



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 30, 2015

Vericom Co., Ltd.
Myung-Hwan Oh
R&D Center, Dental
48, Toegyegongdan 1-Gil
Chuncheon-si, Gangwon-Do 200-944
REPUBLIC OF KOREA

Re: K152518
Trade/Device Name: Vonflex S Putty
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: July 28, 2015
Received: September 3, 2015

Dear Myung-Hwan Oh:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

 Tina
Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number K 152518

Device Name: Vonflex S™ Putty

Indication for use:

It is used for all crown, bridge and orthodontic impression techniques.

Prescription Use OR Over-The-Counter Use
(Per 21 CFR Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

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

Date: July 28, 2015

1. Company making the submission:

	Submitter
Name	VERICOM Co., Ltd.
Address	48, Toegyegongdan 1-Gil, Chuncheon-Si, Gangwon-Do, Republic of Korea 200-944
Phone	+82 31 441-2881
Fax	+82 31 441-2883
Contact	Myung-Hwan Oh omh@vericom.co.kr
Internet	www.vericom.co.kr

2. Device:

Proprietary Name – Vonflex S™ Putty
Common Name – Impression Materials
Classification Name – Material, Impression

3. Predicate Device:

Delikit Putty, Sherpa Korea, K103346

4. Description:

Vonflex S™ Putty, as the additional polymerization silicone type, is composed of vinyl polysiloxane impression materials that make oral tissue shape precisely. Vonflex S™ Putty is very easy to mix and has good dimensional stability, helps to make precise impression taking.

5. Indication for use:

It is used for all crown, bridge and orthodontic impression techniques.

6. Technological Characteristics and Performance Testing:

Vonflex S™ Putty has compared to the predicate device with regard to indications for use, physical properties and etc. The evaluation items are in accordance with the requirements of ISO 4823. According to the test results, Vonflex S™ Putty is substantially equivalent to the predicate device.

Biocompatibility tests have been performed to assure biological safety in consideration of the ISO 10993. Vonflex S™ Putty is tested through the following test: Cytotoxicity (ISO 10993-5), Sensitization and Irritation (ISO 10993-10) and *In vitro* genotoxicity (Ames test) (ISO 10993-3). The conclusion of the assessments is that Vonflex S™ Putty is biocompatible for its intended use.

Comparison table

	Subject Device	Predicate Device	Summary
510(K) Number	N/A	K103346	-
Proprietary name	Vonflex S™ Putty	Delikit Putty	-
Manufacturer	VERICOM CO., LTD.	Sherpa Korea	-
Indications for use	It is used for all crown, bridge and orthodontic impression techniques.	It is an addition-cure vinyl polysiloxane dental impression material that is used for all crown and bridge, edentulous, orthodontic and implant impression techniques.	The indication for use of the subject and predicate device is to make impression taking, but it is not limited to the applications listed in the indications for use.
Standard conformed	ISO4823	ISO4823	Claims are the same
Physical properties	<ul style="list-style-type: none"> - Classification according to ISO4823: Type 0 - Dimensional accuracy: Max.1.5% - Consistency: Max. 35mm - Compatibility with the die and cast materials: 75μm reproduction - Curve of the shrinkage (Strain in compression): Min.0.8 ~ Max.20% 	<ul style="list-style-type: none"> - Classification according to ISO4823: Type 0 - Dimensional accuracy: Max.1.5% - Consistency: Max.35mm - Compatibility with the die and cast materials: 75μm reproduction - Curve of the shrinkage (Strain in compression): Min.0.8 ~ Max.20% 	The classification of the subject and predicate device is complied with ISO 4823 (Type 0). According to the description and bench test result, the physical properties of the subjective devices are similar to these of the predicate device.
Raw Material	Vinyl polysiloxane	Vinyl polysiloxane	Claims are the same
Mixing Ratio	1:1	1:1	Claims are the same
Method of Manipulation	Hand-kneaded mixes	Hand-kneaded mixes	Claims are the same

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 S™ Putty is 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
