DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

November 3, 2016

Re: K152615
Trade/Device Name: Vonflex S
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: August 10, 2015
Received: September 14, 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,

Tina Kiang, Ph.D.
Acting 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 _____

Device Name: Vonflex S™

Indication for use:

- Impression material in a dual phase impression technique
- Precise duplication of models
- Capturing multiple unit impressions
- Impression of inlay, crown, bridge and partial denture etc.

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: August 10, 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™
   Common Name – Impression Materials
   Classification Name – Material, Impression
   Class of device – Class II
   CFR Number – 872.3660
   Product Code - ELW

3. Predicate Device:
   Aquasil Ultra Smart Wetting Impression Material, DENTSPLY International, K113406

4. Description:
   Vonflex S™, as the additional polymerization silicone type, is composed of a two component (base and catalyst, mixing ratio 1:1) hydrophilic vinyl polysiloxane impression material for all dental impression techniques. Vonflex S™ consists of light-bodied, medium-bodied or heavy-bodied consistencies in delivery systems of cartridges and/or tubes. It has normal set and fast set that would be desired by the operator.

5. Indication for use:
   - Impression material in dual phase impression technique
   - Precise duplication of models
   - Capturing multiple unit impressions
   - Impression of inlay, crown, bridge and partial denture etc.

6. Technological Characteristics and Performance Testing:

   Vonflex S™ has compared to the predicate device with regard to indications for use, physical and mechanical properties, and chemical composition. Below evaluation items are in accordance with the requirements of FDA guideline & ISO4823.
   - Flow properties
   - Wettability
   - Working time
   - Setting reaction time
   - Tear strength
   - Dimensional accuracy
   - Consistency
   - Compatibility with the die and cast materials
   - Curve of the shrinkage
   - Viscosity

   According to the test results, the comparison for indications for use, performance data, and chemistry shows that Vonflex S™ is substantially equivalent to the predicate device.

Comparison table - Vonflex S™ Heavy

Name				Vonflex S™ Heavy - Normal setting	Vonflex S™ Heavy - Fast setting	Aquasil Ultra Rigid Smart Wetting Impression Material
510(k) Submitter Number				VERICOM CO., LTD. New device		DENTSPLY International K113406
Similarity	Indications for use			- Impression material in dual phase impression technique - Precise duplication of models - Capturing multiple unit impressions - Impression of inlay, crown, bridge and partial denture etc.		It is indicated for all dental impression techniques.
	Physical properties	Flow properties		3.57 ㎜	2.42 ㎜	1.82 ㎜
		Wettability		62.06°	65.67°	65.70°
		Working time		2'15"	1'30"	2'15"-2'45"
		Setting reaction time		4'00"	2'30""	5'00"
		Tear strength		10.74 N/㎜	8.73 N/㎜	8.51 N/㎜
		Dimensional accuracy		0.11%	0.07%	0.12%
		Consistency		34.76 ㎜	34.78 ㎜	34.78 ㎜
		Compatibility with the die and cast materials		Reproduced for 0.05 ㎜	Reproduced for 0.05 ㎜	Reproduced for 0.05 ㎜
		Curve of the shrinkage		2.56%	2.38%	1.84%
		Viscosity	Base	123,000mPas	131,000mPas	136,00mPas
			Catalyst	113,000mPas	108,000mPas	101,000mPas
	Chemical composition	Vinyl terminated group		Vinyl siloxanes		Polydimethylsiloxane polymer
		Filler		Silica, Fumed silica		Silicon Dioxide, Sodium Aluminosilicate
		Cross linker		Hydrogen polysiloxane		Polymethyl hydrogen siloxane
		Catalyst		Organo platinum complex		Organic platinum complex
		Colorant		Pigments		Pigments
		Surfactant		Surfactant		Surfactant
	Standard Conformed			ISO4823		ISO4823
	Biocompatibility			Yes		Yes
	Use			Prescription / Hospital		Prescription / Hospital
Difference	Physical properties	Color		- Light orange(Light orange/White) - Blue (Blue/White) - Dark green (Dark green/White) - Dark purple (Dark purple/White) - Yellow (Yellow/White)		- Green (Green/White)

Vonflex S™ Heavy is composed to Vinyl terminated group, Filler, Cross linker, Catalyst, Colorant and Surfactant as the predicate device. Many kinds of filler is used as a thickening agent in the impression materials. In general, Silica is synonym for silicon dioxide. So, The chemical composition of Vonflex S™ Heavy is equivalent to the predicate device, Aquasil Ultra Rigid Smart Wetting impression Material. Indication for use of Vonflex S™ Heavy provide more detailed information than the predicate device for the user to have a better understanding of what Vonflex S™ Heavy is indicated for. Through above table, most physical properties, Indications for use and chemical composition of Vonflex S™ Heavy is similar to these of the predicate device.

The difference between Vonflex S™ Heavy and predicate device is the color. But it doesn't affect to safety and effectiveness of product considerably. The two components of impression materials are requested contrasting colors to check the mixing condition, and the mixture should be distinguished from the oral tissue and blood. In this connection, the colors of Vonflex S™ Heavy and predicate devices are satisfied these conditions.

Comparison table - Vonflex S™ Medium

Name				Vonflex S™ Medium - Normal setting	Vonflex S™ Medium - Fast setting	Aquasil Ultra Monophase Smart Wetting Impression Material
510(k) Submitter Number				VERICOM CO., LTD. New device		DENTSPLY International K113406
Similarity	Indications for use			- Impression material in dual phase impression technique - Precise duplication of models - Capturing multiple unit impressions - Impression of inlay, crown, bridge and partial denture etc.		It is indicated for all dental impression techniques.
	Physical properties	Flow properties		7.04 ㎜	6.99 ㎜	8.35 ㎜
		Wettability		66.19°	66.63°	65.98°
		Working time		2'15"	1'30"	2'15"-2'45"
		Setting reaction time		4'00"	2'30""	5'00"
		Tear strength		10.43 N/㎜	9.16 N/㎜	15.85 N/㎜
		Dimensional accuracy		0.17%	0.13%	0.17%
		Consistency		40.25 ㎜	39.44 ㎜	38.78 ㎜
		Compatibility with the die and cast materials		Reproduced for 0.05 ㎜	Reproduced for 0.05 ㎜	Reproduced for 0.05 ㎜
		Curve of the shrinkage		4.95%	3.79%	5.90%
		Viscosity	Base	85,000mPas	83,000mPas	89,500mPas
			Catalyst	107,000mPas	101,000mPas	65,000mPas
	Chemical composition	Vinyl terminated group		Vinyl siloxanes		Polydimethylsiloxane polymer
		Filler		Silica, Fumed silica		Silicon Dioxide, Sodium Aluminosilicate
		Cross linker		Hydrogen polysiloxane		Polymethyl hydrogen siloxane
		Catalyst		Organo platinum complex		Organic platinum complex
		Colorant		Pigments		Pigments
		Surfactant		Surfactant		Surfactant
	Standard Conformed			ISO4823		ISO4823
	Biocompatibility			Yes		Yes
	Use			Prescription / Hospital		Prescription / Hospital
Difference	Physical properties	Color		- Light green(Light green/White) - Green(Green/White) - Yellow(Yellow/White) - Dark purple(Dark purple/White) - Blue(Blue/White)		- Purple (Purple/White)

Vonflex S™ Medium is composed to Vinyl terminated group, Filler, Cross linker, Catalyst, Colorant and Surfactant as the predicate device. Many kinds of filler is used as a thickening agent in the impression materials. In general, Silica is synonym for silicon dioxide. So, The chemical composition of Vonflex S™ Medium is equivalent to the predicate device, Aquasil Ultra Monophase Smart Wetting impression Material. Indication for use of Vonflex S™ Medium provide more detailed information than the predicate device for the user to have a better understanding of what Vonflex S™ Medium is indicated for. Through above table, most physical properties, Indications for use and chemical composition of Vonflex S™ Medium is similar to these of the predicate device.

The difference between Vonflex S™ Medium and predicate device is the color. But it doesn't affect to safety and effectiveness of product considerably. The two components of impression materials are requested contrasting colors to check the mixing condition, and the mixture should be distinguished from the oral tissue and blood. In this connection, the colors of Vonflex S™ Medium and predicate devices are satisfied these conditions.

Comparison table - Vonflex S™ Light

Name				Vonflex™ S Light - Normal setting	Vonflex™ S Light - Fast setting	Aquasil Ultra LV Smart Wetting Impression Material
510(k) Submitter Number				VERICOM CO., LTD. New device		DENTSPLY International K113406
Similarity	Indications for use			- Impression material in dual phase impression technique - Precise duplication of models - Capturing multiple unit impressions - Impression of inlay, crown, bridge and partial denture etc.		It is indicated for all dental impression techniques.
	Physical properties	Flow properties		9.18 ㎜	8.60 ㎜	8.94 ㎜
		Wettability		60.65°	61.05°	61.07°
		Working time		2'30"	1'30"	2'15"-2'45"
		Setting reaction time		4'00"	2'30""	5'00"
		Tear strength		10.22 N/㎜	10.02 N/㎜	9.97 N/㎜
		Dimensional accuracy		0.08%	0.09%	0.15%
		Consistency		43.43 ㎜	42.02 ㎜	39.23 ㎜
		Compatibility with the die and cast materials		Reproduced for 0.05 ㎜	Reproduced for 0.05 ㎜	Reproduced for 0.05 ㎜
		Curve of the shrinkage		7.71%	5.24%	3.68%
		Viscosity	Base	51,500mPas	61,500mPas	67,500mPas
			Catalyst	71,000mPas	83,000mPas	54,667mPas
	Chemical composition	Vinyl terminated group		Vinyl siloxanes		Polydimethylsiloxane polymer
		Filler		Silica, Fumed silica		Silicon Dioxide, Sodium Aluminosilicate
		Cross linker		Hydrogen polysiloxane		Polymethyl hydrogen siloxane
		Catalyst		Organo platinum complex		Organic platinum complex
		Colorant		Pigments		Pigments
		Surfactant		Surfactant		Surfactant
	Standard Conformed			ISO4823		ISO4823
	Biocompatibility			Yes		Yes
	Use			Prescription / Hospital		Prescription / Hospital
Difference	Physical properties	Color		- Light red(Light red/White) - Red(Red/White) - Blue(Blue/White) - Yellow(Yellow/White) - Dark green(Dark green)		- Bluish green (Bluish green /White)

Vonflex S™ Light is composed to Vinyl terminated group, Filler, Cross linker, Catalyst, Colorant and Surfactant as the predicate device. Many kinds of filler is used as a thickening agent in the impression materials. In general, Silica is synonym for silicon dioxide. So, The chemical composition of Vonflex S™ Light is equivalent to the predicate device, Aquasil Ultra LV Smart Wetting impression Material. Indication for use of Vonflex S™ Light provide more detailed information than the predicate device for the user to have a better understanding of what Vonflex S™ Light is indicated for. Through above table, most physical properties, Indications for use and chemical composition of Vonflex S™ Light is similar to these of the predicate device.

The difference between Vonflex S™ Light and predicate device is the color. But it doesn't affect to safety and effectiveness of product considerably. The two components of impression materials are requested contrasting colors to check the mixing condition, and the mixture should be distinguished from the oral tissue and blood. In this connection, the colors of Vonflex S™ Light and predicate devices are satisfied these conditions.

Comparison table - Vonflex S™ Light XLV

Name				Vonflex S™ Light XLV -Normal setting	Vonflex S™ Light XLV -Fast setting	Aquasil Ultra XLV Smart Wetting Impression Material
510(k) Submitter Number				VERICOM CO., LTD. New device		DENTSPLY International K113406
Similarity	Indications for use			- Impression material in dual phase impression technique - Precise duplication of models - Capturing multiple unit impressions - Impression of inlay, crown, bridge and partial denture etc.		It is indicated for all dental impression techniques.
	Physical properties	Flow properties		23.25 ㎜	17.49 ㎜	23.26 ㎜
		Wettability		56.98°	57.40°	54.96°
		Working time		2'30"	1'30"	2'15"-2'45"
		Setting reaction time		4'00"	2'30""	5'00"
		Tear strength		15.98 N/㎜	16.72 N/㎜	15.32 N/㎜
		Dimensional accuracy		0.08%	0.11%	0.17%
		Consistency		45.73 ㎜	45.44 ㎜	47.18 ㎜
		Compatibility with the die and cast materials		Reproduced for 0.05 ㎜	Reproduced for 0.05 ㎜	Reproduced for 0.05 ㎜
		Curve of the shrinkage		9.98%	4.20%	10.79%
		Viscosity	Base	45,333mPas	44,000mPas	39,375mPas
			Catalyst	59,000mPas	55,050mPas	23,125mPas
	Chemical composition	Vinyl terminated group		Vinyl siloxanes		Polydimethylsiloxane polymer
		Filler		Silica, Fumed silica		Silicon Dioxide, Sodium Aluminosilicate
		Cross linker		Hydrogen polysiloxane		Polymethyl hydrogen siloxane
		Catalyst		Organo platinum complex		Organic platinum complex
		Colorant		Pigments		Pigments
		Surfactant		Surfactant		Surfactant
	Standard Conformed			ISO4823		ISO4823
	Biocompatibility			Yes		Yes
	Use			Prescription / Hospital		Prescription / Hospital
Difference	Physical properties	Color		- Light red(Light red/White) - Light orange(Light orange/White) - Orange(Orange/White) - Purple(Purple/White)		- Orange (Orange/White)

Vonflex S™ Light XLV is composed to Vinyl terminated group, Filler, Cross linker, Catalyst, Colorant and Surfactant as the predicate device. Many kinds of filler is used as a thickening agent in the impression materials. In general, Silica is synonym for silicon dioxide. So, The chemical composition of Vonflex S™ Light XLV is equivalent to the predicate device, Aquasil Ultra XLV Smart Wetting impression Material. Indication for use of Vonflex S™ Light XLV provide more detailed information than the predicate device for the user to have a better understanding of what Vonflex S™ Light XLV is indicated for. Through above table, most physical properties, Indications for use and chemical composition of Vonflex S™ Light XLV is similar to these of the predicate device.

The difference between Vonflex S™ Light XLV and predicate device is the color. But it doesn't affect to safety and effectiveness of product considerably. The two components of impression materials are requested contrasting colors to check the mixing condition, and the mixture should be distinguished from the oral tissue and blood. In this connection, the colors of Vonflex S™ Light XLV and predicate devices are satisfied these conditions.

7. Biocompatibility

The biocompatibility evaluation for the Vonflex S™ was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1:Evaluation and Testing'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1 : Evaluation and Testing Within a Risk Management Process" as recognized by FDA. The device of testing included the following tests:

- Cytotoxicity, ISO 10993-5[2009]
- Genotoxicity(Ames), ISO 10993-3[2003]
- Oral mucous Irritation, ISO 10993-10[2010]
- Sensitization(LLNA), ISO 10993-10[2010]

Vonflex S™ showed none cytotoxicity and none genotoxicity. Also it didn't show the irritation and sensitization response. So Vonflex S™ can be claimed to be biocompatible

8. Conclusions :

Most physical properties, instruction for use, chemical composition and etc. of Vonflex S™ is similar to the predicate device. The difference between Vonflex S™ and predicate devices is the color. But it doesn't affect to performance of product considerably.
Therefore, it is concluded that Vonflex S™ is substantially equivalent to the legally marketed predicate devices.

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