



September 21, 2026

Spident Co., Ltd.
Seong Kiyoun
RA Staff
203 & 312, Korea Industrial Complex, 722, Gojan-Dong, Namdong-Gu
Incheon, Incheon 405-821
REPUBLIC OF KOREA

Re: K262982
Trade/Device Name: Core-it Dual
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF
Dated: August 26, 2026
Received: August 27, 2026

Dear Seong Kiyoun:

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, 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)

K262982

Device Name

Core-it Dual

Indications for Use (Describe)

The principal use for Core-it Dual is as a core material either with adhesives or with pins or posts.

Core-it Dual can also be used for:

- Luting of abutments to dentures
- Splinting of teeth in combination with wires, Kevlar or Ribbond-type materials
- Repair material for provisionals
- Bite registration material
- Build up material for plastic bite rails (occlusal individualisation).
- Cement for pins and posts
- Semipermanent restorative material (e.g., in childrens' teeth)

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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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	Core-it Dual
Common Name	Tooth shade resin material
Classification Name	Material, Tooth Shade, Resin
Regulation Number	872.3690
Product Code(s)	EBF

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K092572	Core-it Dual	EBF

Device Description Summary

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

Core-it Dual is dual-cured composite resin designed for the fabrication of all kinds of core build-ups & build-up fillings. It has the characteristics of good depth of polymerization, high compressive strength, and radiopaque. Core-it dual has various shades (Yellow, blue, White).

Intended Use/Indications for Use

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

The principal use for Core-it Dual is as a core material either with adhesives or with pins or posts.

Core-it Dual can also be used for:

- Luting of abutments to dentures
- Splinting of teeth in combination with wires, Kevlar or Ribbond-type materials
- Repair material for provisionals
- Bite registration material
- Build up material for plastic bite rails (occlusal individualisation).
- Cement for pins and posts
- Semipermanent restorative material (e.g., in childrens' teeth)

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.

Technological Comparison

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

Design, material, shape, mechanical, physical properties, labeling, packaging and intended use for Core-it Dual and the predicate devices of the type currently marketed in the U.S. are similar. The difference between Core-it Dual and predicate device is the composition and the slight mechanical and physical characteristics.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

The performance test results (Sensitivity to ambient light, Colour and colour stability, Working time, Setting time, Flexural strength, Water Sorption and Solubility, Radiopacity, and Depth of cure) of the subject device and predicate device meet the requirements of ISO 4049, and the values of those performances were as good as those of the predicate device. Also, the compressive strength value of the subject device was higher than that of the predicate device, and the result of polymerization shrinkage met the criteria. Therefore, it can be considered that our subject device is as safe, effective, and performs as well as or better than the predicate device.