June 21, 2024

Genoss Co., Ltd.
Hayoung Sung
Official Correspondent
12F, 76, Changryong-daero 256beon-gil, Yeongtong-gu
Suwon-si, Gyeonggi-do
SOUTH KOREA

Re: K233885
Trade/Device Name: rainbow Paste Stain SE
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: November 15, 2023
Received: December 8, 2023

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233885

Device Name

rainbowTM Paste Stain SE

Indications for Use *(Describe)*

rainbow Paste Stain SE is indicated for use as a veneering material for fixed prosthesis in crowns and bridges. This device is used in prosthetic dentistry by forming a porcelain veneer on to a ceramic substructure.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K233885

06/18/2024

1. Company

	Submitter
Name	GENOSS Co., Ltd.
Address	Head Office: 12F, 76, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea Manufacturing site: 1F 106, Jeongoksandan-ro, Seosin-myeon, Hwaseong-si, Gyeonggi-do, Republic of Korea
Phone/Fax	+82-70-7098-8920
Contact person	Hayoung Sung/ RA hysung@genoss.com
Summary Date	06/18/2024

2. Device Name

Proprietary name:	rainbow™ Paste Stain SE
Regulation description:	Porcelain Powder for clinical use
Classification name:	Powder, Porcelain
Regulation Number:	21 CFR 872.6660
Product Code:	EIH

3. Predicate Device

K151731	rainbow™ Paste Stain

4. Description

rainbow™ Paste Stain SE is a dental veneering material in paste form used for color staining and glazing of the surfaces of restorations such as porcelain-fused zirconia, full-contoured zirconia, or lithium disilicate.

The intended use of general porcelain is to make artificial teeth (dental prosthesis) more similar with natural teeth. The subject device is pre-mixed paste form, which can help dental technicians exclude mixing process of porcelain powder and liquid.

5. Indication for use

rainbow™ Paste Stain SE is indicated for use as a veneering material for fixed prosthesis in crowns and bridges. This device is used in prosthetic dentistry be forming a porcelain veneer on to a ceramic substructure.

6. Technological Characteristics

rainbow™ Paste Stain SE was compared with the predicate device 'rainbow™ Paste Stain' 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 rainbow™ Paste Stain SE and rainbow™ Paste Stain Material are as following;

Device name		**rainbow™ Paste Stain SE**	**rainbow™ Paste Stain**
Manufacture		Genoss Co.,Ltd.	Genoss Co., Ltd.
510(K) Number		K233885	K151731
Classification		Class II	Class II
Product code		EIH	EIH
	Indication for use	rainbow™ Paste Stain SE is indicated for use as a veneering material for fixed prosthesis in crowns and bridges. This device is used in prosthetic dentistry be forming a porcelain veneer on to a ceramic substructure.	rainbow™ Paste Stain is indicated for use as a veneering material for fixed prosthesis in crowns and bridges. This device is used in prosthetic dentistry be forming a porcelain veneer on to a ceramic substructure.
	Form	Paste	Paste
	Use	Prescription	Prescription
Technical	**Type, Class of dental ceramic of ISO 6872**	Type I – Class I	Type I – Class I
	Flexural strength	72.5 MPa	79 MPa
	Chemical solubility (μg/cm²)	31.3	24
	Linear thermal expansion coefficient	$(8.6 \pm 0.5) \times 10^{-6}k^{-1}$	$(9.5 \pm 0.5) \times 10^{-6}k^{-1}$

	Glass transition temperature	503.6°C	476°C
Biological	**Chemical Safety**	Biocompatible	Biocompatible
	Sterilization	Non-sterile	Non-sterile

7. Biocompatibility Data

Biocompatibility testing on the proposed rainbow™ Paste Stain SE 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
1	Cytotoxicity	ISO 10993-05	None cytotoxicity	P
2	Sensitization	ISO 10993-10	None sensitization	P
3	Irritation or intracutaneous reactivity	ISO 10993-10	None irritation	P
4	Systemic toxicity(acute)	ISO 10993-11	None systemic toxicity	P
5	Genotoxicity	ISO 10993-03	No Toxicity	P
6	Subchronic toxicity	ISO 10993-11	No Toxicity	P
7	Implantation	ISO 10993-06	No Toxicity	P
8	Chronic toxicity	ISO 10993-11	No Toxicity	P
9	Carcinogenicity	ISO 10993-03	No Toxicity	P

8. Performance Data

The proposed rainbow™ Paste Stain SE was evaluated using the following performance bench testing to confirm the performance characteristics:

No.	Items	Criteria	Result	Standard
1	Appearance	No impurities and No specific changes	No impurities and No specific changes	Internal Standard
2	Weight	Standard weight <±5%	Standard weight <±5%	Internal Standard
3	Package	No damage	No damage	Internal Standard
4	Uniformity	After firing, the color shall be uniformly dispersed	Uniform	ISO 6872 5.1
5	Extraneous materials	Free from extraneous materials	Free from extraneous materials	ISO 6872 5.2
6	Radioactivity	^{238}U Less than 1.0 Bq/g	^{238}U less than 0.001 Bq/g	ISO 6872 7.2
7	Chemical solubility	Less than 100 ㎍/㎠	Solubility: 31.3 ㎍/㎠	ISO 6872 7.6
8	Flexural strength	More than 50MPa	Average: 72.5MPa	ISO 6872 7.3
9	Linear thermal expansion	N/A	Average: $8.6 \times 10^{-6}K^{-1}$	ISO 6872 7.4
11	Glass transition temperature	N/A	Average: 503.6℃	ISO 6872 7.5

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the rainbow™ Paste Stain SE 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™ Paste Stain SE is substantially equivalent to predicate device.