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

510(k) Summary K103164

NOV 10 2010

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

Date: July 1, 2010

1. Company making the submission:

	Submitter
Name	VERICOM Co., Ltd.
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Phone	+82 31 441-2881
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Contact	Myung-Hwan Oh
Internet	mh-oh@hanmail.net

2. Device:
   Proprietary Name – Vonflex™ Heavy/ Vonflex™ Light
   Common Name – Impression Materials
   Classification Name – Material, Impression

3. Predicate Device:
   Aquasil ultra rigid smart wetting impression material, Dentsply Intl., K021413
   Aquasil ultra lv smart wetting impression material, Dentsply Intl., K021416

4. Description:
   Vonflex™ Heavy/ Vonflex™ Light as the additional polymerization silicone type, is a rubber impression material that makes oral tissue shape precisely. And it is very easy to handle and has low deformation, helping to make precise impression taking.

5. Indication for use:
   - Impression material in a dual phase impression technique
   - Precise duplication of models
   - Capturing multiple unit impressions
   - All impression techniques where the operator needs a heavy or low viscosity material

6. Review:

Vonflex™ Heavy/ Vonflex™ Light has the similar characteristics as the predicate device; Use concept, flow properties, setting time and compatibility with the die and cast materials and so on.

Vonflex™ Heavy/ Vonflex™ Light 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 International 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 Vonflex™ Heavy/ Vonflex™ Light 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 reasonably necessary by the FDA.

END

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

Vericom Company, Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 NW Lake Road
Camas, Washington DC 38607-9526

NOV 10 2010

Re: K103164
Trade/Device Name: Vonflex™ Heavy Vonflex™ Light
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: October 5, 2010
Received: October 27, 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.

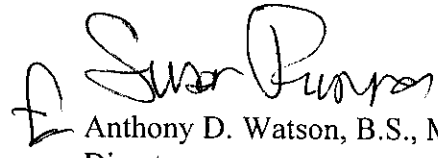
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/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 K103164

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Device Name: Vonflex™ Heavy/ Vonflex™ Light

Indication for use:

- Impression material in a dual phase impression technique
- Precise duplication of models
- Capturing multiple unit impressions
- All impression techniques where the operator needs a heavy or low viscosity material

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)

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

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