DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Genoss Co. Ltd.
Byungsun Kim
Official Correspondent
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Suwon-si, KR 443-270 Gyeonggi-do

November 10, 2016

Re: K160079
Trade/Device Name: rainbow™ Shine
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: October 7, 2016
Received: October 11, 2016

Dear Byungsun 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,

Susan Runner DDS, MA

Tina Kiang, Ph.D.
Acting 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: **K160079**

Device Name: rainbow™ Shine

Indication for use:

rainbow™ Shine is used in the manufacture of a dental core through milling by machine (MAD/MAM or CAD/CAM) followed by sintering.

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) Number: **K160079**

510(k) Summary

11/07/2016

1. Company

	Submitter
Name	GENOSS Co., Ltd.
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Phone/Fax	+82-31-888-5100/ +82-31-888-5105
Contact person	Byungsun Kim/RA bskim@genoss.com
Summary Date	11/07/2016

2. Device Name

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

3. Predicate Device

K151842 rainbow™ High Shine

4. Description

rainbow™ Shine is a partially sintered dental ceramic made out of colored ZrO_2(Y-TZP). These blanks are fabricated into dental core (zirconia substructure) of crowns and bridges. The core can be used as final prosthesis by itself or can be layered with porcelain.

rainbow™ Shine 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_2, and fitted to the patients as crowns and bridges.

rainbow™ Shine 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 single crowns, bridges including from 2-bridge to 16-bridge(full arch). It is also supplied in six different colors (A0, A0.5, A1, A2, A3, A4) for each shapes.

rainbow™ Shine 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™ Shine is used in the manufacture of a dental core through milling by machine (MAD/ MAM or CAD/CAM) followed by sintering.

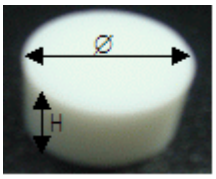
6. Technological Characteristics

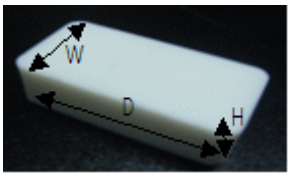
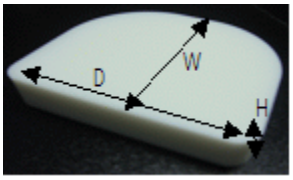
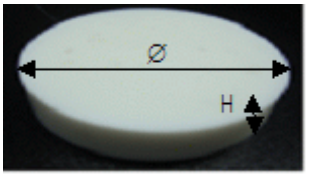
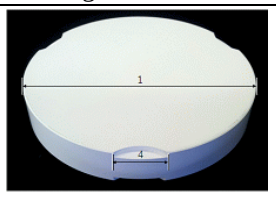
The following comparison table of the technological characteristics of the subject device and the predicate devices outlines and provides the similarities and the substantial equivalency of the rainbow™ Shine and the predicate.

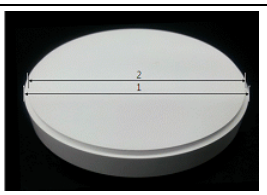
Comparison of Characteristics

Device name	**rainbow™ Shine**	**rainbow™ High Shine**	**Comparison**
Manufacturer	Genoss Co., Ltd.	Genoss Co., Ltd.	Same

510(k) Number	K160079	K151842	-
Materials	ZrO_2(Y-TZP)	ZrO_2(Y-TZP)	Same
Form	Preformed block	Preformed block	Same
Type, class of dental ceramic	Type II - Class 5	Type II - Class 5	Same
Sterilization	Non-sterile	Non-sterile	Same
Indication for use	rainbow™ Shine is used in the manufacture of a dental core through milling by machine (MAD/ MAM or CAD/CAM) followed by sintering.	rainbow™ High Shine is used in the manufacture of a dental core through milling by machine (MAD/ MAM or CAD/CAM) followed by sintering.	Same
Principle of operations	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.	rainbow™ High Shine is a partially sintered zirconia block. To make dental prosthesis, rainbow™ High Shine is processed by milling machine(CAD/CAM or MAD/ MAM) and is finally sintered.	Same
Use	Prescription	Prescription	Same
Technical characteristics			
Bending Strength (Flexural strength)	865MPa	706MPa	Bending strength is higher than required by ISO 6872:2008 for Class 5 dental ceramics. (> 500 Mpa)
Sintering Density (g/cm^3)	6	6	Same
Radioactivity (Bq/g)	< 1.0	< 1.0	Same
Linear thermal expansion ($10^{-6}K^{-1}$)	10.4(±0.5)	10.4(±0.5)	Same
Chemical Solubility ($\mu g/cm^2$)	0	3	Chemical solubility satisfies requirement by ISO 6872:2008 for Class 6 dental ceramics. (< 100 $\mu g/cm^2$)
Biocompatibility	Biocompatible	Biocompatible	Same

Shape	**Single**	 Diameter 25mm Height 12, 16, 22mm	Same

Shape	**2~9 bridge**	 Diameter 44.5~75.5mm Width 25.5, 25, 26, 38mm Height 12, 16, 22mm	Same
	10~16 bridge	 Diameter 89, 95mm Width 55, 75mm Height 12, 16, 22mm	
	Disk	 Diameter 87, 95, 98, 100mm Height 10~28mm	
	Step block	 Diameter 95mm Height 10~28mm	

		 Diameter 98mm Height 10~28mm	

There is a minor difference that is worth discussing:

1) The differences of technological charcteristics(Bending strength, chemical solubility) are within what is expected of this type of device. The rainbow High Shine has a lower bending strength than the predicate device, due to the fact that the material is completely stabilized with Y_2O_3 in order to achieve higher translucency. However, the performance test results satisfy the requirement by ISO 6872:2008

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
- Chemical Solubility
- Linear thermal expansion coefficient
- Radioactivity

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)
- Acute systemic toxicity(ISO 10993-11)
- Genotoxocity(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™ Shine is substantially equivalent to the predicate device.