510(k) Summary

SEP 2 8 2007

K072069

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

Date: July 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

2. Device :
   Proprietary Name – Spacer™
   Common Name - Temporary Filling Materials
   Classification Name – Material, Tooth Shade, Resin

3. Predicate Device :
   Clip, VOCO GMBH, K926418

4. Description :
   Spacer™ is a light-curing temporary filling material included nano-sized silver. Spacer™ is used for the temporary restoration of inlay and onlay preparations and all kind of temporary fillings. Spacer™ is easy to handle because it is not sticky. Spacer™ has high elasticity and strength. Spacer™ shows excellent marginal sealing and can be easily removed all at once without any debris in the cavity.

5. Indication for use :
   - Temporary restoration of inlay and onlay preparations
   - Temporary fillings and sealings

"of all kinds" eliminated
Amended 9-8-07

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2007

Dr. Albert Rego
Consultant
Vericom Company, Limited
27001 La Paz Road, Suite 312
Mission Viejo, California 92691

Re: K072069
Trade/Device Name: Spacer™
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Codes: EBG, EBF
Dated: September 8, 2007
Received: September 18, 2007

Dear Dr. Rego:

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.

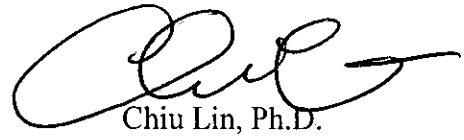
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known) K072069

Device Name: Spacer™

Indication for use:

- Temporary restoration of inlay and onlay preparations
- Temporary fillings and sealings

Prescription Use ✓ OR Over-The-Counter Use _____
(21CFR801 Subpart D) (21CFR801 Subpart C)

(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

510(k) Number: K072069