July 1, 2021

Vericom Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt STE 200
Irvine, California 92620

Re: K203672
Trade/Device Name: MAZIC Claro CAD and MAZIC Claro Press
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 1, 2021
Received: May 7, 2021

Dear Priscilla Chung:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*

K203672

Device Name

MAZIC Claro CAD and MAZIC Claro Press

Indications for Use *(Describe)*

MAZIC Claro Press 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.

MAZIC Claro 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.

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.

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510(k) Summary
(k203672)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: June 28, 2021

1. 510K Applicant / Submitter:

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Gangwon-Do, 200-944, Republic of Korea
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2. Submission Contact Person

LK Consulting Group USA, Inc.
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3. Device

- Proprietary Name: MAZIC Claro CAD and MAZIC Claro Press
- Common Name: Dental Frame Material for Dental prosthesis
- Classification: Porcelain Powder for Clinical Use, Class II (21 CFR 872.6660)
- Product Code: EIH
- Review Panel: Dental

4. Predicate Device

IPS E.MAX PRESS (K120134) by Ivoclar Vivadent AG
IPS E.MAX CAD (K051705) by Ivoclar Vivadent AG

5. Description:

The MAZIC Claro Press, dental glass ceramic ingot, is to make dental restorative prosthesis such as inlays, onlays, veneers, crowns and bridges. Having a variety of shade, the user can choose a suitable color that matches the natural teeth of the patient. The prosthesis can be made through regular press process.
The MAZIC Claro CAD, dental glass ceramic block, is to make dental restorative prosthesis such as inlays, onlays, veneers and crowns. Having a variety of shade, the user can choose a

suitable color that matches the natural teeth of the patient. The prosthesis can be made through milling procedure by dental CAD/CAM.

8. Indications for Use

MAZIC Claro Press 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.

MAZIC Claro 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.

9. Substantial Equivalence Discussion:

9.1. MAZIC Claro Press

	Subject Device	**Predicate Device**
Trade Name	MAZIC Claro Press	IPS E.MAX PRESS
Manufacturer	VERICOM CO., LTD.	Ivoclar Vivadent AG
510K Number	K203672	K120134
Product Code	EIH	EIH

Indications for Use	MAZIC Claro Press 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.	IPS e.max Press and IPS e.max 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 termiinal abutment Crown, splinted crown or 3 unit bridge up to the second premolar placed on top of an implant abutment.
Type and class according to ISO6872	- Type II - Class 3.a) Monolithic ceramic for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration adhesively or non-adhesively cemented.	- Type II - Class 3.a) Monolithic ceramic for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration adhesively or non-adhesively cemented.
Chemical Compositions	SiO_2 Li_2O K_2O MgO ZnO Al_2O_3 P_2O_5 ZrO_2 Other oxides	SiO_2 Li_2O K_2O ZnO P_2O_5 ZrO_2 Other oxides
Summary of sizes and shades	Form of Ingots: Ø12.7 x 10 ㎜, Ø12.7 x 20 ㎜	Form of Ingots: Ø12.7 x 10 ㎜, Ø12.7 x 20 ㎜
Shade	High translucency : 16 A-D and 4 Bleach shades Low translucency : 16 A-D and 4 Bleach shades Medium opacity : 5 shades High opacity: 3 shades	High translucency : 16 A-D and 4 Bleach shades Low translucency : 16 A-D and 4 Bleach shades Medium opacity : 5 shades High opacity: 3 shades
Principle of operation	Fabricating restorations using hot press technique	Fabricating restorations using hot press technique
Sterility	Non-sterile	Non-sterile
Physical properties	Conforms to ISO 6872 Uniformity(Consistency), Freedom of extraneous materials(Foreign materials), Flexural strength Chemical solubility Linear thermal expansion/Coefficient of thermal expansion(CTE) Radadiopacity(Radiation emission)	Conforms to ISO 6872 Flexural strength Chemical solubility Coefficient of thermal expansion(CTE) Radiopacity

Substantial Equivalence Discussion

The subject device has the same indications for use and the same principle of operation as the predicate device. Although the subject device and the predicate device might have a slight difference in raw material, the both devices produced after manufacturing process at high temperatures have SiO_2, Li_2O, K2O, ZnO and P_2O_5 as major ingredients.
Despite this difference, the test results per ISO6872 shows that the subject device is substantially equivalent to the predicate device in physical and chemical properties and meets the necessary requirements. We also performed biocompatibility tests on the subject device and the test results show that it confirms the ISO 10993 requirements. Therefore, the difference does not raise a question in safety and effectiveness and the subject device is substantially equivalent to the predicate device.

9.2. MAZIC Claro CAD

	Subject Device	**Predicate Device**
Trade Name	MAZIC Claro CAD	IPS E.MAX CAD
Manufacturer	VERICOM CO., LTD.	Ivoclar Vivadent AG
510K Number	K203672	K051705
Product Code	EIH	EIH
Indications for Use	MAZIC Claro Press 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 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.
Type and class according to ISO6872	- Type II - Class 3.a) Monolithic ceramic for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration adhesively or non-adhesively cemented.	- Type II - Class 3.a) Monolithic ceramic for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration adhesively or non-adhesively cemented.
Chemical Compositions	SiO_2 Li_2O K_2O MgO ZnO Al_2O_3 P_2O_5 ZrO_2 Other oxides	SiO_2 Li_2O K_2O MgO ZnO Al_2O_3 P_2O_5 ZrO_2 Other oxides
Summary of sizes and shapes	Form of Blocks: 12 x 10 x 15 ㎜, 14 x 12 x 18 ㎜, 14.5 x 14.5x 32 ㎜, 15.2 x 15.x 38 ㎜	Form of Blocks: 12.5 x 10.4 x 15 ㎜, 14.5 x 12.4 x 18 ㎜, 15.8 x 17.8 x 18 ㎜, 14.5 x 14.5 x 32 ㎜, 15.2 x 15.2 x 38 ㎜

Shade	High translucency : 3 A shades Low translucency : 3 A shades Medium opacity : 3 shades Bleach : 2 shades	High translucency : 16 A-D and 4 Bleach shades Low translucency : 16 A-D and 4 Bleach shades Medium opacity : 5 shades Opalescence: 2 shades
Principle of operation	Fabricating restorations using CAD/CAM technique	Fabricating restorations using CAD/CAM technique
Sterility	Non-sterile	Non-sterile
Physical properties	Conforms to ISO 6872 Uniformity, Freedom of extraneous materials, Flexural strength Chemical solubility Linear thermal expansion/Coefficient of thermal expansion(CTE) Radadiopacity(Radiation emission)	Conforms to ISO 6872 Flexural strength Chemical solubility Coefficient of thermal expansion(CTE) Radiopoacity

Substantial Equivalence Discussion

The subject device has the same indications for use and the same principle of operation as the predicate device. Although the subject device and the predicate device might have a slight difference in raw material, the both devices produced after manufacturing process at high temperatures have SiO_2, Li_2O, K_2O, MgO, ZnO, Al_2O_3, P_2O_5 and ZrO_2 as major ingredients. Despite this difference, the test results per ISO6872 shows that the subject device is substantially equivalent to the predicate device in physical and chemical properties and meets the necessary requirements.
Another difference is the shades the devices offer. This difference is also related to raw materials. We also performed biocompatibility tests on the subject device and the test results show that it confirms the ISO 10993 requirements. Therefore, the differences do not raise a question in safety and effectiveness and the subject device is substantially equivalent to the predicate device.

10. Performance Tests (Non-clinical)

- Performance Tests in accordance with ISO 6872

No.	Test	Standard
1	Uniformity	ISO 6872
2	Freedom from extraneous materials	ISO 6872
3	Flexural strength	ISO 6872
4	Chemical solubility	ISO 6872
5	Radioactivity	ISO 6872
6	Linear thermal expansion coefficient	ISO 6872
7	Glass transition temperature	ISO 6872

- Biocompatibility Tests in accordance with ISO 10993

No.	Test	Standard
1	Cytotoxicity (Agar diffusion)	ISO10993-5
2	Sensitization	ISO10993-10
3	Acute systemic toxicity (Oral)	ISO10993-11
4	Oral mucosa irritation	ISO10993-10
5	Bacterial reverse mutation (Ames test)	ISO10993-3

The test results of non-clinical tests performed on the subject device supported that it is substantially equivalent to the predicate devices despite the differences.

11. Conclusions:

Based on the information provided in this premarket notification, Vericom Co., Ltd. concludes that the MAZIC Claro CAD and MAZIC Claro Press are substantially equivalent to the predicate device as described herein in.