May 30, 2025

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

Re: K250317
Trade/Device Name: EsFlow PLUS
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: April 30, 2025
Received: April 30, 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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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250317

Device Name

EsFlow PLUS

Indications for Use *(Describe)*

- Direct restorations
- Base and Liner
- Block out undercut
- Repair of (in)direct aesthetic restorations
- Core build-up

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.

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510(k) #: K250317

510(k) Summary

Prepared on: 2025-02-13

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	EsFlow PLUS
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
K173500	Nmf004a (G-ænial Universal Injectable)	EBF

Device Description Summary

21 CFR 807.92(a)(4)

EsFlow PLUS is a light-cured radiopaque flowable composite resin used for direct restoration. It has a smooth surface, so it is applied smoothly to the teeth, and has good gloss and aesthetics. In addition, it has high mechanical strength, so it can sufficiently withstand the occlusal force. EsFlow PLUS has two types of viscosities, so it can be applied to various clinical cases. The inorganic filler of EsFlow PLUS has a particle size range of 0.01 to 0.5 μm, and a volume ratio of about 42 to 47% depending on the model.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

- Direct restorations
- Base and Liner
- Block out undercut
- Repair of (in)direct aesthetic restorations
- Core build-up

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 direct restorations, base and liner, block out undercut, repair of (in)direct aesthetic restorations, and core build-up. Therefore, this would not raise any new questions of safety and effectiveness.

Technological Comparison

21 CFR 807.92(a)(6)

Principle Operation, Biocompatibility, Application Area, Target Population of subject device and predicate device are the same. The performance results of the subject device and predicate device is not the same, but all products meet the requirements of ISO 4049. Light curing time between the subject device and predicate device is different, but the light curing time of the subject device is longer than that of the predicate device. Therefore, this would not raise any new questions of safety and effectiveness. Also, both subject device and predicate device have the similar intended operator.
In case of storage condition, both products have similar limit of temperature.
Therefore, EsFlow PLUS is substantially equivalent with predicate device, G-ænial Universal Injectable, and at least as safe and effective as the predicate device.

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

Depth of cure, flexural strength, and compressive strength test of the subject device (EsFlow PLUS) and the predicate device (G-ænial Universal Injectable) were performed in accordance with ISO 4049 and part of ISO 9917-1 (Compressive strength).

Not Applicable

The depth of cure and flexural strength test results of the subject device and predicate device meet the ISO 4049 requirements, and the values of those performances were as good as those of predicate device. Also, the compressive strength value of the subject device was higher than that of predicate device. Therefore, It can be considered that our subject device is as safe, effective and performs as well as or better than the predicate device.