



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 14, 2016

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

Re: K151846

Trade/Device Name: rainbow™ LS Pressing
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Dated: December 4, 2015
Received: December 8, 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" (21CFR 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
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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: K151846

Device Name: rainbow™ LS Pressing

Indication for use:

rainbow™ LS Pressing is used in the manufacture of Inlay, Onlay and Crown.

Prescription Use
(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

01/05/2016

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	01/05/2016

2. Device Name

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

3. Predicate Device

K120134 IPS e.max Press and IPS e.max Press Multi

4. Description

rainbow™ LS Pressing is a lithium disilicate glass-ceramic ingot for use with the press technique with similar strength and esthetics to natural tooth.

5. Indication for use

rainbow™ LS Pressing is used in the manufacture of Inlays, Onlays and Crowns.

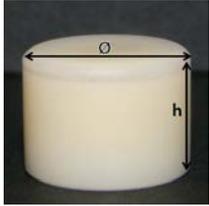
6. Technological Characteristics

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™ LS Pressing and the predicate.

Comparison of Characteristics

Device name	rainbow™ LS Pressing	IPS e.max Press and IPS e.max Press Multi	Comparison
Manufacturer	Genoss Co., Ltd.	Ivoclar Vivadent, Incorporated	N/A
510(k) Number	New Device	K120134	N/A
Materials	SiO ₂ , Li ₂ CO ₃ , Ca ₃ (PO ₄) ₂ , P ₂ O ₅ , ZnO, Al ₂ O ₃ , La ₂ O ₃ , K ₂ CO ₃ . etc.	SiO ₂ , Li ₂ O, K ₂ O, MgO, ZnO, Al ₂ O ₃ , P ₂ O ₅ etc.	<p>Similar</p> <p>The major materials of lithium disilicate dental ceramic(subject and predicate device) are SiO₂ and Li₂O.</p> <p>The each composition of other materials is less than 5%.</p> <p>The difference of composition is Ca₃(PO₄)₂. Ca₃(PO₄)₂ is decomposed into 3CaO and P₂O₅. The CaO acts as stabilizer.</p>
Form	Pre-formed Ingot	Pre-formed Ingot	Same
Type, class of dental ceramic	Type II - Class 2	Type II - Class 3	<p>Similar</p> <p>Although the subject device refers to Type II-Class 2 dental ceramic, the bending strength satisfies requirement by ISO 6872:2008 for Class 3 dental ceramics (> 300 MPa).</p>
Sterilization	Non-sterile	Non-sterile	Same

Indication for use	rainbow™ LS Pressing is used in the manufacture of Inlays, Onlays and Crowns.	IPS e.max Press and IPS emax Press Multi is an all-ceramic system for the creation of Occlusal veneers, Thin Veneers, Veneers, Inlays, Onlays, Crowns in the anterior and posterior region, 3-unit bridges in the anterior region, 3-unit bridges in the premolar region up to the second premolar as the terminal abutment, Crown, splinted crown or 3 unit bridge up to the second premolar placed on top of an implant abutment.	Similar The subject and predicate devices can be used to make Inlays, Onlays and Crowns, because the bending strength and chemical solubility of devices satisfy requirement by ISO 6872:2008 for Class 4 dental ceramics. (> 300 Mpa, < 2000µg/cm ²)
Use	Prescription	Prescription	Same
Technical characteristics			
Bending Strength (Flexural strength)	569 MPa	400 Mpa	Bending strength is higher than required by ISO 6872:2008 for Class 3 dental ceramics. (> 300 Mpa)
Linear thermal expansion coefficient	$(10.3 \pm 0.5) \times 10^{-6} \text{K}^{-1}$	$10.5 \times 10^{-6} \text{K}^{-1}$	Same
Chemical Solubility (µg/cm²)	35.75	40	Chemical solubility satisfies requirement by ISO 6872:2008 for Class 2 or 3 dental ceramics. (< 100µg/cm ²)
Glass transition temperature	(550±20) °C	approx. 549°C	Same
Biocompatibility	Biocompatible	Biocompatible	The Products are biocompatible according to ISO 10993-1 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

<p>Shapes & Sizes</p>	 <p>Ø : 12.5mm H : 10mm</p>	 <p>Ø : 12.5mm H : 10, 20mm</p>	<p>Similar</p>
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There are three minor differences that are worth discussing:

- 1) The difference of ‘Indication for use’ is not critical to the intended use.
 Considering the bending strength of devices satisfies requirement by ISO 6872:2008 for Class 4 dental ceramics(> 300 MPa), the subject and predicate devices can be used to make Inlays, Onlays and Crowns.
- 2) The subject and predicate device have slight difference in materials. But they both are lithium disilicate dental ceramic which have SiO₂ and Li₂O as the major materials. The each composition of other materials is less than 5%. The difference of chemical composition is Ca₃(PO₄)₂, which is decomposed into 3CaO and P₂O₅. The CaO acts as stabilizer. It enhances the structure of Li₂O-SiO₂ system(the basic lithium disilicate system) and increases the viscosity of glass. This difference has no effect on the device. The non-clinical tests(bench test and biocompatibility test) demonstrate the Technical characteristics.
- 3) The differences of technological characteristics(Bending strength, chemical solubility) are within what is expected of this type of device. The performance test results satisfy the requirement for Type II - Class 2 or 3 dental ceramic by ISO 6872:2008.

7. Summary of non-clinical testing

Non-clinical device testing was conducted to confirm the performance of the subject device. Bench 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 criteria for Type II - Class 2 or 3' dental ceramic by ISO 6872:2008. Slight differences between the proposed and predicate devices do not raise any new issues of safety and effectiveness.

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)
- 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 rainbowTM LS Pressing is substantially equivalent to predicate device.