June 20, 2025

Spident Co., Ltd.
Hyemin Kwon
RA Staff
203 & 312, Korea Industrial Complex, 722, Gojan-Dong,
Namdong-Gu
Incheon, Incheon 405-821
SOUTH KOREA

Re: K250566
Trade/Device Name: EsCem RMGI
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: May 20, 2025
Received: May 20, 2025

Dear Hyemin Kwon:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250566

Please provide the device trade name(s).

EsCem RMGI

Please provide your Indications for Use below.

Final cementation of
- Metal inlays, onlays, crowns and bridges
- Resin inlays, onlays, crowns and bridges
- Ceramic inlays
- Zirconia crowns and bridges
- Metal, ceramic and fiber posts

Please select the types of uses (select one or both, as applicable).

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

510(k) #: K250566

510(k) Summary

Prepared on: 2025-06-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	SPIDENT CO., LTD.
Applicant Address	203 & 312, Korea Industrial Complex, 722, Gojan-Dong, Namdong-Gu, Incheon, Korea, 405-821 Incheon Incheon 405-821 Korea, South
Applicant Contact Telephone	+82-32-821-0072
Applicant Contact	Ms. Hyemin Kwon
Applicant Contact Email	hyemin729@spident.co.kr

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	EsCem RMGI
Common Name	Dental cement
Classification Name	Cement, Dental
Regulation Number	872.3275
Product Code(s)	EMA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K111185	RelyX™ Luting Plus Automix	EMA

Device Description Summary

21 CFR 807.92(a)(4)

EsCem RMGI is a radiopaque resin modified glass ionomer luting cement corresponding to ISO 9917-2, Class 3. This product facilitates the removal of excess cement through the tack-cure option, allowing for quick treatment. The contents consisting of base and catalyst are provided in a dual syringe and are used to cement indirect restoration by mixing the two types of paste.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Final cementation of
- Metal inlays, onlays, crowns and bridges
- Resin inlays, onlays, crowns and bridges
- Ceramic inlays
- Zirconia crowns and bridges
- Metal, ceramic and fiber posts

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indication for use of the subject device are all included in the indication for use of the predicate device. There are some differences in expression, but they both can be used in final cementation of indirect restorations.

Technological Comparison

21 CFR 807.92(a)(6)

Principle operation, biocompatibility, self-curing setting time, application area, and intended operator of subject device and predicate device are the same. The mechanical performance results of the subject device and predicate device are not the same. For example, the

subject device has a slighter higher flexural strength, film thickness, and radiopacity than the predicate device. However, both products meet the requirements of ISO 9917-2.
Therefore, EsCem RMGI is substantially equivalent with predicate device, RelyX™ Luting Plus Automix (K111185).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The flexural strength and film thickness tests of the subject device (EsCem RMGI) were conducted in accordance with ISO 9917-2. Additionally, the technical data sheet of the predicate device (RelyX™ Luting Plus Automix) was referenced for mechanical properties such as flexural strength and film thickness. The flexural strength and film thickness test results of the subject device and predicate device meet the ISO 9917-2 requirements, and the values of those performances are comparable to those of the predicate device.

In addition, biocompatibility testing was performed in accordance with ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. The subject device is classified as externally communicating with tissue/bone/dentin (direct patient contact) for >30 days. Test performed for the subject device include in vitro cytotoxicity (ISO 10993-5), skin sensitization (ISO 10993-10), and irritation testing (ISO 10993-23).

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate device, the data demonstrates that the subject device, EsCem RMGI, is substantially equivalent to the predicate device.