K042124 0011

AUG 1 3 2004

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: July 12, 2004

1. Company:

	Company
Name	VERICOM Co., Ltd.
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Phone	+82 31 441-2881
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Contact	Myung-Hwan Oh
Internet	omh@vericom.co.kr

2. Device:
   Proprietary Name – DenFil™
   Common Name - Dental Composites and Filling Materials
   Classification Name – Material, Tooth Shade, Resin

3. Predicate Device:
   Clearfil AP-X, Kuraray Medical Inc., K012740
   Clearfil AP-X PLT, Kuraray Medical Inc., K023002
   Multiple, Dentsply Intl., K863092

4. Classifications Names & Citations:
   21CFR 872.3690, EBF, Material, Tooth shade, Resin, Class2
   Guidance for the Preparation of Premarket Notifications for Dental Composites

5. Description:
   DenFil™ is light-cured restorative hybrid composite resin and accessories for use in both Posterior and Anterior restoration.

6. Indication for use:
   DenFil™ is indicated for the following restorative applications;
   1. Class Ⅰ, Ⅱ, Ⅴ restorations of posterior teeth
   2. Class Ⅲ, Ⅳ, Ⅴ restorations of anterior teeth
   3. Cervical cavities or defects involving root surfaces

7. Contra-indications:
   Patients with allergies to methacrylate monomers.

8. Review:
   DenFil™ has the same device characteristics as the predicate device. Material, design and use concept is similar.

   DenFil™ has been subjected to extensive safety, performance, and product validations prior to release. Safety tests have been performed to ensure the devices comply to applicable industry and US regulations.

   An extensive review of literature pertaining to the safety and biocompatibility of DenFil™ has been conducted. Appropriate safeguards have been incorporated in the design of DenFil™.

9. 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 Vericom Co., Ltd. concludes that DenFil™ is safe and effective and substantially equivalent to predicate devices as described herein.

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

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 3 2004

Vericom Company, Limited
C/O Mr. Marc M. Mouser
Office Coordinator
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 N.W. Lake Road
Camas, Washington 98607-8542

Re: K042124
Trade/Device Name: Denfil™
Regulation Number: 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: July 27, 2004
Received: August 6, 2004

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.

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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,

for 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 K042124

Device Name: DenFil™

Indication for use: DenFil™ is indicated for the following restorative applications;

1. Class: I, II, V restorations of posterior teeth
2. Class III, IV, V restorations of anterior teeth
3. Cervical cavities or defects involving root surfaces

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21CFR801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON AMOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Angela Blackwell for MSR

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

510(k) Number: K042124