July 24, 2023

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

Re: K231523
Trade/Device Name: EsCom250
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: May 23, 2023
Received: May 26, 2023

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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., 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

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)*

K231523

Device Name
EsCom250

Indications for Use *(Describe)*

- Direct anterior and posterior restorations
- Restoration of fractured (broken) teeth due to trauma
- Restoration of deciduous teeth
- Direct restorative for diastema closure

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

K231523

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

Date: June 21, 2023

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 : Eunok Choi/RA Manager

2. Device Name and Classification

Proprietary Name : EsCom250
Common name : Dental light-cured composite resin
Classification name : Tooth shade resin material [CFR 872.3690]
Product code : EBF
Class : II

3. Predicate Devices (Legally Marketed Devices)

The predicate devices for EsCom250 is :

- **Filtek Z250 Universal Restorative,** 3M ESPE Dental Products, K183476

4. Description:

EsCom250 is the polymer-based dental restorative material. It can be light-cured intra orally for anterior and posterior restoration including occlusal surface. Filler size ranges from 16nm to 1.2 ㎛. Various shades of A1, A2, A3, A3.5, A4, B1, B2, C2, D2, G1, AO2, AO3 and TW for esthetic restoration are provided. All shades of EsCom250 are radio-opaque.

5. Indications for Use

- Direct anterior and posterior restorations
- Restoration of fractured (broken) teeth due to trauma
- Restoration of deciduous teeth
- Direct restorative for diastema closure

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

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 10993-18:2020, Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 7405:2018, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry

8. Substantial Equivalence Discussion

Product Name	EsCom250	Filtek Z250 Universal Restorative
510(k)	N/A	K183476
Manufacturer	SPIDENT CO., LTD.	3M ESPE Dental Products
Product description	EsCom250 is the polymer-based dental restorative material. It can be light-cured intra orally for anterior and posterior restoration including occlusal surface. Filler size ranges from 16nm to 1.2um. Various shades of A1, A2, A3, A3.5, A4, B1, B2, C2, D2, G1, AO2, AO3 and TW for esthetic restoration are provided. All shades of EsCom250 are radio-opaque.	3M™ ESPE™ Filtek™ Z250 Universal Restorative material is a visible-light activated, radiopaque, restorative composite. It is designed for use in both anterior and posterior restorations. The filler in Filtek Z250 restorative is zirconia/silica. The inorganic filler loading is 60% by volume (without silane treatment) with a particle size range of 0.01 to 3.5 µm. Filtek Z250 restorative contains BIS-GMA, UDMA, and BIS-EMA resins. A dental adhesive, such as manufactured by 3M ESPE, is used to permanently bond the restoration to the tooth structure. The restorative is available in a variety of shades. It is packaged in traditional syringes and single-dose capsules.
Chemical composition of Resin	Methacrylate monomer Filler Photo initiator Photo inhibitor Photo stabilizer pigment	Methacrylate monomer Filler Etc.
Indications for use	• Direct anterior and posterior restorations • Restoration of fractured (broken) teeth due to trauma • Restoration of deciduous teeth • Direct restorative for diastema closure	• Direct anterior and posterior restorations • Core buildups • Splinting • Indirect restorations including inlays, onlays and veneers
Principle of operation	Light cured	Light cured
Mechanical Properties • Depth of cure (mm)	2.27 (A3 shade) 1.53 (AO3 shade)	2.80

• Flexural strength (Mpa)	127.62	157.96
• Water sorption (μg/mm^3)	11.52	16.00
• Solubility (μg/mm^3)	0.0	0.0
• Sensitivity to light	After ambient light expose, the material remained physically homogeneous	After ambient light expose, the material remained physically homogeneous
• Radio-opacity (mmAl)	3.6 (A3) 3.1 (AO3)	2.9
• Knoop hardness (kgf/mm^2)	55.4	77.9
• Compressive strength (MPa)	334	346
• Elastic modulus (GPa)	3.03	4.04
Standard conformed	≥ISO 4049	ISO 4049
Biocompatibility	Yes	Yes
Light Curing Time	20 Seconds (1200 mW/cm^2 light)	A1, A2, A3, A3.5, A4, B1, B2, B3, C2, D3, I : 20 sec. UD : 30 sec. (minimum intensity of 400 mW/cm^2)
Intensity for curing	1200mW/cm^2	400mW/cm^2
Wavelength for curing	440~490nm	400~500 nm
Filler particle size distribution	16nm~1.2μm	10nm~3.5μm
Application Area	Tooth	Tooth
Target Population	Dental patient	Dental patient
Intended Operator	Dentist who has experience of dental light-cured composite restoration	Dentist
Storage condition	2-27℃	No higher than 27℃
Shade	A1, A2, A3, A3.5, A4, B1, B2, C2, D2, G1, AO2, AO3, TW	A1, A2, A3, A3.5, A4, B1, B2, B3, C2, D3, I, UD

9. Similarities and Differences with Marketed Devices:

The subject device, EsCom250 and the predicate device, Filtek Z250 Universal Restorative were compared as above. Both products have the similar product description as a dental light-cured composite resin.

In case of composition, subject device and predicate device contain slightly different raw materials, but the subject device and predicate device both mainly composed of monomers and fillers. In addition, specific information on initiator, inhibitor, and pigment is not known, but considering that the predicate device is a dental light-cured composite resin which has various shades, it can be expected that raw materials such as initiator, inhibitor, and pigment were used in the predicate device like the subject device. Therefore, even if there is a slight difference in the raw materials used, it can be expected that there will be no significant difference in performance and safety from the Filtek Z250 Universal Restorative. Also, the results of the Performance test according to ISO 4049 and the Biocompatibility test according to ISO 10993-1 confirmed that the subject device had no problems related to performance and biological safety.

The indications for use of the subject device are as follows.

1. Direct anterior and posterior restorations
2. Restoration of fractured (broken) teeth due to trauma
3. Restoration of deciduous teeth
4. Direct restorative for diastema closure

The indications for use above are not perfectly same with the indications for use of predicate device, but the indications for use of subject device are included in the indications of predicate device.

Principle Operation, Biocompatibility, Application Area and Target Population of subject device and predicate device are the same. The performance results of the subject device and predicate device are not the same, but both products meet the requirements of ISO 4049. Also, both products have similar intended operator.

Light curing time, Intensity for curing, Wavelength for curing, storage condition, and shade between the subject device and predicate device are slightly different, but these differences would not raise any questions of safety and effectiveness.

Therefore, EsCom250 is substantially equivalent with predicate device, Filtek Z250 Universal Restorative, and at least as safe and effective as the predicate device.

10. Conclusion

Based on a comparison of subject device, EsCom250 (SPIDENT CO., LTD.) and predicate device, Filtek Z250 Universal Restorative (3M ESPE Dental Products), it is confirmed that the subject device is substantially equivalent to predicate device.