December 19, 2022

Spident Co., Ltd.
Eunok Choi
Manager
203 & 312, Korea Industrial Complex, 722
Gojan-Dong, Namdong-Gu, Incheon 405-821
SOUTH KOREA

Re: K214076
Trade/Device Name: EsCem
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: November 9, 2022
Received: November 18, 2022

Dear Eunok Choi:

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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K214076

Device Name

EsCem

Indications for Use *(Describe)*

Final cementation of all-ceramic, metal-based inlays, onlays, posts, crown and bridge

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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Section 5. 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: December 22, 2021

1. Company and Correspondent making the submission:

Company Name : SPIDENT CO., LTD.
Address : 203 & 312 Korea Industrial Complex, 722, Gojan-Dong, Namdong-Gu, Incheon, Korea 405-821
Tel : +82-32-821-0071
Fax : + 82-32-821-0074
Company Contact : J.M. Ahn / President

2. Device Name and Classification

Proprietary Name : EsCem
Common name : Self-Adhesive Resin Cement
Classification name : Dental Cement [CFR 872.3275]
Product code : EMA
Class : II

3. Predicate Devices (Legally Marketed Devices)

The predicate devices for EsCem is :

- **G-CEM LinkAce (GAM-200),** GC AMERICA INC., K120243

4. Description:

EsCem is a dual-cured resin cement that can be self-etched and self-adhesive.
It is classified as type 2 and class 3 according to ISO 4049. It is easy to handle with 'one step' system that does not need pre-treatment process, and it is easy to remove excess cement, so it is possible to perform quick operation. It is also easy to identify because it has a radio-opacity(1.2mm Al). And it offers various shades for aesthetics and color stable.

5. Indications for Use
Final cementation of all-ceramic, metal-based inlays, onlays, posts, crown and bridge

6. Performance Testing - Bench
The performance test was conducted to prove the substantially equivalence of the subject device, and the standards applied to the performance test are as follows.

- ISO 4049:2019, Dentistry — Polymer-based restorative materials

Performance	Test method	Requirement
Film thickness	ISO 4049:2019 -7.5 Measurement of film thickness of luting materials	shall be no greater than 50 µm.
Working time	ISO 4049:2019 -7.7 Working time, Class 1 and Class 3 luting materials	during its formation there shall be no detectable change in its homogeneity.
Setting time	ISO 4049:2019 -7.8 Setting time, Class 1 and Class 3 materials	shall be no more than 10 min.
Flexural strength	ISO 4049:2019 -7.11 Flexural strength	shall be equal to or greater than 50 MPa
Water sorption	ISO 4049:2019 -7.12 Water sorption and solubility	shall be equal to or less than 40 µg/mm^3.
Solubility	ISO 4049:2019 -7.12 Water sorption and solubility	shall be equal to or less than 7,5 µg/mm^3.
Radio-opacity	ISO 4049:2019 -7.14 Radio-opacity	shall be equal to or greater than that of the same thickness of aluminium
Sensitivity to light	ISO 4049:2019 -7.9 Sensitivity to light, Class 2 materials	the material shall remain physically homogeneous.
Color stability	ISO 4049:2019 -7.13 Shade and colour stability after irradiation and water sorption	no more than a slight change in colour shall be observed

7. Biocompatibility
Biocompatibility tests and biological safety evaluation were performed and the results proved that the subject device is at least as biocompatible and biologically safe as the predicate device.
The standards applied are as follows.

- ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-3:2014, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in

vitro cytotoxicity

- ISO 10993-6:2016, Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
- ISO 10993-10:2010, Biological evaluation of medical devices. Tests for irritation and skin sensitization
- ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 7405:2018, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry

8. Substantial Equivalence Discussion

Product Name	EsCem	G-CEM LinkAce
510(k)	N/A	K120243
Manufacturer	SPIDENT CO., LTD.	GC Corporation
Product description	EsCem is a dual-cured resin cement that can be self-etched and self-adhesive and is classified as type 2 and class 3 according to ISO 4049. It is easy to handle with 'one step' system that does not need pre-treatment process, and it is easy to remove excess cement, so it is possible to perform quick operation. It is also easy to identify because it has a radiopaque. And it offers various shades for aesthetics.	GC G-CEM LinkAce is a dual-cure self-adhesive universal resin luting cement delivered in double barrel automix syringe, designed for the adhesive luting of all-ceramic, metal or composite indirect restorations.
Chemical composition of Resin	Methacrylate monomer Filler Initiator Inhibitor pigment	Methacrylate monomer Filler Initiator Inhibitor pigment
Indications for use	Final cementation of all-ceramic, metal-based inlays, onlays, posts, crown and bridge	- Cementation of all types of all ceramic, resin and metal-based inlays, onlays, crowns and bridges. - Cementation of metal, ceramic, fibre posts, and cast post and cores.
Principle of operation	Dual cured	Dual cured

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Mechanical Properties • Setting time (sec)	Less than 600 sec	Less than 600 sec
• Flexural strength (MPa)	More than 50	More than 50
• Film thickness (μm)	Less than 50	Less than 50
• Water sorption (μg/mm^3)	Less than 40	Less than 40
• Solubility (μg/mm^3)	Less than 7.5	Less than 7.5
• Radio-opacity (mmAl)	More than 1 mm	More than 1 mm
Standard conformed	ISO 4049	ISO 4049
Biocompatibility	Yes	Yes
Light Curing Time	20 Seconds	20 Seconds
Application Area	Tooth	Tooth
Target Population	Dental patient	Dental patient
Intended Operator	Dentist	Dentist
Storage condition	2-27℃	4-25℃
Shade	A2, A3, TW	A2, AO3, BO1, Translucent

9. Similarities and Differences with Marketed Devices:

The subject device, EsCem and the predicate device, G-CEM LinkAce (GAM-200) was compared as above. Both products have the similar product description as a dental cement. In case of composition, two products contain slightly different raw materials, but the subject device and the predicate device show the same performance as monomer, filler, photo inhibitor (stabilizer), self-cure initiator, photo initiator and pigment. For this reason, despite difference in material, both the subject device and the equivalent device have no problem in terms of the clinical performance.

Indication for use of the two products are almost same and both products can be used as dual cure. The performance results of the two products are not the same, but both products meet the requirements of ISO 4049. Biocompatibility, Light Curing Time, Application Area, Target Population, Intended Operator of both products are the same. In case of Storage condition and Shade, there is a slight difference but performance and biocompatibility test showed that these differences would not raise any new questions of safety and effectiveness. Therefore, EsCem is substantially equivalent with predicate device, G-CEM LinkAce, and at least as safe and effective as the predicate device.

10. Conclusion

Based on a comparison of subject device, EsCem (SPIDENT CO., LTD) and predicate device, G-CEM LinkAce (GC America INC.), it is confirmed that the subject device is substantially equivalent to predicate device.