July 28, 2023

Genoss Co., Ltd.
Boram Choi
Assistant Manager
D-factory, 56, Changnyong-daero 256beon-gil, Yeongtong-gu
Suwon-si, Gyeonggi-do 16229
SOUTH KOREA

Re: K231480
Trade/Device Name: Bright MTA Sealer Plus
Regulatory Class: Class II
Product Code: KIF
Dated: April 5, 2023
Received: May 22, 2023

Dear Boram Choi:

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,

Michael E. Adjodha -S

Michael Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231480

Device Name
Bright MTA Sealer Plus

Indications for Use *(Describe)*
Bright MTA Sealer Plus is used for filling root canals

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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K231480

510(k) Summary

02/05/2023

1. Company

	Submitter
Name	GENOSS Co., Ltd.
Address	**Head office:** 1F Gyeonggi R&DB center, 105 Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16229, Republic of Korea **Factory:** D-factory, 56, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16256, Republic of Korea
Phone/Fax	+82-70-7098-6352/ +82-31-888-5595
Contact person	Boram Choi / RA brchoi@genoss.com
Summary Date	02/05/2023

2. Device

Proprietary name:	Bright MTA Sealer Plus
Common Name:	Root filling material
Classification Name:	Root canal filling resin
Regulation Number:	21 CFR 872.3820
Product Code:	KIF
Regulatory Class:	Class II

3. Predicate Device

K170175	Endoseal MTA

4. Device Description

Bright MTA Sealer Plus is a ready-to-use, injectable paste-like material for root canal filling, which is hardened and obturated after being injected into the root canal space. The product based on calcium silicate exhibits excellent biocompatibility as well as a low film thickness suitable for easy penetration of lateral and accessory canals.

5. Indication for use

Bright MTA Sealer Plus is used for filling root canals.

6. Technological Characteristics

Bright MTA Sealer Plus was compared with the predicate device 'ENDOSEAL MTA' in clinical, technical, biological view. The characteristics that differed from the predicate device were performed by gap analysis, which confirmed equivalence with the predicate device. Technological characteristics of Bright MTA Sealer Plus and ENDOSEAL MTA are as following;

Device name		SUBJECT DEVICE **Bright MTA Sealer Plus**	PREDICATED DEVICE **Endoseal MTA (K170175)**
Manufacture		Genoss Co.,Ltd.	Maruchi
Classification		Class II	Class II
Product code		KIF	KIF
Clinical	**Target population**	Human tooth root canal	Human tooth root canal
	Purpose	Bright MTA Sealer Plus is used for filling root canals.	Materials used for root canal filling
	Site of application	root canal	root canal
	Clinical Performance	Repair of root resorption Root-end-filling	Repair of root resorption Root-end-filling
Technical	**Principle of operation**	Bright MTA Sealer Plus is an injectable paste like material for root canal filling, which is hardened and obturated after being injected into the root canal space.	Endoseal MTA is an endodontic sealer based on MTA, providing a root canal filling.
	Solubility	0.2 %	0.7 %
	Flow test	27 mm	21 mm
	Setting time	Within 360 min	12.31 min
	Film Thickness	30 ㎛	15 ㎛
	Radio-opacity	4.6 mm	10.5 mm
Biolo	**Material**	$CaCO_3$, Al_2O_3, SiO2, $NaHCO_3$ (Calcium silicate) ZrO_2, Li_2Co_3, 1,3-Propandiol,	$CaCO_3$, Al_2O_3, SiO_2, Fe_2O_3 (Natural pure cement) ZrO_2, Bi_2O_3, Bentonite Clay,

		Polyethylene glycol, Polar acidic ester of long chain alcohols	N-Methyl-2-Pyrrolidone, Hypromellose
	Chemical Safety	Biocompatible	Biocompatible
	Sterile	Non sterile	Non sterile
	Shelf-Life	2 years	2 years
	Packaging	Pre-loaded syringe	Pre-loaded syringe
	Duration of Contact	Permanent contact - contact exceeds 30d	Permanent contact - contact exceeds 30d

7. Performance Data

Biocompatibility testing

Biocompatibility testing on the proposed Bright MTA Sealer 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:

No.	Test	Standard & Method	Acceptance criteria	Evaluation
1	Cytotoxicity	EN ISO 10993-5 Agar diffusion assay	Non cytotoxic (Scale 0)	Scale 0 (Non cytotoxic)
2	Oral mucosal irrittation	EN ISO 10993-23	Irritation index 0	Irritation index 0
3	Skin Sensitization	EN ISO 10993-10 GPMT	Sensitization score and rate 0	Sensitization score and rate 0
4	Acute systemic toxicity	EN ISO 10993-11 Single dose	No Acute systemic toxicity	No Acute systemic toxicity
5	Systemic toxicity	EN ISO 10993-11 Pyrogen test	No abnomal signs and dead	No abnomal signs and dead
6	Genotoxicity	EN ISO 10993-3 Back mutation,	No back mutation regardless of the	No back mutation

		Chromosomal aberration	presence or absenve of a metabolic activation system	
			No chromosomal aberration in CHL/IU cells	No chromosomal aberration in CHL/IU cells
7	Implantation	EN ISO 10993-6 Implantation	Biocompatible	Biocompatible
8	Sub-chronic toxicity	EN ISO 10993-11 Subchronic toxicity	No Subchronic toxicity	No Subchronic toxicity
9	Chronic toxicity	EN ISO 10993-11 Chronic toxicity	No chronic toxicity	No chronic toxicity
10	Carcinogenicity	EN ISO 10993-3 Carcinogenicity	No Carcinogenicity	No Carcinogenicity

Mechanical testing

The proposed Bright MTA Sealer Plus was evaluated using the following performance bench testing to confirm the performance characteristics:

No.	Items	Standard & Method	Acceptance Criteria	Result
1	Visual test	ISO 4049 Bare eyes	No alien substance and suitable for using the product	No alien substance and suitable for using the product
2	Capacity test	ISO 4049 Weight difference	Standard weight < ±5%	1.50 %
3	Package test	ISO 4049 Bare eyes	No damages, cracks	The package was completely sealed, and there were no damages, cracks.
4	Extraneous matter test	ISO 4049 Bare eyes	No extraneous matter	No Extraneous Matter
5	Flow test	EN ISO 6876: 2012 5.2	Diameter ≥ 17mm	27mm
6	Setting time test	EN ISO 6876: 2012 5.4	≤ 360 min	Within 360min
7	Film thickness test	EN ISO 6876: 2012 5.5	≤ 50㎛	30㎛
8	Radio-opacity test	EN ISO 6876: 2012 5.7	More than 3mm	4.6mm
9	Solubility test	EN ISO 6876: 2012 5.6	≤ 3%	0.2%

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the Bright MTA Sealer Plus 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. concluded that Bright MTA Sealer Plus is acceptable and safe, substantially equivalent to predicate device.