



Food and Drug Administration  
10903 New Hampshire Avenue  
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October 28, 2015

Genoss  
c/o Mr. Dachan Kwon  
iCT America, Inc.  
180 Sylvan Avenue, 2nd Floor  
Englewood Cliffs, New Jersey 07632

Re: K151723  
Trade/Device Name: rainbow™ Trans  
Regulation Number: 21 CFR 872.6660  
Regulation Name: Porcelain Powder for Clinical Use  
Regulatory Class: II  
Product Code: EIH  
Dated: September 21, 2015  
Received: September 23, 2015

Dear Mr. 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:** k151723

**Device Name:** rainbow™ Trans

**Indication for use:** rainbow™ Trans is used in the manufacture of a dental core.

**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)**

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

**510(K) Summary****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
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<b>Contact person</b>	Byungsun Kim / RA bskim@genoss.com
<b>Summary Date</b>	10/16/2015

**2. Device Identification**

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

**3. Predicate Device**

K092513 Predicate  
K093560 Reference

**4. Description**

rainbow™ Trans is a partially sintered dental ceramic made out of colored ZrO<sub>2</sub>(Y-TZP). rainbow™ Trans is milled into cores of artificial teeth and then is finally sintered in a furnace to harden the ZrO<sub>2</sub>. Then, the core is layered with porcelain to make a finished tooth.

### 5. Indication for use

rainbow™ Trans is used in the manufacture of a dental core.

### 6. Comparison of Technological Characteristics

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

Device name	rainbow™ Trans	RAINBOW BLOCK	Upcera Zirconia Blanks
<b>Manufacturer</b>	Genoss Co., Ltd.	Genoss Co., Ltd.	Shenyang Upcera Co., Ltd.
<b>510(k) Number</b>	New Device	K092513	K093560
<b>Materials</b>	ZrO <sub>2</sub> (3Y-TZP*) * 3Y-TZP : 3mol% Ytria Tetragonal Zirconia Polycrystal	ZrO <sub>2</sub> (3Y-TZP*)	ZrO <sub>2</sub> (3Y-TZP*)
<b>Form</b>	Preformed block	Preformed block	Preformed block
<b>Sterilization</b>	Non-sterile	Non-sterile	Non-sterile
<b>Indication for use</b>	rainbow™ Trans is used in the manufacture of a dental core.	Rainbow Block is used in the manufacture of a dental core through milling by machine (MAD/MAM or CAD/CAM) followed by sintering.	Upcera Zirconia Blanks are intended for use in the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.
<b>Use</b>	Prescription	Prescription	Prescription
<b>Properties</b>			
<b>Bending Strength (Flexural strength)</b>	902MPa	1144MPa	1200MPa
<b>Sintering Density (g/cm<sup>3</sup>)</b>	6.00~6.04	6.00~6.04	6
<b>Radioactivity (Bq/g)</b>	0.01	0.01	0.015
<b>Chemical Solubility (μg/cm<sup>2</sup>)</b>	9	14.47	17.00
<b>Biocompatibility</b>	Biocompatible	Biocompatible	Biocompatible

The Indication for use and material of subject device and predicate device are equivalent.

And the differences of technological characteristics(Flexural strength, chemical solubility) are within what is expected of this type of device. According to the standard ISO 6872:2008, both

subject device and predicate device are classified as Type II Class 6 dental ceramic indicated for prostheses involving four or more units, and both devices satisfy the mechanical and chemical properties (Flexural strength:  $\geq 800\text{MPa}$ , Chemical solubility:  $\leq 100\mu\text{g}/\text{cm}^2$ ). Therefore, the subject device is substantially equivalent to the predicate devices.

## 7. Performance Data

Biocompatibility testing on the proposed rainbow™ Trans 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	None genotoxicity	None genotoxicity	ISO 10993-3

The proposed rainbow™ Trans 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 $< \pm 5\%$	Size error of; Standard Size $< \pm 5\%$	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	$^{238}\text{U}$ Less than 1.0 Bq/g	$^{238}\text{U}$ : $< 0.000124\text{Bq/g}$ $^{226}\text{Ra}$ : $< 0.010\text{Bq/g}$	ISO 6872
7	Chemical solubility	Less than 100 $\mu\text{g}/\text{cm}^2$	Solubility: 9 $\mu\text{g}/\text{cm}^2$	ISO 6872

8	Flexural strength	More than 800MPa	Average: 902MPa	ISO 6872
9	Linear thermal expansion	$10.8(\pm 0.5) \times 10^{-6} \text{K}^{-1}$	Average: $10.8 \times 10^{-6} \text{K}^{-1}$	ISO 6872
10	Shipping Test	Result: Pass	Pass	ISTA2011 Integrity Test 3A

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

## 8. Conclusion

The information provided in this premarket notification from GENOSS Co., Ltd. supports the conclusion that rainbow™ Trans is substantially equivalent to the predicate devices