



February 23, 2024

Genoss Co., Ltd.  
Hayoung Sung  
Staff  
1F, 106, Jeongoksandan-ro, Seosin-myeon  
Hwaseong-si, Gyeonggi-do 16229  
Korea, South

Re: K232174

Trade/Device Name: rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono  
Regulation Number: 21 CFR 872.6660  
Regulation Name: Porcelain Powder For Clinical Use  
Regulatory Class: Class II  
Product Code: EIH  
Dated: January 23, 2024  
Received: January 23, 2024

Dear Hayoung Sung:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

The logo for the U.S. Food and Drug Administration (FDA), consisting of the letters "FDA" in a large, light blue, sans-serif font.

Bobak  
Shirmohammadi -  
S

For Michael E. Adjodha, M. ChE., RAC, CQIA  
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

## Indications for Use

Submission Number (if known)

K232174

Device Name

rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono

Indications for Use (Describe)

rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono is used in the manufacture of a dental core through milling by machine followed by sintering

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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## 510(k) Summary-K232174

02/22/2024

### 1. Company

	Submitter
<b>Name</b>	GENOSS Co., Ltd.
<b>Address</b>	<b>Head Office</b> : 12F, 76, Changnyong-daero 256beon-gil, Yeontong-gu, Suwon-si, Gyeonggi-do, Republic of Korea <b>Manufacturing site</b> : 106, Jeongoksandan-ro, Seosin-myeon, Hwaseong-si, Gyeonggi-do, Republic of Korea
<b>Phone/Fax</b>	+82-70-7098-8920/ +82-31-888-5105
<b>Contact person</b>	Hayoung Sung / RA hysung@genoss.com
<b>Summary Date</b>	29/06/2023

### 2. Device Name

Proprietary name: rainbow™ Multi-Layer Block /  
bright 3-Layer / bright Mono

Regulation description: Porcelain Powder for clinical use

Classification name: Powder, Porcelain

Regulation Number: 21 CFR 872.6660

Regulation Code: EIH

Regulation Class: Class II

### 3. Predicate Device

K160079 rainbow™ Shine



#### **4. Description**

rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono is a partially sintered dental ceramic made out of colored ZrO<sub>2</sub>(Y-TZP). rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono is milled into core (zirconia substructure) of artificial teeth and then is finally sintered in a furnace to harden the ZrO<sub>2</sub>.

rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono is fabricated by CAD/CAM or MAD/MAM machining processes. At the dental lab, the blanks are held to the milling machine which is used to machine to the final dental restoration. After machining steps, the dental restoration is fully sintered in the furnace to harden the ZrO<sub>2</sub>, and fitted to the patients as crowns and bridges.

rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono is available in numerous shapes and sizes in order to be compatible with multiple milling machines. According to the shapes, they are used for fabricating of each intended dental restoration, such as anterior crowns, posterior crowns, bridges

rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono is not for use or intended for use to fabricate the top-half of an abutment/titanium base and is for the fabrication of dental restorations only.

#### **5. Indication for use**

rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono is used in the manufacture of a dental core through milling by machine followed by sintering.

#### **6. Technological Characteristics**

rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono was compared with the predicate device 'rainbow™ Shine' 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 rainbow™ Multi-Layer



Block / bright 3-Layer / bright Mono and rainbow™ Shine Material are as following;

Device name		SUBJECT DEVICE	PREDICATED DEVICE
		rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono	rainbow™ Shine
Manufacture		Genoss Co., Ltd.	Genoss Co., Ltd.
510(K) Number		New device	K160079
Classification		Class II	Class II
Product Code		EIH	EIH
Clinical	Target population	Human tooth	Human tooth
	Indication for use	rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono is used in the manufacture of a dental core through milling by machine followed by sintering.	rainbow™ Shine is used in the manufacture of a dental core through milling by machine (MAD/ MAM or CAD/CAM) followed by sintering.
	Form	Block	Block
	Use	Prescription	Prescription
Technical	Principle of operation	rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono is a partially sintered zirconia block. To make dental prosthesis rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono is processed by milling machine (CAD/CAM or MAD/ MAM) and is finally sintered	rainbow™ Shine is a partially sintered zirconia block. To make dental prosthesis, rainbow™ Shine is processed by milling machine (CAD/CAM or MAD/ MAM) and is finally sintered
	Type, Class of dental ceramic of ISO 6872	Type II – Class 4 (ISO 6872:2015)	Type II – Class 5 (ISO 6872:2008)
	Flexural strength	807.1 MPa	865 MPa
	Radioactivity (Bq/g)	< 1.0	< 1.0
	Linear thermal expansion (10 <sup>-6</sup> K <sup>-1</sup> )	10.7	10.4±(0.5)
	Chemical Solubility (µg/cm <sup>2</sup> )	28.8	0
Material	Zirconia Powder	Zirconia Powder	



<b>Chemical Safety</b>	Biocompatible	Biocompatible
<b>Sterilization</b>	Non-sterile	Non-sterile
<b>Shelf-Life</b>	None	None

## 7. Performance Data

### Biocompatibility testing

Biocompatibility testing on the proposed rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono has been completed. Requirements for biological evaluation of the proposed device were based on FDA recognized consensus 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 10993-05	None cytotoxicity	P	MGK-2019-001058
2	Sensitization	ISO 10993-10	None sensitization	P	MGK-2019-001060
3	Irritation or intracutaneous reactivity	ISO 10993-10	None irritation	P	MGK-2019-001059
4	Systemic toxicity(acute)	ISO 10993-11	None systemic toxicity	P	MGK-2019-001061
5	Genotoxicity	ISO 10993-03	No Toxicity	P	MGK-2019-001062 MGK-2019-001063 MGK-2019-001064
6	Subchronic toxicity	ISO 10993-11	No Toxicity	P	BSE-2020-06
7	Implantation	ISO 10993-06	No Toxicity	P	BSE-2020-06
8	Chronic toxicity	ISO 10993-11	No Toxicity	P	BSE-2020-06
9	Carcinogenicity	ISO 10993-03	No Toxicity	P	BSE-2020-06



### Mechanical testing

The proposed rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono was evaluated using the following performance bench testing to confirm the performance characteristics:

No.	Items	Properties	Method	Doc No.
1	Visual	No impurities and No specific changes	ISO 6872	MT22-00554
2	Size	Standard weight $<\pm 5\%$	ISO 6872	
3	Package	No damage	ISO 6872	
4	Uniformity	Uniform after sintering	ISO 6872	
5	Freedom from extraneous materials	Free from extraneous materials	ISO 6872	
6	Radioactivity	$^{238}\text{U}$ Less than 1.0 Bq/g	ISO 6872	
7	Flexural strength	More than 500MPa	ISO 6872	
8	Linear thermal expansion	$(10.7 \pm 0.5) \times 10^{-6} \text{K}^{-1}$	ISO 6872	
9	Chemical solubility	Less than 100 $\mu\text{g}/\text{cm}^2$	ISO 6872	

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono met the established specifications necessary for consistent performance according to its intended use.

## 9. Conclusion

Based on the information provided in this premarket notification of GENOSS Co., Ltd. concluded that rainbow™ Multi-Layer Block / bright 3-Layer / bright Mono are acceptable and safe, substantially equivalent to predicate device.