DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 25, 2016

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

Re: K152274
Trade/Device Name: MSCB-001
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Dated: February 22, 2016
Received: February 24, 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" (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,

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): K152274

Device Name: MSCB-001

Indications for Use:

1. Metal free indirect restorations: full crown, inlays, onlays, laminated veneer

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)

Section 5 – 510(k) Summary

GC AMERICA INC.
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1. Submitter:

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Date Prepared: August 7, 2015

2. Device Name:

Proprietary Name: MSCB-001
Classification Name: Porcelain Powder for Clinical Use
Device Classification: Class II, 872.6660
Product Code: EIH

3. Predicate Devices:

Company	Device	510(k) No.	Date Cleared
Vita Zahnfarbrik	VITABLOCS FOR CEREC MARK II	K022408	7/24/2002

4. Description of Device:

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.

MSCB-001 system is a feldspathic (glass) porcelain system based on partially crystalline but mostly vitreous materials derived from phyllosilicates such as potash or sodafeldspar, several commercially available fluxes, and various refractive oxides for mechanical enhancement.

5. Indications for Use:

1. Metal free indirect restorations: full crown, inlays, onlays, and laminated veneer

6. Package

1. 3 sizes: 12/ 14/ 14L
2. 5 blocks in one package
3. Available CAD/CAM system: Aadva/ CEREC /E4D

7. Shades

5 Vita* shades available in two translucencies:

- High Translucency (HT): A1 HT, A2 HT, A3 HT, A3.5 HT, B1 HT
- Low Translucency (LT): A1 LT, A2 LT, A3 LT, A3.5 LT, B1 LT

- One bleach shade (BL)
- Low Translucency (LT): A1 LT, A2 LT, A3 LT, A3.5 LT, B1 LT
- One bleach shade (BL)

*Vita® is a registered trademark of Vita Zahnfabrik, Bad Säckingen, Germany.

8. Shelf Life:
10 years from date of manufacture

9. Biocompatibility
According to ISO 10993-1: 2009, the following is stated:

*Sec 4.1 "Evaluation may include both a study of relevant preclinical and clinical experience and actual testing. Such an evaluation might result in the conclusion that no testing is needed if the material has a demonstrable safe history of use in a specified role and physical form that is equivalent to that of the device under design."

*Sec 6.1 "Material characterization: "If the combination of all materials, chemicals and processes has an established history of safe use in the intended application, then further characterization and biological evaluation might not be necessary."

All components in MSCB-001 have been used in predicate product, such as VITABLOCS FOR CEREC. Based on above, MSCB was considered to have an acceptable level of biocompatibility

All devices come in contact with the same body tissues (tooth - enamel, dentin) for more than 24 hours.

10. Performance Testing – Bench:
It is confirmed that the device conforms to the required specifications of ISO 6872:2008 and is suitable for its intended use.

Performance testing includes:
- Chemical solubility
- Flexural strength
- Linear thermal expansion
- Radioactivity

11. Technological characteristics:
All the components of the applicant device, MSCB-001, have already been used in the predicate device (VITABLOCS FOR CEREC MARK II).

12. Substantial equivalence:
The new and predicate device (VITABLOCS FOR CEREC MARK II) are the same in function, and similar in composition and intended use. This supports that the compatibility of the applicant device is substantially equivalent to the predicate devices.

The substantial equivalence was viewed looking at comparison to standards as well as the predicate device.

Differences:
Compared to VITABLOCS FOR CEREC MARK II, MSCB-001 has a higher flexural strength using ISO 6872.

13. Conclusion
Based on a comparison of intended use, indication for use, composition, and shelf life, GC concludes that MSCB-001 is substantially equivalent to the predicate device (VITABLOCS FOR CEREC MARK II: K022408).

Table 5.1.1 Comparison Table

	Applicant device	Comparative device	Difference Y/N	Rationale
Product category	CAD/CAM restorative	CAD/CAM restorative		
Trade name	MSCB-001	VITABLOCS FOR CEREC MARK II (K022408)		
Manufacturer	Klema Dentalprodukte	Vita Zahnfarbrik		
Indications	1. Metal free indirect restorations: full crown, inlays, onlays, laminated veneer	Fabrication of inlays, onlays, partial and full crowns, endo-crowns of molars, and veneers	Y	We have added the word "metal free" to clarify the classification of material type the applicant device is part of. Since the applicant & predicate device are both metal free ceramics, the technical description & function have not changed.
Product description	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.	VITABLOCS are industrially manufactured, fine-structure feldspar ceramic blocks used to fabricate inlays, onlays, veneers and crowns with CEREC and inLab CAD/CAM systems of Sirona Dental Systems GmbH.	Y	Though the verbiage is different, the type of material, Feldspar type ceramic is the same as well as its form (Block on mandrel). Both products fabricate indirect restoration using the same technology. The different term that the applicant device used is "CAD/CAM milling machine."
Instructions for use	1. Preparation design 2. Milling 3. Finishing and polishing 4. Cementation with sandblasting technique 5. Cementation without sandblasting technique 6. Characterization	Fabrication of the restoration in the dental laboratory: 1. CAD design with inLab 3D software. 2. Milling of the restoration with inLab. 3. Placing the restoration on the model. 4. Finishing & polishing on the model. Alternatively: characterization/individualization of the shade Fabrication of the restoration in the dental practice: 1. Finishing & polishing. 2. Alternatively: Characterization of the shade, individualizing/glazing. 3. Adhesive bonding: • Ceramic etching • Silinization	Y	No impact. Different verbiage for similar processes.

		• Enamel/dentine etching • Adhesive system • Adhesive composite • Oxygen protection gel 4. Finishing & final polishing		

Differences in verbiage of indications, product description and instructions for use are noted above. Review of these categories between predicate and applicant device demonstrated that these products had similar indications (same clinical utilization), similar description and instructions.

The variations noted and described demonstrate that the predicate and applicant device have similar clinical use that can be manage by the dental professional.

Table 5.2.1 Summary of Performance Specifications

Property /Unit	Standards	Requirements	Test results		
			MSCB LT A2	**MSCB HT A2**	**CEREC VITABLOCS MK2**
Chemical solubility	**ISO** 6872: 2008	Less than 100 µg/cm^3	34 µg/cm^3 31 µg/cm^3 29 µg/cm^3	33 µg/cm^3 35 µg/cm^3 39 µg/cm^3	29 µg/cm^3 30 µg/cm^3 35 µg/cm^3
		Average	31	35	31
		St. Dev.	2.5	3.0	3.2
Flexural strength	**ISO** 6872: 2008	Greater than 100 MPa	210 MPa 215 MPa 205 MPa	207 MPa 220 MPa 215 MPa	154 MPa 140 MPa 142 MPa
		Average	210	214	145
		St. Dev.	5	6.5	7.5
Linear thermal expansion	**ISO** 6872: 2008	TG(°C) +/- 10	470°C 468°C 472°C	465°C 468°C 475C	780°C 790°C 785°C
		Average	470°C	469°C	785°
		St. Dev.	2	5	5
Radioactivity	ISO 6872: 2008	Radioactivity A ≤ 1.0 By/g an ^{238}U	Conformed	Conformed	Conformed

Comparing test results between applicant and predicate device for the properties of chemical solubility they were statistically equivalent and met or exceeded requirements of ISO 6872:2008.

Comparing test results between application and predicate device for the properties of flexural strength, they were statistically different with MSCB-001 having higher values. Both devices exceeded performance specification minimum.

Comparing test results between predicate and applicant device for linear thermal expansion with a TG of +/- 10°C, the standard deviation of products tested were within the SD limitations requirement.

The properties listed, tested and results indicate that the application and predicate device are within the standard ISO 6872:2008. When compared to the predicate device already in the market, the performances of MSCB-001 are at least statistically equivalent and, therefore, can be considered clinically acceptable.