa	16 MPa	CDM-18-0161-09
8	Bonding Strength (Enamel)	ISO 29022:2013 7	≥ 8 MPa	14 MPa	CDM-18-0161-10

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the Bright Bond Universal 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 Bond Universal is acceptable and safe, substantially equivalent to predicate devices.