



September 25, 2026

Spident Co., Ltd.
Seong Kiyoungh
RA Staff
203 & 312, Korea Industrial Complex, 722, Gojan-Dong, Namdong-Gu
Incheon, Incheon 405-821
Republic Of Korea

Re: K262983
Trade/Device Name: EsTemp Implant
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: August 26, 2026
Received: August 27, 2026

Dear Seong Kiyoungh:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,



Bobak
Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
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

Indications for Use

510(k) Number (if known)
K262983

Device Name
EsTemp Implant

Indications for Use (Describe)

- For temporary cementation of provisional restorations attached to implant abutments.
- For temporary retention and retrievable cementation of implant-supported restorations.

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
PRASStaff@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."

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, Republic of
Applicant Contact Telephone	82-10-3166-9702
Applicant Contact	Mr. Seong Kiyoun
Applicant Contact Email	chunhon88@spident.co.kr

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	EsTemp Implant
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
K134021	EsTemp Implant	EMA

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

EsTemp Implant is non-eugenol, dual-cured dental temporary cement for luting implant-retained crowns. EsTemp Implant has strength and durability which allow long-term cementation of implant-retained crowns. It has mechanical retention only – not chemical – with ideal elasticity so that it is easy to remove temporary restorations. The dual syringe allows for control of the ratio of base, catalyst, and the total dispensed amount. When used with auto-mix tips, it can be directly applied to crowns. The dual-cure formula makes it quicker to remove excess material after light-cure.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

- For temporary cementation of provisional restorations attached to implant abutments.
- For temporary retention and retrievable cementation of implant-supported restorations.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

There are some differences in expression between the subject and predicate device Indication for Use statements. The differences in expression between the two statements do not imply a new intended use for the subject device. Both devices are intended to be used for temporary cementation of provisional restorations attached to implant abutments and temporary retention of implant-supported restorations.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Mechanical property testing of the subject device (EsTemp Implant) and predicate device (EsTemp Implant, K134021) demonstrated

comparable performance across all test items, with no clinically significant differences observed. Flow, water sorption, water solubility, flexural strength, working time, setting time, and film thickness were all within a comparable range between the two devices and adhered to the methodology and acceptance criteria outlined in ISO 4049:2009. Notably, the extrusion force was reduced from 55 ± 1 N (predicate) to 33 ± 1 N (subject device), representing an improvement in handling and ease of dispensing. Based on these results, the subject device performs as well as the predicate device with respect to mechanical properties.

A biological safety evaluation and biocompatibility testing was performed for cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), oral mucosal irritation (ISO 10993-23), acute systemic toxicity, and pyrogenicity (ISO 10993-11). Justification for other endpoint testing not performed is included in the biological safety evaluation/analysis. All testing performed demonstrated that the subject device is biocompatible per the methodology outlined in the previously mentioned ISO 10993 standards.

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

The performance test results of the subject device and predicate device meet the ISO 4049 requirements, and the extrusion force of the subject device was lower than that of the predicate device, indicating improved handling. The biocompatibility test results and biological safety evaluation of the subject device confirmed no biological safety concerns. Therefore, it can be considered that the subject device is as safe, effective, and performs as well as or better than the predicate device.