August 21, 2020

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

Re: K193260
Trade/Device Name: U-Cem Premium & MAZIC Cem
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: July 21, 2020
Received: July 24, 2020

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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)*
K193260

Device Name

U-Cem™ Premium & MAZIC® Cem

Indications for Use *(Describe)*

1. Luting metal crowns, bridge, inlay and including porcelain-fused-to-metal and composite-to-metal varieties
2. Luting resin crowns, bridges, inlays, onlays and veneers
3. Luting metal or non-metal/fiber posts
4. Luting orthodontic appliances
5. Luting porcelain inlays, onlays, crowns and veneers (includes alumina and zirconia)

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.

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510(k) Summary
(K193260)

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

Date: July 16, 2020

1. 510K Applicant / Submitter:

Vericom Co., Ltd.
48,Toegyegongdan 1-Gil, Chuncheon-Si,
Gangwon-Do, 200-944, Republic of Korea
Tel: +82-31-441-2881 Fax: +82-31-441-2883

2. Submission Contact Person

LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200, Irvine CA 92620
Priscilla Juhee Chung
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Proprietary Name: U-Cem™ Premium & MAZIC® Cem
- Common Name: Luting Cement
- Classification: Dental Cement, Class II (21 CFR 872.3275)
- Product Code: EMA

4. Predicate Device

BisCem (K082449) by Bisco, Inc.

5. Description:

The U-Cem™ Premium and the MAZIC® Cem are dual-cured self-adhesive resin cement. The U-Cem™ Premium and the MAZIC® Cem are the same product yet with different label design for different volume packages as shown below. The brand name, MAZIC® Cem, is specifically for 8.5g.
It is fluoride-releasing paste type, and has radiopaque. U-Cem™ Premium is available in both Automix and Double Dispenser types, and offers three different shades: Clear, Universal, and Opaque for esthetics.

It is used for cementation of ceramics, metals or composite inlays, onlays, crowns, bridges, posts and screws.

8. Indications for Use

1. Luting metal crowns, bridge, inlay and including porcelain-fused-to-metal and composite-to-metal varieties
2. Luting resin crowns, bridges, inlays, onlays and veneers
3. Luting metal or non-metal/fiber posts
4. Luting orthodontic appliances
5. Luting porcelain inlays, onlays, crowns and veneers (includes alumina and zirconia)

9. Substantial Equivalence Discussion:

The U-Cem™ Premium/ the MAZIC® Cem has the same intended use and the principle of operation, and also has similar physical properties demonstrating comparable performance specifications to the predicate device: BisCem (K082449) by Bisco, Inc.

The Indications for Use statement of the subject device is similar to that of the predicate device, but it is described in a slightly different way. However, fundamentally the predicate device's indications cover the subject device's claims.
One of the differences is the subject device has an additional delivery system which is the Double Dispenser type. This Double Dispenser has the same mixing ration as the auto mix type so this difference does not raise a question in substantial equivalence.
Another difference is that the subject device has three shades, whereas, the BisCem has two shades, and some raw materials used might be different. However, bench performance and biocompatibility testing performed demonstrates that these differences would not raise a new question in substantial equivalence. For the tests that were performed according to the standards, both devices satisfied the standards' requirements. For the testing that does not have an international standard, the test results of the subject device were substantially equivalent to the predicate device.
The Physical and Performance properties are also very similar except setting time. The subject device shows faster setting time which is 2 minutes and 12 seconds. Both devices meet the ISO 4049 requirement for the setting time, and it does not a raise an issue to support substantial equivalence.

Based on the information provided herein, it is concluded that the U-Cem™ Premium/ the MAZIC® Cem is substantially equivalent to the predicate device.

	Subject Device	**Predicate Device**
Device Name	U-Cem™ Premium	BisCem
510k #	K193260	K082449
Manufacturer	VERICOM CO., LTD.	Bisco, Inc.

Indications for use			1. Luting metal crowns, bridge, inlay and including porcelain-fused-to-metal and composite-to-metal varieties 2. Luting resin crowns, bridges, inlays, onlays and veneers 3. Luting metal or non-metal/fiber posts 4. Luting orthodontic appliances 5. Luting porcelain inlays, onlays, crowns and veneers (includes alumina and zirconia)	1. Luting metal crowns, bridge, inlay and including porcelain-fused-to-metal and composite-to-metal varieties 2. Luting resin crowns, bridges, inlays, onlays and veneers 3. Luting metal or non-metal/fiber posts 4. Luting orthodontic appliances 5. Luting porcelain inlays, onlays, crowns and veneers (includes alumina and zirconia)
Principle of operation			Dual cured	Dual cured
Physical & Perform-ance properties	Working Time (at 60sec. after completion of mixing)		Physically homogeneous and forming the thin layer	Physically homogeneous and forming the thin layer
	Setting time		2 m 12s	9 m 08 s
	Compressive strength		236.35㎫	189.15㎫
	Flexural strength		135.87㎫	101.93㎫
	Film thickness		11㎛	23㎛
	Shear bond strength	Composite -Dentin	12.85㎫	7.68㎫
		Composite -Enamel	19.16㎫	16.32㎫
		Glass Ceramic -Litium disilicate	6.21㎫	5.49㎫
		Ceramic - Aluminum oxide	7.28㎫	4.27㎫
		Metal	12.70㎫	4.38㎫
		Zirconia	9.05㎫	5.12㎫
	Fluoride release		2.42 ppm	10.02 ppm
	Radio-opacity		1.45	None
	Solubility		0.87 ㎍/㎣	1.53㎍/㎣
	Polymerization shrinkage		4.38%	4.18%
Chemical Composition	Filler		Amorphous silica	Amorphous silica
	Resin composition		Methacrylate based	Methacrylate based
	Method of application		Bonding agent not required	Bonding agent not required
	Ions released		Fluoride	Fluoride
Standard Conformed			ISO 4049	ISO 4049
Biocompatibility			Yes	Yes
Use			Prescription / Hospital	Prescription / Hospital
Delivery system			Dual syringe(Base:Catalyst=1:1), Automix and Double Dispenser type	Dual-syringe(Base:Catalyst=1:1), Automix type
Storage condition			2~8℃ (at refrigerator temperature)	2~8℃ (at refrigerator temperature)

Physical properties	Shade	- Clear - Universal - Opaque	- Translucent - Opaque

10. Performance Tests (Non-clinical)

- Performance Test:
  - ISO 4049 Fourth edition 2009-10-01 Dentistry - Polymer-based restorative materials
  - ISO 9917-1 Second edition 2007-10-01 Dentistry - Water-based cements - Part 1: Powder/liquid acid-base cements, Annex D.
  - ISO /TS 11405 Third edition 2015-02-01 Dentistry - Testing of adhesion to tooth structure

- Biocompatibility Tests
  - ISO 10993-1 Fourth edition 2009-10-15, biological evaluation of medical devices - part 1: evaluation and testing within a risk management process [including: technical corrigendum 1 (2010)]. (Biocompatibility)
  - ISO 10993-3 Third edition 2014-10-1 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
  - ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
  - ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
  - ISO 10993-11 Second edition 2006-08-15 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

- Shelf Life Test Performance Tests in accordance with ISO 4049 and ISO 9917-1

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 U-Cem™ Premium & MAZIC® Cem is substantially equivalent to the predicate device as described herein in.