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

Vericom Co., Ltd.
Myung-Hwan Oh
R&d Director
48 Toegyegongdan 1-gil
Chuncheon-si, 200-944
REPUBLIC OF KOREA

March 17, 2017

Re: K163346
Trade/Device Name: Mazic Duro
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, POW
Dated: December 28, 2016
Received: December 30, 2016

Dear Myung-Hwan Oh:

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,

Susan Runner DDS, MA

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
MAZIC™ Duro

Indications for Use *(Describe)*

· Fabrication of inlays, onlays, veneers and crowns

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

MAZIC™Duro

Date: December 28, 2016

I. SUBMITTER

Vericom Co., Ltd.
48 Toegyegongdan 1-gil, Chuncheon-si, Gangwon-do 200-944, Korea
Tel: +82-31-441-2881
Fax: +82-31-441-2883

Contact Name: Myung-Hwan Oh
Email: omh@vericom.co.kr

II. DEVICE

Name of Device:	MAZIC™Duro
Regulation Name:	Tooth shade resin material
Classification Name:	Tooth shade resin material
Regulatory Class:	2
Product Code:	EBF

III. Predicate Device

K133824, CERASMART, GC AMERICA INC.

IV. DEVICE DESCRIPTION

MAZIC™Duro, a dental restorative material, is a radiopaque, block type, hybrid ceramic that is intended for the fabrication of inlays, onlays, veneers and crowns. The device can be matched to the patient's tooth shade and is intended for use in dental CAD/CAM milling procedures.

V. INDICATIONS FOR USE

· Fabrication of inlays, onlays, veneers and crowns

VI. COMPARISON OF TECHNILOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

		Subject Device	Predicate Device	Summary
Device Name		MAZIC™Duro	CERASMART	-
Manufacturer		Vericom Co., Ltd.	GC AMERICA INC.	-
510(k) Number		New	K133824	-
Intended user		Dental professionals	Dental professionals	-
Similarity	**Description**	MAZIC™Duro, a dental restorative material, is a radiopaque, block type, hybrid ceramic that is intended for the fabrication of inlays, onlays, veneers and crowns. The device can be matched to the patient's tooth shade and is intended for use in dental CAD/CAM milling procedures.	CERASMART is a pre-cured composite block for milling CAD/CAM indirect restorations. The milled device is used for the restorations of both anterior and posterior teeth.	Description of subject device and predicate device is very similar; pre-curd composite block for milling by dental CAD/CAM
	Indications for Use	Fabrication of inlays, onlays, veneers and crowns	The product is indicated for inlays, onlays, veneers and full crown restorations, including crowns on implants	Both device are used for inlays, onlays, veneers and crowns.
	Design	Pre-cured block	Pre-cured block	Both devices are provided in pre-curd block
	Chemical composition	Resin base	Resin base	Both devices are resin based composite block.
	Physical and performance properties	ISO 4049 -Compressive strength: 534.40 MPa -Flexural Strength: 213.30 MPa -Elastic modulus: 10.17 GPa -Radio-opacity: 2.4 step wedge -Vicker'smicrohardness: 85.28 HV0.2 -Water sorption: 15.51 $\mu g/cm^3$ -Solubility: 1.90 $\mu g/cm^3$	ISO 4049 -Compressive strength: 501.76 MPa -Flexural Strength: 207.91 MPa -Elastic modulus: 9.15 GPa -Radio-opacity : 2.6 step wedge -Vicker'smicrohardness: 70.97 HV0.2 -Water sorption: 20.67 $\mu g/cm^3$ -Solubility : 2.10 $\mu g/cm^3$	Physical and performance properties of the subjective device is substantial equivalent to predicate device.
	Biocompatibility	-Cytotoxicity(Agar diffusion) -Acute systemic toxicity(Oral)	Device is biocompatible when used as directed by dental professionals per ISO 10993-1.	Both devices are biocompatible.

		-Oral mucosa irritation -Sensitization(GPMT) -Genotoxicity(Ames)		
	Sterilization	Non-sterile	Non-sterile	Same
	Storage condition	· Avoid exposure to the sunlight. · Store at room temperature(2-27℃).	Recommended for optimal performance, store at room temperature(4-25℃ / 39.2-77.0℉) away from direct sunlight and high humidity.	Both devices are recommended at room temperature away from sunlight.
	Shelf Life	5 years	5 years	Same
Difference	**Shade**	30 shades(A1 HT, A2 HT, A3 HT, B1 HT, B2 HT, B3 HT, C1 HT, C2 HT, C3 HT, D2 HT, D3 HT, E HT, 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, W1 LT, W2 LT)	33 shades(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 HT, 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, BL)	Shade is an option that is selected according to patient's teeth color.
	Size	-Rectangular type: [12]10.2*12.2*15, [14L]14.5*14.5*18 -Disc type: Φ98*8T/10T/12T/14T, Φ100*8T/10T/12T/14T, Φ95*8T/10T/12T/14T	3 sizes(12, 14, 14L)	Size is an option that is selected according to patient's application region. The disc type of subject device provide several restorations.

VII. NON-CLINICAL PERFORMANCE TESTING

MAZIC™ Duro and the predicate device, CERASMART were tested for the non-clinical performance including compressive strength, flexural strength, elastic modulus, radio-opacity, vicker's micro hardness, water sorption, and solubility.

All of test results obtained from these tests indicated that MAZIC™ Duro is substantially equivalent to the predicate device, CERASMART, in terms of physical properties and performance.

The biocompatibility evaluation for the MAZIC^{TM} Duro was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1:Evaluation and Testing'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1 : Evaluation and Testing Within a Risk Management Process" as recognized by FDA. The device of testing included the following tests:

- Cytotoxicity(Agar diffusion), ISO 10993-5[2009]
- Genotoxicity(Ames), ISO 10993-3[2003]
- Oral mucous Irritation, ISO 10993-10[2010]
- Sensitization(GPMT), ISO 10993-10[2010]
- Acute systemic toxicity, ISO 10993-11[2006]

The results of test indicated that MAZIC^{TM} Duro is considered to be biocompatible and therefore equivalent with its predicate device, CERASMART, that considered biocompatibility per ISO 10993-1.

VIII. SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject device is similar to predicate device in terms of indication for use, design, chemical composition, physical properties and performance etc. The subject device consists of resin base composite block, as is the predicate device. The physical properties and performance of subject device are not significantly different from the predicate device, as indicated by non-clinical performance testing.

The variety of shades and sizes are different between subject device and predicate device.

IX. CONCLUSIONS

The indications and technological characteristics of MAZIC™ Duro are very similar to predicate device. Therefore, MAZIC™ Duro is substantially equivalent to the identified predicate device.