



Food and Drug Administration  
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April 15, 2016

GENOSS Co. Ltd.  
Mr. Byungsun Kim  
Regulatory Affairs Assistant  
105 Gwanggyo-ro  
Suwon-si Yeongtong-gu  
Gyeonggi-do  
443-270  
KOREA

Re: K151731  
Trade/Device Name: rainbow™ Paste Stain  
Regulation Number: 21 CFR 872.6660  
Regulation Name: Porcelain Powder For Clinical Use  
Regulatory Class: Class II  
Product Code: EIH  
Dated: March 14, 2016  
Received: March 15, 2016

Dear Mr. Kim:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Erin I. Keith -S**

Erin I. Keith, M.S.

Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure



**Indication for use**

**510(k) Number:** K151731

**Device Name:** rainbow™ Paste Stain

**Indication for use:**

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 by forming a porcelain veneer on to a ceramic substructure.

**Prescription Use**  **(21 CFR 801 Subpart D)**

**AND/OR**

**Over-The-Counter Use**  **(21 CFR 801 Subpart C)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**510(k) Summary**

04/11/2016

**1. Company**

	<b>Submitter</b>
<b>Name</b>	GENOSS Co., Ltd.
<b>Address</b>	1F, Gyeonggi R&DB Center / 226, 2F, GSBC, 105 Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea
<b>Phone/Fax</b>	+82-31-888-5100/ +82-31-888-5105
<b>Contact person</b>	Byungsun Kim / RA bskim@genoss.com
<b>Summary Date</b>	04/11/2016

**2. Device Name**

Proprietary name : rainbow™ Paste Stain  
Regulation number : 21 CFR 872.6660  
Classification name : Porcelain powder for clinical use  
Product code : EIH  
Device class : Class II

**3. Predicate Device**

K060441 Primary predicate  
K052710 Reference predicate

**4. Description**

rainbow™ Paste Stain 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 the 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.

The subject device is composed of 16 shade paste and thinner (Paste Stain Liquid), does not include powder only. The thinner is used to control viscosity of paste.

Each paste has 3 volumes of 3g, 5g and 7g. The kit package is composed of various pastes and a liquid.

The subject device is not intended to be marketed with multiple components or accessories. It is only composed with the products in this submission which are powder and liquid.

## 5. Indication for use

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 by forming a porcelain veneer on to a ceramic substructure.

## 6. Technological Characteristics

rainbow™ Paste Stain has the similar technological characteristics as the predicate device; main material, indication for use and design. Technological characteristics of rainbow™ Paste stain and Vita VM®(K060441, K052710) are as following

### Comparison of Characteristics

Device name	rainbow™ Paste Stain	Vita VM® (VITA VM9)	Comparison
<b>Manufacturer</b>	Genoss Co., Ltd.	Vident	N/A
<b>510(k) Number</b>	New Device	K06044, K052710	N/A
<b>Materials</b>	Feldspar, SiO <sub>2</sub> , Na <sub>2</sub> CO <sub>3</sub> , K <sub>2</sub> CO <sub>3</sub> , Li <sub>2</sub> CO <sub>3</sub> , CaCO <sub>3</sub> , ZnO, etc.	Feldspar, Na <sub>2</sub> CO <sub>3</sub> , Al <sub>2</sub> O <sub>3</sub> , , CaCO <sub>3</sub> , K <sub>2</sub> CO <sub>3</sub> , BaCO <sub>3</sub> , etc.	Similar The subject and predicate device both have feldspar and several oxides as the major component.
<b>Form</b>	Paste	Powder + Liquid	Similar The subject device is pre-mixture of powder and liquid for ease of use

<b>Type, class of dental ceramic</b>	Type I - Class I	Type I - Class I	Same
<b>Sterilization</b>	Non-sterile	Non-sterile	Same
<b>Indication for use</b>	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 by forming a porcelain veneer on to a ceramic substructure.	Vita VM® porcelains are indicated for use as a veneering material for fixed prosthesis in crowns, bridges, and dental implant abutments. These devices are used in prosthetic dentistry by forming a porcelain veneer on to a ceramic or metal substructure into the shape of a dental crown.	Similar  The predicate device has several proprietary names (VM7, VM9, VM11, VM13)  The subject device and Vita VM9 are used to veneer over the ceramic substructure (denatl core) *Vita VM7 is applicable to alumina substructures. *Vita VM9 is applicable to zirconia substructures. *Vita VM11 is applicable to lithium silicate substructures. *Vita VM13 is applicable to gold or metal substructures.
<b>Use</b>	Prescription	Prescription	Same
<b>Technical characteristics</b>			
<b>Bending Strength (Flexural strength)</b>	79 MPa	approx. 100 MPa	Flexural strength is lower, but higher than required by ISO 6872:2008 for Class I dental ceramics (> 50 MPa).
<b>Chemical Solubility (µg/cm<sup>2</sup>)</b>	24	approx. 10	Chemical solubility satisfies requirement by ISO 6872:2008 for Class I dental ceramics (< 100µg/cm <sup>2</sup> ).
<b>Linear thermal expansion coefficient</b>	$(9.5 \pm 0.5) \times 10^{-6} \text{K}^{-1}$	$(9.0 \sim 9.2) \times 10^{-6} \text{K}^{-1}$	Similar
<b>Glass transition temperature</b>	476 °C	approx. 600 °C	The subject and predicate device have each firing schedule reflecting these two technological characteristics
<b>Biocompatibility</b>	Biocompatible	Biocompatible	Same

There are three minor differences that are worth discussing:

- 1) The differences of 'Indication for use' are not critical to the intended use. The general

intended use of porcelain like subject and predicate device is to make the artificial teeth (dental prosthesis) more similar with natural teeth by building up porcelains on the dental coping made of zirconia or metal.

- 2) The subject and predicate device have slight difference in composition. But they both have feldspar and several oxides as the major component. This difference has no effect on substantial equivalence of the device. The non-clinical tests (bench test and biocompatibility test) demonstrate the Technical characteristics.
- 3) The differences of flexural strength and chemical solubility are within what is expected of this type of device. The performance test results satisfy the requirement for Type I - Class I dental ceramic by ISO 6872:2008.

The subject and predicate device have each firing schedule reflecting the linear thermal expansion coefficient and glass transition temperature.

## **7. Summary of non-clinical testing**

Non-clinical device testing was conducted to confirm the performance of the subject device. Testing was conducted in accordance with the FDA recognized consensus standard (Recognition number : 4-178: ISO 6872 Third edition 2008-09-01, dentistry - ceramic materials) Bench tests for performance comparison of the subject device and the predicate device includes the following testing:

- Bending Strength
- Linear thermal expansion coefficient
- Chemical Solubility
- Glass transition temperature

Technical characteristics of both devices satisfy the requirements by ISO 6872:2008. The slight differences between the subject and predicate devices do not raise any new issues.

Biocompatibility testing was conducted on the device pursuant to the ISO 10993-1:2009 Biological evaluation of medical device - Part 1: Evaluation and testing within a risk management process.

- Cytotoxicity test (ISO 10993-5)
- Irritation or intracutaneous reactivity (ISO 10993-10)
- Sensitization (ISO 10993-10)



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- Acute systemic toxicity (ISO 10993-11)
- Genotoxicity (ISO 10993-03)

The result of biocompatibility testing demonstrated that no issue of biocompatibility arises.

## **8. Conclusion**

Based on the information provided in this premarket notification of GENOSS Co., Ltd. Concludes that rainbow<sup>TM</sup> Paste Stain is substantially equivalent to the predicate device.