July 2, 2026

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

Re: K261129
Trade/Device Name: OrthoFit
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin And Tooth Conditioner
Regulatory Class: Class II
Product Code: DYH
Dated: April 6, 2026
Received: April 6, 2026

Dear Choi Eunok:

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 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

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.

510(k) Number *(if known)*
K261129

Device Name
OrthoFit

Indications for Use *(Describe)*
• Bonding of orthodontic brackets, bands, and other orthodontic attachments (such as buttons and cleats).
• Fixation of lingual retainers.

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
PRAStaff@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."

510(k) #: K261129

510(k) Summary

Prepared on: 2026-04-16

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 405-821 Korea, Republic of
Applicant Contact Telephone	+82-10-4222-615
Applicant Contact	Mrs. Choi Eunok
Applicant Contact Email	eochoi@spident.co.kr

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OrthoFit
Common Name	Bracket adhesive resin and tooth conditioner
Classification Name	Adhesive, Bracket And Tooth Conditioner, Resin
Regulation Number	872.3750
Product Code(s)	DYH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K150128	GC Ortho Connect	DYH

Device Description Summary

21 CFR 807.92(a)(4)

Light-cured Orthodontic Adhesive, OrthoFit is a type of light-curable cement can be activated by visible light, bonding orthodontic brackets, bands, and other orthodontic appliances to the tooth surface.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

-. Bonding of orthodontic brackets, bands, and other orthodontic attachments (such as buttons and cleats).
-. Fixation of lingual retainers.

Indications for Use Comparison

21 CFR 807.92(a)(5)

A comparison of the Indications for Use between our device and the predicate device reveals that they are substantially equivalent in terms of clinical purpose and intended application. While there are minor differences in terminology, our device employs a more comprehensive description—the core scope remains identical. Both devices are intended for the bonding of orthodontic brackets, bands, and other attachments, as well as the fixation of lingual retainers. Consequently, these descriptive variations do not raise any new questions regarding safety and effectiveness.

Technological Comparison

21 CFR 807.92(a)(6)

The principles of operation, biocompatibility, field of application, and target patient populations of the subject device are identical to those of the predicate device. While the performance data of the two devices are not identical, both fulfill the requirements of ISO 29022. Therefore, these differences do not raise any new questions regarding safety and effectiveness. Furthermore, the intended users of the subject device and the predicate device are similar, and the temperature limits for storage conditions are also comparable. In conclusion,

OrthoFit is substantially equivalent to the predicate device, GC Ortho Connect, and demonstrates a level of safety and effectiveness at least equivalent to that of the predicate.

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

The Shear Bond Strength test of the subject device (OrthoFit) and the predicate device (Ortho Connect) were performed in accordance with ISO 29022. Also the Water sorption test, Solubility test and depth of cure test of the subject device (OrthoFit) were performed in accordance ISO 4049.

Biocompatibility testing was conducted on the subject device in accordance with the applicable parts of ISO 10993 to demonstrate substantial equivalence, including tests for cytotoxicity, oral mucosal irritation, skin sensitization, acute systemic toxicity, and material mediated pyrogenicity. The results indicate that the subject device does not present any new toxicological risks compared to the predicate device.

The Shear bond strength test result of the subject device and predicate device meet the ISO 29022 requirements, and the biocompatibility testing of the subject device showed that the material composition does not raise any new questions of safety or effectiveness compared to the 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. Based on the Indications for Use, technological characteristics, performance testing, and comparison to the predicate device, the data demonstrates that the subject device, OrthoFit, is substantially equivalent to the predicate device.