

FEB 17 2010

**SPIDENT Co., Ltd.**

#312, 151B-6L, NamdongKongDan, Incheon, Korea 405-821  
 Tel: +82(32)819-4570 Fax: +82(32)819-4572

## 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: November 27, 2009

## 1. Company and Correspondent making the submission:

|         | Company  |
|---------|--|
| Name    | SPIDENT Co., Ltd.  |
| Address | #312, 151B-6L, NamdongKongDan,<br>Incheon, Korea 405-821 |
| Phone   | +82(32)819-4570  |
| Fax     | +82(32)819-4572  |
| Contact | K. H. Baek   |

## 2. Device:

Proprietary Name – EsTemp NE  
 Common Name – Dental Cement  
 Classification Name – Cement, Dental

## 3. Predicate Device:

TempBond NE, K894219

## 4. Classifications Names &amp; Citations:

EMA, 872.3275

## 5. Description:

EsTemp NE is light-curing temporary filling materials. It has characteristics of high elasticity and high compressive strength. This elastic consistency assures easy removal from cavity, even in case of undercuts, final treatment of cavity is not necessary.

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



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6. Indication for use:

Cementation of temporary and provisional restoration such as crowns, bridges, inlay and onlay.

7. Review:

EsTemp NE has the similar device characteristics as the predicate device, the TempBond NE; intended use, material, chemical composition, design and use concept are similar.

EsTemp NE have the similar mechanical properties as the predicate device; compressive strength, flexural strength, flow thickness, wear, polymerization shrinkage and thermal expansion coefficient.

EsTemp NE 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 3107.

Based on the comparison of intended use and technical features, the EsTemp NE 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 EsTemp NE 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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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, Incorporated  
2600 NW Lake Road  
Camas, Washington 98607-9526

FEB 17 2010

Re: K100290  
Trade/Device Name: EsTemp NE  
Regulation Number: 21CFR 872.3275  
Regulation Name: Dental Cement  
Regulatory Class: II  
Product Code: EMA  
Dated: January 19, 2010  
Received: February 2, 2010

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.

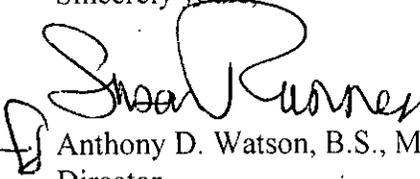
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/ucml15809.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 K100290

Device Name: EsTemp NE

Indication for use:

Cementation of temporary and provisional restoration such as crowns, bridges, inlay and onlay.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K100290