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

July 21, 2016

GENOSS Co., Ltd.
% Kim Byungsun
Assistant Manager
ICT America, Inc.
180 Sylvan Avenue, 2nd Floor
Englewood Cliffs, New Jersey 07632

Re: K160144
Trade/Device Name: rainbow™ LS Block
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: June 13, 2016
Received: June 15, 2016

Dear Kim Byungsun:

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,

Michael J. Ryan -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:

Device Name: rainbow™ LS Block

Indication for use:

rainbow™ LS Block can be used for manufacturing Crown, Veneer, Inlay and Onlay.

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) Summary

03/28/2016

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/ +82-31-888-5595
Contact person	Han Yein / RA yihan@genoss.com
Summary Date	03/28/2016

2. Device Name

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

3. Predicated Device

K051705 IPS e.max CAD

4. Description

rainbow™ LS Block is a dental ceramic made out of Lithium disilicate. rainbow™ LS Block is milled into cores of teeth and then is fired in a furnace to harden the $Li_2Si_2O_5$. Then, the core is layered with porcelain to make a finished tooth.

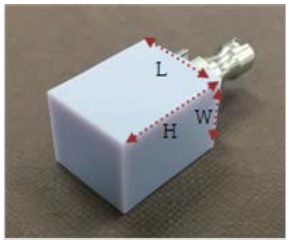
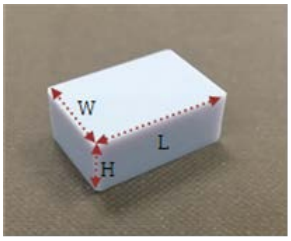
5. Indication for use

rainbow™ LS Block can be used for manufacturing Crown, Veneer, Inlay and Onlay.

6. Technological Characteristics

rainbow™ LS Block has the similar technological characteristics as the predicate device; main material, indication for use and design. Technological characteristics of rainbow™ LS Block, IPS e.max CAD is as following

Device name	rainbow™ LS Block	IPS e.max CAD	Comparison
Manufacturer	Genoss Co., Ltd.	ivoclar vivadent	N/A
510(k) Number	New Device	K051705	N/A
Materials	SiO_2, Li_2CO_3, $Ca_3(PO_4)_2$, P_2O_5, ZnO, Al_2O_3, La_2O_3, K_2CO_3, ZrO_2	SiO_2, Li_2O, K_2O, MgO, ZnO, Al_2O_3, P_2O_5, ZrO_2	Similar The major materials of lithium disilicate dental ceramic(subject and predicate device) are SiO2 and Li2O. The each composition of other materials is less than 5%.
Form	Preformed block	Preformed block	Same
Type, class of dental ceramic	Type II - Class 2	Type II - Class 2	Same
Sterilization	Non-sterile	Non-sterile	Same
Indication for use	rainbow™ LS Block can be used for manufacturing Crown, Veneer, Inlay and Onlay.	IPS e.max CAD is a CAD/CAM machinable glass ceramic based on lithium disilicate for the preparation of full ceramic crowns, inlays, onlays, and full ceramic 3-unit anterior bridges.	Similar The subject has more strong bending strength than the predicate devices. Subject not intended for anterior bridges.
Use	Prescription	Prescription	Same
Technical characteristics			
Bending Strength (Flexural strength)	370MPa	360MPa	Similar Bending strength is little higher than predicate device but there is no differences in performance and safety.

Linear Thermal expansion ($10^{-6}K^{-1}$)		10.3±0.5	10.45	Same
Radioactivity (Bq/g)		0.00628	<0.03	Radioactivity is lower than predicate device
Chemical Solubility ($\mu g/cm^2$)		12	40	Chemical solubility satisfies requirement by ISO 6872:2008 for Class 2 dental ceramics. (< 100μg/cm2)
Glass transition temperature		(579±20) ℃	approx. 549℃	Similar Glass transition temperature of the subject and predicate device are similar. Each have individual sintering schedule by glass transition temperature.
Biocompatibility		None cytotoxicity None sensitization None systemic toxicity None acute oral toxicity None genotoxicity	None cytotoxicity None sensitization None systemic toxicity None acute oral toxicity None genotoxicity	same
Shapes & Sizes	**C-type**	 Width 8.0~15.5mm Length 8.0~15.5mm Height 15.0~40mm	 Width 12.5~15.85mm Length 10.4~17.85mm Height 15.0~38.95mm	Similer
	Disk type	 Width 15, 20mm Length 22mm Height 3, 5, 7, 9mm	 Width 12.5~15.85mm Length 10.4~17.85mm Height 15.0~38.95mm	

7. Performance Data

Biocompatibility testing on the proposed rainbow™ LS Block 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	None genotoxicity	ISO 10993-3
		Micronucleus			ISO 10993-3

The proposed rainbow™ LS Block 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%	(C-type) Size error of; Standard Size < ±5% W 0.03%, L 3.90%, H 0.21%	ISO 6872
			(Disk type) Size error of; Standard Size < ±5% W 3.42%, L2.36% H 0.07%	
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: < 0.00628Bq/g	ISO 6872
7	Chemical solubility	Less than 100 ㎍/㎠	Solubility: 12㎍/㎠	ISO 6872
8	Flexural strength	More than 100MPa	Average: 370MPa	ISO 6872

9	Linear thermal expansion	9.95(±0.5) X $10^{-6}K^{-1}$	Average: 9.95 X $10^{-6}K^{-1}$	ISO 6872
10	Glass-transition temperature	Less than 579±20℃	579℃	ISO 6872

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the rainbow™ LS Block 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™ LS Block is acceptable and substantially equivalent to predicate devices