DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 30, 2016

GC America Inc.
Mark Heiss, D.D.S.
Director, Academic & Regulatory Affairs
3737 W. 127th Street
Alsip, Illinois 60803

Re: K153136
Trade/Device Name: Initial LiSi Press
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: May 27, 2016
Received: June 1, 2016

Dear Dr. Heiss:

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,

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

Section 4 – Indications for Use Statement

Indications for Use

510(k) Number (if known): K153136

Device Name: Initial LiSi Press

Indications for Use:

Fabrication 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 unit, crown or splinted crown on top of an implant abutment and 3-unit bridge up to the second premolar placed on top of an implant abutment.

Prescription Use ___X____ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

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1. Submitter

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Date Prepared: May 27, 2016

2. Device Name

Proprietary Name: Initial LiSi Press
Classification Name: Powder, Porcelain
Device Classification: Class II, 872.6660
Product Code: EIH

3. Predicate Device

Company	Device	510(k) No.	Code No.	Predicate
IVOCLAR VIVADENT, INC	IPS E.MAX PRESS / IPS E.MAX PRESS MULTI	K120134	EIH	Primary
IVOCLAR VIVADENT, INC	IPS E.MAX CAD / IPS E.MAX ZIRCAD	K051705	EIH	Reference

4. Description of Device

Initial LiSi Press is a press-heated ceramic ingot formed through melting the raw materials at a very high temperature. The melting process eliminates all volatile substances and the final product is a complex oxide ceramic available in various shades and translucencies. All of the components of the applicant device have already been used in the predicate devices.

The restorations may be further characterized through layering, glazing and staining, and are then cemented in place as the final restoration.

The device is packaged in 5 ingots per tube and is available in a range of shades, including high, medium and low translucency, as well as high and medium opacity.

HT (High Translucency): HT-BLE, HT-EOP, HT-E57, HT-E58, HT-E59, HT-E60, HT-NTL, HT-AMB, HT-B00, HT-B0, HT-A0, HT-A1, HT-A2, HT-A3, HT-A3.5, HT-A4, HT-B1, HT-B2, HT-B3, HT-B4, HT-C1, HT-C2, HT-C3, HT-C4, HT-D2, HT-D3, HT-D4 (27)
MT (Medium Translucency): MT-B00, MT-B0, MT-A0, MT-A1, MT-A2, MT-A3, MT-A3.5, MT-A4, MT-B1, MT-B2, MT-B3, MT-B4, MT-C1, MT-C2, MT-C3, MT-C4, MT-D2, MT-D3, MT-D4, MT-0, MT-A, MT-B, MT-C, MT-D (24)
LT (Low Translucency): LT-B00, LT-B0, LT-A0, LT-A1, LT-A2, LT-A3, LT-A3.5, LT-A4, LT-B1, LT-B2, LT-B3, LT-B4, LT-C1, LT-C2, LT-C3, LT-C4, LT-D2, LT-D3, LT-D4, LT-0, LT-A, LT-B, LT-C, LT-D (24)
MO (Medium Opacity): MO-0, MO-1, MO-2, MO-3, MO-4 (5)
HO (High Opacity): HO-0, HO-1, HO-2, HO-3, HO-4 (5)

5. Indications for Use

Fabrication 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 unit, crown or splinted crown on top of an implant abutment and 3-unit bridge up to the second premolar placed on top of an implant abutment.

6. Non Clinical Performance Testing

A biocompatibility assessment was completed according to ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

Bench performance testing was conducted in accordance with ISO 6872:2008 (Dentistry – Ceramic materials) and is suitable for its intended use.

7. Clinical Performance Testing

No clinical testing has been performed on this device.

8. Technological characteristics

The applicant device is a silica and lithium based glass ceramics that includes silicon dioxide (SiO_2), lithium oxide (Li_2O), other oxides, and coloring oxides. The glass ceramic applicant device is formed into an ingot which is used in heat-pressed technology to fabricate all ceramic dental restorations. The percentage of chemical components varies to yield a range of shades and transmission of light from high translucent to opaque to optimize esthetics when restorations are placed near natural teeth or other previously restored teeth.

Table 5.1 Comparison of applicant device to primary and reference predicate

	Applicant device	Primary Predicate	Reference Predicate
Product category	**Initial LiSi Press**	**IPS e.max Press**	**IPS e.max CAD**
Trade name	Press-heated ceramic ingot	Press-heated ceramic ingot	CAD/CAM ceramic block
Manufacturer	GC CORPORATION	IVOCLAR VIVADENT, INC	IVOCLAR VIVADENT, INC
Indications for use	Fabrication 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 unit, crown or splinted crown on top of an implant abutment and 3-unit bridge up to the second premolar placed on top of an implant abutment.	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 and crown, splinted crown or 3 unit bridge up to the second premolar placed on top of an implant abutment.	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. IPS e.max ZirCAD consists of machinable zirconia blocks for the preparation of full ceramic crowns, onlays and 3- and 4- unit bridges and inlay bridges (anterior and molar.)
Product description	Initial LiSi Press is a heat-pressed ceramic ingot for full ceramic restorations of both anterior and posterior.	IPS e.max Press is lithium disilicate glass-ceramic ingots for the Press technology.	IPS e.max CAD is a lithium disilicate glass-ceramic blocks for the CAD/CAM technology. IPS e.max ZirCAD is a yttrium-stabilized zirconium oxide block.

9. Substantial equivalence

The applicant device and primary predicate device both are silica lithium based ceramics with formulations of ceramic oxides used in combination to create a range of shades and translucencies; and that the form of the device is an ingot that is used in heat-pressed technology to fabricate all ceramic restorations. The difference is that the chemical formulation is not identical; however bench testing for both devices was conducted in accordance with ISO 6872:2008 (Dentistry – Ceramic Materials) confirming that the physical properties of the applicant device are comparable to the primary predicate for the same intended use.

The applicant device is similar to the reference device in that both are also silica lithium based ceramics and includes other glass and ceramic oxides in the device formulation. While the technology used to fabricate the all ceramic restoration differs in that the applicant device uses heat-pressed technology and the reference device uses CAD/CAM technology; the differences in chemical composition and technology used to fabricate the all ceramic restorations do not alter the raise concerns about the intended use of the applicant device.

Wording of indications for use statement of the applicant device for fabrication of crown or splinted crown on top of an implant abutment has the same intended meaning as the words for creation of crown, and splinted crown. The indications for use are equivalent for Initial LiSi Press and the primary predicate device.

10. Conclusion

Based on device formulation and non clinical performance testing, including bench testing and biocompatibility assessment, Initial LiSi Press is substantially equivalent to the predicate devices.