July 22, 2024

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

Re: K241445
Trade/Device Name: K-Bond Universal
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: May 14, 2024
Received: May 22, 2024

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 (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.

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,
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241445

Device Name

K-Bond Universal

Indications for Use *(Describe)*

-Bonding of all direct composite restorations
-Bonding of dual/self cure composite and core build-ups
-Repairs of composite fillings
-Root surface desensitization

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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510(k) Summary

Prepared on: 2024-06-19

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	+821042226153
Applicant Contact	Mrs. Eunok Choi
Applicant Contact Email	eochoi@spident.co.kr

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	K-Bond Universal (K-Bond Universal)
Common Name	Resin tooth bonding agent
Classification Name	Agent, Tooth Bonding, Resin
Regulation Number	872.3200
Product Code(s)	KLE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K110302	Adhesive EXL 759 (Single Bond Universal)	KLE

Device Description Summary

21 CFR 807.92(a)(4)

K-Bond Universal is a bonding system that offers exceptional bonding strength through a convenient single bottle application. This single-component bonding agent is specifically formulated to effectively bond various types of direct composite restorations to dentin, enamel, as well as composite.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

-Bonding of all direct composite restorations
-Bonding of dual/self cure composite and core build-ups
-Repairs of composite fillings
-Root surface desensitization

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 bonding of all direct composite restorations, bonding of dual/self cure composite and core build-ups, repairs of composite fillings and root surface desensitization. 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 are not the same, but all products meet the internal requirements (dentin : ≥15 MPa, enamel : 8 MPa).
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, K-Bond Universal is substantially equivalent with predicate device, Single Bond Universal.

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

Shear bond test of the subject device (K-Bond Universal) and the predicate device (Single Bond Universal) was performed in accordance with ISO 29022. Also, we conducted dentin tubule blockage test of the subject device to confirm the root surface desensitization effect.

Not Applicable

The shear bond strength test showed that the bonding strength of the subject device is as good as the predicate device. And the dentinal blockage test showed that the subject device also can block the dentinal tubule. Therefore, It can be considered that our subject device is as safe, effective and performs as well as or better than the predicate device.