

K120767

MAY 24 2012



SPIDENT Co., Ltd.

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510(k) Summary

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

Date: January 10, 2012

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
Phone	+82(32)819-4570
Fax	+82(32)819-4572
Contact	J. M. Ahn/President

2. Device:

Proprietary Name – EsBond
Common Name – Dental bonding adhesive
Classification Name – Resin tooth bonding Agent

3. Predicate Device:

ECLIPTOMER, BISCO, INC., K945604

4. Classifications Names & Citations:

KLE, 872.3200

5. Description:

EsBond is 5th generation that provides high bonding strengths in a convenient single bottle application. That single component bonding agent designed to bond all classes of direct composite restorations to dentin, enamel, as well as composite, treated porcelain and set amalgam.

EsBond is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. It is substantially equivalent in design, function and intended use to the predicate devices.

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6. Indication for use:

- 1) All Direct Composite Restorations
- 2) Directed Shrinkage Composite Restorations
- 3) Desensitization of Crown Preparations Prior to Impression Making/Provisionalization
- 4) Composite Core Build-Ups
- 5) Composite to Composite (Repair)
- 6) Composite to Metal/Set Amalgam (Direct Veneering)
- 7) Root Desensitization

7. Review:

The EsBond has the similar device characteristics as the predicate device, the ECLIPTOMER; intended use, material, chemical composition, design and use concept are similar.

The EsBond has the similar mechanical properties as the predicate device; compressive strength, flexural strength, flow thickness, wear, polymerization shrinkage and thermal expansion coefficient.

The EsBond has been subjected to extensive safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the US regulations and ISO 4049.

Based on the comparison of intended use and technical features, the EsBond is substantially equivalent to the predicate devices.

8. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, FDA's "Guidance for the Preparation of Premarket notifications for Dental Composite" and based on the information provided in this premarket notification SPIDENT Co., Ltd. concludes that the EsBond is safe and effective and substantially equivalent to predicate devices as described herein.

9. SPIDENT Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA.

END

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spident Company, Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Inc.
2600 NW Lake Road
Camas, Washington 98607

MAY 24 2012

Re: K120767
Trade/Device Name: EsBond
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: April 18, 2012
Received: April 26, 2012

Dear Mr. Mouser:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K K120767

Device Name: EsBond

Indication for use:

1. All Direct Composite Restorations
2. Directed Shrinkage Composite Restorations
3. Desensitization of Crown Preparations Prior to Impression Making/Provisionalization
4. Composite Core Build-Ups
5. Composite to Composite (Repair)
6. Composite to Metal/Set Amalgam (Direct Veneering)
7. Root Desensitization

Prescription Use AND/OR Over-The-Counter Use
(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Jones
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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