



Food and Drug Administration
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October 16, 2015

Genoss Co., Ltd.
c/o Dachan Kwon
iCT America, Inc.
180 Sylvan Avenue, 2nd Floor
Englewood Cliffs, NJ 07632

Re: K151844
Trade/Device Name: Rainbow™ Shade
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: July 15, 2015
Received: July 22, 2015

Dear Dachan Kwon:

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,

 Tina Kiang
-S

for 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: K151844

Device Name: rainbow™ Shade

Indication for use:

rainbow™ Shade is a pre-sintered zirconia(Y-TZP) block for fabrication of single-tooth and bridgework restoration.

Prescription Use √
(Part 21 CFR 801 Subpart D)

AND/OR

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

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)



510(k) Summary

10/06/2015

1. Company

Submitter	
Name	GENOSS Co., Ltd.
Address	1F, Gyeonggi R&DB Center / 226, 2F, GSBC, 105 Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea
Phone/Fax	+82-31-888-5100/ +82-31-888-5105
Contact person	Byungsun Kim / RA bskim@genoss.com
Summary Date	10/06/2015

2. Device Name

Proprietary name: rainbow™ Shade

Regulation description : Porcelain powder for clinical use

Classification name: Powder, porcelain

3. Predicated Device

K092513 RAINBOW BLOCK

4. Description

rainbow™ Shade is a dental ceramic made out of colored $ZrO_2(Y-TZP)$. rainbow™ Shade is milled into cores of teeth and then is fired in a furnace to harden the ZrO_2 . Then, the core is layered with porcelain to make a finished tooth.

5. Indication for use

rainbow™ Shade is a pre-sintered zirconia(Y-TZP) block for fabrication of single-tooth and bridgework restoration.



6. Technological Characteristics

rainbow™ Shade has the similar technological characteristics as the predicate device; main material, indication for use and design. Technological characteristics of rainbow™ Shade and RAINBOW BLOCK are as following

Device name	rainbow™ Shade	RAINBOW BLOCK
Manufacturer	Genoss Co., Ltd.	Genoss Co., Ltd.
510(k) Number	New Device	K092513
Materials	ZrO ₂ (Y-TZP)	ZrO ₂ (Y-TZP)
Form	Preformed block	Preformed block
Sterilization	Non-sterile	Non-sterile
Indication for use	rainbow™ Shade is a pre-sintered zirconia(Y-TZP) block for fabrication of single-tooth and bridgework restoration.	Rainbow Block is used in the manufacture of a dental core through milling by machine (MAD/MAM or CAD/CAM) followed by sintering.
Use	Prescription	Prescription
Properties		
Bending Strength (Flexural strength)	913MPa	1144MPa
Sintering Density (g/cm ³)	6	6.00~6.04
Radioactivity (Bq/kg)	0.01	0.01
Chemical Solubility (μg/cm ²)	22.65	14.47
Biocompatibility	Biocompatible	Biocompatible

The differences of ‘Indication for use’ are not critical to the intended use. The general intended use of zirconia blank is to manufacture a dental prosthesis using milling machine. The dental core means single or bridgework restoration.

And the differences of technological characteristics(bending strength, chemical solubility) are within what is expected of this type of device.



7. Performance Data

Biocompatibility testing on the proposed rainbow™ Shade 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:

No.	Items	Criteria	Result	Standard
1	Cytotoxicity	None cytotoxicity	None cytotoxicity	ISO 10993-5
2	Sensitization (Local Lymph Node Assay)	None sensitization	None sensitization	ISO 10993-10
3	Oral mucosa irritation	Less than stimulus threshold	Minimal irritation	ISO 10993-10
4	Acute systemic toxicity	None acute Systemic toxicity	None acute Systemic toxicity	ISO 10993-11
5	Genotoxicity	Ames	None genotoxicity	ISO 10993-3
		Micronucleus		ISO 10993-3

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

No.	Items	Criteria	Result	Standard
1	Visual	No impurities and No specific changes	No impurities and No specific changes	ISO 6872
2	Size	Size error of; Standard Size < ±5%	Size error of; Standard Size < ±5% H 0.43%, Ø 0.03%	ISO 6872
3	Package	No damage	No damage	ISO 6872
4	Uniformity	Uniform	Uniform	ISO 6872
5	Freedom from extraneous materials	Not Freedom from extraneous materials	Not Freedom from extraneous materials	ISO 6872
6	Radioactivity	²³⁸ U Less than 1.0 Bq/g	²³⁸ U: < 0.000124Bq/g ²²⁶ Ra: < 0.010Bq/g	ISO 6872
7	Chemical solubility	Less than 100 µg/cm ²	Solubility: 0µg/cm ²	ISO 6872
8	Flexural strength	More than 800MPa	Average: 913MPa	ISO 6872
9	Linear thermal expansion	10.8(±0.5) X 10 ⁻⁶ K ⁻¹	Average: 10.44 X 10 ⁻⁶ K ⁻¹	ISO 6872
10	Shipping Test	Result: Pass	Pass	ISTA2011 Integrity Test 3A



Low Temperature degradation test				
1	Monoclinic phase fraction	Normal: Less than 20% after low temperature degradation: Less than 25%	Normal: 1.26% 134°C, 5 hours: 1.69%	ISO 6872
2	Flexural strength	Less than 20% and more than 800MPa before/ after low temperature degradation	Normal: 850MPa 134°C, 5 hours: 832MPa	ISO 6872

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the rainbow™ Shade met the established specifications necessary for consistent performance according to its intended use.

7. Conclusion

Based on the information provided in this premarket notification of GENOSS Co., Ltd. Concludes that rainbow™ Shade is substantially equivalent to the predicate device.