DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 13, 2016

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

Re: K153130
Trade/Device Name: Initial Lisi Block
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: June 14, 2016
Received: June 15, 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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number : K153130

Device Name: Initial LiSi Block

Indications for Use:

To fabricate 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, implant superstructures for single tooth restorations (anterior and posterior region).

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

1. Submitter Information:

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Date Prepared: June 14, 2016

2. Device Name:

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

3. Predicate Device:

Product	Applicant	510(k) No.	Code No.	Predicate
IPS E.MAX CAD / IPS E.MAX ZIRCAD	IVOCLAR VIVADENT, INC	K051705	EIH	Primary
MSCB-001	GC CORPORATION	K152274	EIH	Reference

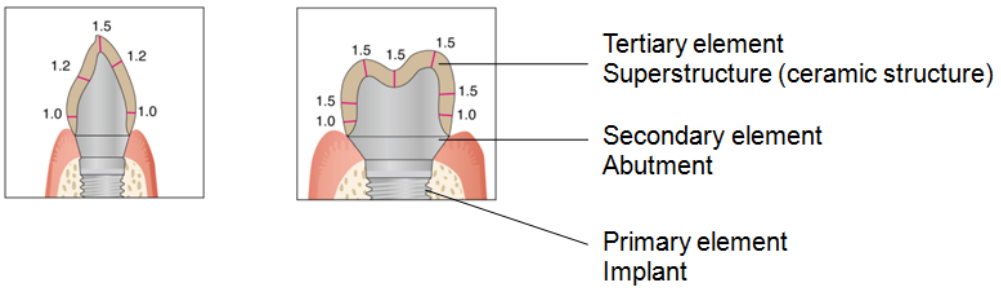
NOTE: In order to distinguish between device name and product name in this 510(k), device names are expressed in the following manner:

Product (Device name)	510(k) No.	Product name
IPS E.MAX CAD / IPS E.MAX ZIRCAD	K051705	IPS e.max CAD
MSCB-001	K152274	MSCB

4. Description of Device:

Initial LiSi Block is a block system consisting of a glass ceramic block cemented to a milling machine specific mandrel. This block is designed to be milled in a CAD/CAM milling machine that is programmed to fabricate indirect restorations such as 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 implant superstructures for single-tooth restorations.

Initial LiSi Block is intended to fabricate the tertiary element/exostructure of the implant superstructure, such as a crown. This structure sits on top of an abutment to achieve esthetic and generate compatible occlusal forces. The implant superstructure is classified as a fixed prosthesis.



After milling, the restoration can be customized by use of porcelain stain. The composition and manufacturing process of this product allows for milling without the need to fire (sintering) in a porcelain furnace.

All raw materials are melted at very high temperatures and the melting process prior to distribution eliminates all volatile substances. Final product is provided as complex oxide ceramics.

The device is available in a range of shades, including high, medium, and low translucency, as well as medium and high 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)

- Shelf Life: 10 years from the date of manufacture
- Storage: Recommended for optimal performance, store at room temperature (4-25^{o}C/39.2-77.0^{o}F) away from direct sunlight and high humidity.

5. Indications for Use:

To fabricate 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, implant superstructures for single tooth restorations (anterior and posterior region).

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.

Initial LiSi Block is a CAD/CAM machineable glass ceramic block for the preparation of full ceramic restoration and does come in contact with body tissues (tooth – enamel, dentin) for more than 24 hours.

In conclusion, biocompatibility of Initial LiSi Block is acceptable device from the biological evaluation result.

It is confirmed that the device conforms to the required specifications of ISO 6872:2008 – Dentistry – Ceramic Materials and is suitable for its intended use. Performance testing includes:

- Uniformity
- Freedom from extraneous materials
- Radioactivity
- Flexural strength (Biaxial flexure test)
- Chemical solubility
- Glass transition temperature
- Thermal expansion coefficient

Additional physical and chemical property testing includes:

- Shade
- Fracture toughness
- Bulk density

Table 1 Physical and chemical properties required by ISO 6872:2008

	Property	Standards	Test methods	Requirements
1	Uniformity	ISO 6872: 2008 5.1 Uniformity	Check by visual inspection.	Uniformly dispersed throughout the dental ceramic material.
2	Freedom from extraneous materials	ISO 6872: 2008 5.2 Freedom from extraneous materials	Check by visual inspection.	Free from extraneous materials.
3	Radioactivity	ISO 6872:2008 7.2 Radioactivity of dental ceramic	Mill powder using tungsten carbide milling media. Sieve and obtain 50g of powder with a particle size less than 75 μm	Not have more an activity concentration of more than 1.0 Bq $\cdot$ g^{-1} or uranium ^{238} (gamma spectroscopy technique)
4	Flexural strength	ISO 6872: 2008 5.4 Physical and chemical properties	Biaxial flexure test Test specimens are placed on the three supporting balls. Load is applied the center of the test piece. Determine the load required to break the specimen.	Greater than 300 MPa
5	Chemical solubility	ISO 6872: 2008 5.4 Physical and chemical properties	Specimens are soaked in acetic acid, 4% by volume solution in water at 80 °C for 16 hours.	Less than 100μg・cm^{-2}
6	Glass transition temperature	ISO 6872: 2008 5.4 Physical and chemical properties	Graphically determine by referring to the expansion curves obtained by dilatometric measurement.	Not deviate by more than 20^{O}C from the value stated by the manufacturer.
7	Thermal expansion coefficient	ISO 6872: 2008 5.4 Physical and chemical properties	Graphically determine by referring to recorded values indicating the expansion in relation to temperature obtained by dilatometric measurement.	Not deviated by more than 0.5 X 10^{-6} K^{-1} from the value stated by the manufacturer.

Table 2 Additional physical and chemical properties

	Property	Test methods	Requirements
1	Shade	Check by visual inspection.	Equivalent to the standard product.
2	Fracture toughness	Calculate by using Vickers-hardness.	No requirements
3	Bulk density	Calculate.	No requirements

7. Technological characteristics:

Initial LiSi Block is a CAD/CAM machineable glass ceramic block the preparation of full ceramic restoration. Its indications include 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, 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.

Initial LiSi Blocks are supplied in five levels of translucency (HT, MT, LT, MO, HO). Instructions for use include preparation, intraoral imaging, CAD/CAM process, polishing, staining, preparation for cementation, and cementation.

IPS e.max CAD is a CAD/CAM machinable glass ceramic based on lithium disilicate for the preparation of veneers, inlays, onlays, partial crowsn, corwns in the anterior and posterior region, implant superstructures for single-tooth restorations (anterior and posterior region), and primary telescope crown. IPS e.max ZirCAD consists of machinable zirconia blocks for the preparation of crown frameworks for anterior and posterior restorations, 3- to 12-unit bridge frameworks for the anterior and posterior regions, inlay bridge frameworks, primary telescope crowns, implant superstructures (single-tooth and bridge frameworks), and interlocked crown frameworks.

IPS e.max CAD blocks are supplied in four levels of translucency (HT, MT, LT, MO) as well as an impulse version. The monochromatic blocks are available in eight sizes. IPS e.max ZirCAD are supplied in nine block sizes and three shades (MO 0, MO 1, MO 2). Instructions for use include preparation, intraoral imaging, CAD/CAM process, polishing, staining, crystallization, preparation for cementation, and cementation.

MSCB is a block system consisting of a porcelain block cemented to a milling machine specific mandrel. This block/mandrel is designed to be milled in a CAD/CAM milling machine that is programmed to fabricate an indirect restoration. After milling, the restoration can be customized by use of porcelain stain. The composition of this product allows for milling without need to fire in a porcelain furnace. Its indications include fabrication of Metal free indirect restorations: full crown, inlays, onlays, and laminated veneer.

MSCB is supplied in 5 *Vita shades in two translucencies (HT and LT) in three sizes (12/14/14L). Instructions for use include preparation design, milling, finishing and polishing, cementation with sandblasting technique, cementation without sandblasting technique, and characterization.
*Vita® is a registered trademark of Vita Zahnfabrik, Bad Säckingen, Germany.

Table 5.3 Comparison of applicant device to predicate devices

	Applicant device	Primary Predicate Device	Reference Predicate Device
Trade name	**Initial LiSi Block**	**IPS e.max CAD**	**MSCB-001**
Product category	CAD/CAM machineable ceramic block.	CAD/CAM machineable ceramic block.	CAD/CAM restorative
Company	GC CORPORATION	IVOCLAR VIVADENT, INC	GC CORPORATION
510(k) No.	-	K051705	K152274
Indications for use	To fabricate 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, implant superstructures for single tooth restorations (anterior and posterior region).	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.)	Metal free indirect restorations: full crown, inlays, onlays, laminated veneer.
Product description	Initial LiSi Block is a CAD/CAM machineable ceramic block based on lithium silicate for full ceramic restorations of both anterior and posterior.	IPS e.max CAD is a CAD/CAM machineable glass ceramic based on lithium disilicate for the preparation of full ceramic restorations. IPS e.max ZirCAD is a yttrium-stabilized zirconium oxide block.	MSCB is a block system consisting of a porcelain block cemented to a milling machine specific mandrel. This block/mandrel is designed to be milled in a CAD/CAM milling machine that is programmed to fabricate an indirect restoration. After milling, the restoration can be customized by use of porcelain stain. The composition of this product allows for milling without need to fire in a porcelain furnace.
Instructions for use	1. Preparation 2. Intraoral imaging, CAD/CAM process 3. Finishing and polishing 4. Staining 5. Preparation for cementation 6. Cementation	1. Preparation 2. Intraoral imaging, CAD/CAM process 3. Finishing and polishing 4. Staining 5. Crystallization 6. Preparation for cementation 7. Cementation	1. Preparation design 2. Milling 3. Finishing and polishing 4. Cementation with sandblasting technique 5. Cementation without sandblasting technique 6. Characterization

The applicant device and primary predicate device, IPS e.max CAD, are the same in function and intended use, and similar in composition. There is no difference in indications and description. Only difference relates to instructions for use; the predicate device requires crystallization step in process while applicant device is provided in its “as-used” state.

The applicant and reference predicate device MSCB are similar in composition as well as description such that both are a block system intended to be designed and milled in a CAD/CAM milling machine with no requirement to fire in a porcelain furnace as they are provided in its “as-used” state.

The differences in indications for use are in the wording for the different types of restorations fabricated. This does not affect the equivalence to the predicate devices.

8. Substantial equivalence:
The applicant device complies with all the requirements of ISO 6872: 2008 (Dentistry - Ceramic materials) (Table 5.1) as well as additional requirements presented in Table 5.2. Initial LiSi Block and primary predicate IPS e.max CAD are similar in composition that both are silica based glass ceramics. The applicant device and primary predicate device IPS e.max CAD are the same in function and intended use. Only difference relates to instructions for use; the predicate device requires crystallization step in process while applicant device is provided in its "as-used" state. The differences do not affect the equivalency of the applicant device to the primary predicate device.

All of the components of the applicant device have already been used in the primary predicate device. The substantial equivalence of the applicant device was determined by means of comparing to ISO 6872:2008 standards as well as the predicate devices.

9. Differences:
The following technological differences exist between the applicant device and the primary predicate device:
- Slight difference in formulation
- Difference in translucency shades and block sizes available
- Unnecessary crystallization process

However, there is no difference in instructions, indications or description except for crystallization. All of the components of the applicant device have already been used in the primary predicate device.

Compared to reference predicate MSCB, Initial LiSi Block has a higher flexural strength in accordance with ISO 6872:2008 – Dentistry – Ceramic Materials.

10. Conclusion:
Based on chemical composition and non-clinical testing, we find the applicant device substantially equivalent to the predicate devices.