K080265

000015

Vericom Co. Ltd. *Healthy and beautiful teeth with Vericom*

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.

Date: September 1, 2007

1. Company making the submission:

	Submitter
Name	VERICOM Co., Ltd.
Address	#606, 5th Dongyoung Venturestel 199-32, Anyang 7-Dong, Manan-Gu Anyang-Si, Gyeonggi-Do, Republic of Korea 430-817
Phone	+82 31 441-2881
Fax	+82 31 441-2883
Contact	Myung-Hwan Oh
Internet	mh-oh@hanmail.net

FEB - 6 2008

2. Device:
   Proprietary Name – DenFil™ Etchant-37
   Common Name – Etching agent
   Classification Name – Material, Tooth Shade, Resin

3. Predicate Device:
   K-ETCHANT GEL, KURARAY MEDICAL INC, K062409

4. Description:
   DenFil™ Etchant-37 is an etching agent consists of 37% phosphoric acid formulations thickened with natural polymer. It is classified into tooth shade resin material, 21 CFR Section 872.3690, because it is a device intended to be painted on the interior of a prepared cavity of a tooth to improve retention of a restoration.

5. Indication for use:
   Etching the enamel and dentine for adhesive restorations.

6. Review:

DenFil™ Etchant-37 has the same device characteristics as the predicate device; main material, chemical composition, and use concept.

DenFil™ Etchant-37 has the similar mechanical properties as the predicate device; pH, adhesion and viscosity.

DenFil™ Etchant-37 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 applicable Internationl and US regulations.

7. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Vericom Co., Ltd. concludes that DenFil™ Etchant-37 is safe and effective and substantially equivalent to predicate devices as described herein.

8. Vericom Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

606,5th Dongyoung Venturestel, 199-32, Anyang 7-dong, Manan-gu, Anyang-si, Gyeonggi-do 430-817, Korea

VERICOM
Dental materials

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2008

Vericom Company, Limited
C/O Mr. Morten S. Christensen
Responsible Third Party Official
Underwriters Laboratories Incorporated
455 East Trimble Road
San Jose, California 95131-1230

Re: K080265
Trade/Device Name: DenFil™ Etchant-37
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: January 22, 2008
Received: February 1, 2008

Dear Mr. Christensen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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 050365

Device Name: DenFil™ Etchant-37

Indication for use:

- Etching the enamel and dentine for adhesive restorations.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

10(k) Number: K050365