DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 2, 2016

Vericom Co., Ltd.
Myung-Hwan Oh
R&d Director
48 Toegyegongdan 1-gil,
Chuncheon-si, 200-944 KR

Re: K160377
Trade/Device Name: V-varnish™ Premium
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: November 1, 2016
Received: November 4, 2016

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 and Part 809) 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 and Part 809), 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,

Michael J. Ryan -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160377

Device Name
V-varnish™ Premium

Indications for Use *(Describe)*

· For treatment of dentinal hypersensitivity secondary to exposed dentin and root surfaces

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY
K160377

V-varnish™ Premium

Date: November 01, 2016

I. SUBMITTER

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II. DEVICE

Name of Device:	V-varnish™ Premium
Regulation Name:	Cavity Varnish
Classification Name:	Cavity Varnish
Regulatory Class:	Ⅱ
Product Code:	LBH

III. PREDICATE DEVICE

K062683, Enamel Pro Varnish, PREMIER DENTAL PRODUCTS CO.

IV. DEVICE DESCRIPTION

V-varnish™ Premium is cavity varnish containing 5% sodium fluoride(F ion: 22,600ppm). It is applied to teeth for the purpose of treatment dentinal

hypersensitivity. V-varnish™ Premium consists of rosin which adheres to the surface of the teeth, seals exposed dentin tubules. V-varnish™ Premium has four flavors such as bubblegum, strawberry, melon and mint and two colors(clear and white). It is packed in single dose package allows easy mixing and application.

V. INDICATIONS FOR USE

For treatment of dentinal hypersensitivity secondary to exposed dentin and root surfaces

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

			Subject Device	Predicate Device	Summary
Device Name			V-varnish™ Premium	Enamel Pro Varnish	-
Manufacturer			VERICOM CO., LTD.	PREMIER DENTAL PRODUCTS CO.	-
510(k) Number			K160377	K062683	-
Intended user			Dental professional	Dental professional	Same
Similarity	**Description**		V-varnish™ Premium is cavity varnish containing 5% sodium fluoride(F ion: 22,600ppm). It is applied to teeth for the purpose of treatment dentinal hypersensitivity. V-varnish™ Premium consists of rosin which adheres to the surface of the teeth, seals exposed dentin tubules. V-varnish™ Premium has four flavors such as bubblegum, strawberry, melon and mint and two colors(clear and white). It is packed in single dose package allows easy mixing and application.	Enamel Pro Varnish is a 5% sodium fluoride varnish which has a strong desensitizing action when applied to enamel and dentin surfaces. Enamel Pro Varnish may be used on moist teeth and leaves a film of varnish which sets in the mouth to allow for visual control and verification of application.	Description of subject device and predicate device is very similar; containing 5% sodium fluoride, purpose of use, fundamental technology etc. Subject device includes more information about flavor, color and packaging.
	Indication for Use		For treatment of dentinal hypersensitivity secondary to exposed dentin and root surfaces	Enamel Pro® Varnish is a fluoride containing preparation for the treatment of dentinal hypersensitivity, and for the reduction of post operative sensitivity. The varnish can be placed on sensitive root surfaces and under temporary restoratives and cements in order to seal exposed dentinal tissue. It can be used as a cavity liner.	Both devices are used for treatment of dentinal hypersensitivity. But predicate device is used extensively more subject device.
	Design		Blister packaging (Varnish + Brush)	Blister packaging (Varnish + Brush)	Both devices provide varnish and brush in plastic case.
Similarity	**Chemical composition**	**Base materials & blocking dentinal tubul**	Rosin	Rosin	Both devices consist of rosin, ethanol and sodium fluoride mainly. Other components are additives for taste, flavour and colour etc.
			Sodium fluoride	Sodium fluoride	
			Tricalcium phosphate	Dibasic Sodium Phosphate Calcium Sulfate Dihydrate	

		e			
		Solvent	Ethanol	Ethanol	
		Etc.	Sweetener Pigment Flavor etc.	etc.	
	Recommended contact time		For at least 4-6 hours	For approximately 4-6 hours	Both devices remain on the teeth for at least 4-6 hours.
	Physical and performance properties		- Consistency : 27.14±0.62 ㎜ - pH: 6.65 - Fluoride content: 2.15±0.03 % - Dentinal tubule occlusion: 85%	- Consistency: 33.25±0.64 ㎜ - pH: 6.69 - Fluoride content : 1.97±0.05 % - Dentinal tubule occlusion: 77%	According to bench test result, the physical & performance properties of the subjective device and predicate device are substantial equivalent.
	Bio-compatibility		Cytotoxicity Oral mucosa irritation Sensitization(LLNA) Genotoxicity(Ames) Acute systemic toxicity	Device is biocompatible when used as directed by dental professionals per ISO 10993-1.	Both devices are biocompatible
	Sterilization		Non-sterile	Non-sterile	Same
	Shelf Life		2 years	2 years	Same
Difference	**Flavor**		Bubblegum, Strawberry, Melon, Mint	VanillaMint, Strawberrier'n Cream, Bubblegum	Flavor is an option that is selected according to patient's taste. These differences do not raise concerns or questions when comparing the subject device to the predicate device.
	Storage condition		Do not store at elevated temperature or intense light. Do not use after expiry date. Temperature limitation: 0-30℃ (32-86℉)	Keep out of direct sunlight, store at room temperature: 68-77℉(20-25℃). Do not use after expiration date.	It is a condition of storage that is provided from manufacturer for stable use during shelf life. These differences do not raise concerns or

				questions when comparing the subject device to the predicate device.

VII. NON-CLINICAL PERFORMANCE TESTING

In vitro testing was conducted with V-varnish™ Premium and the predicate device, Enamel Pro® Varnish. Properties evaluated include consistency, pH, fluoride content and dentinal tubule occlusion.

Stability testing was conducted by evaluating the physical properties of the device to confirm a shelf life at room temperature of 24 months.

The biocompatibility evaluation for the V-varnish™ Premium 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 tests carried out for the devices and standards applied for each test are:

- Cytotoxicity(MTT), ISO 10993-5[2009]
- Genotoxicity, ISO 10993-3[2003]
- Oral mucous Irritation, ISO 10993-10[2010]
- Sensitization(LLNA), ISO 10993-10[2010]
- Acute systemic toxicity, ISO 10993-11[2006]

V-varnish™ Premium is considered to be in contact with dentin, enamel and oral mucosa for duration of less than 24 hours, while being the external communicating device.

VIII. SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject device is similar to indication for use, design, recommended contact time, chemical composition, physical & performance properties and etc. Also, the physical and performance properties of subjective device are not significant different between the subject device and the predicate device.

The subject device is composed of tricalcium phosphate while predicate device is composed of dibasic sodium phosphate and calcium sulfate dihydrate. All of these raw materials cause blockage of dentinal tubule to achieve the intended function of device. Also tricalcium phosphate of subject device is actually a resultant chemical compound from raw materials of predicate device; dibasic sodium phosphate and calcium sulfate dihydrate in oral condition.

Both subject device and predicate device produced with same amount of sodium fluoride contents.

The flavor and storage condition are different between subject device and predicate device which do not raise question or concerns.

IX. CONCLUSIONS

Based on a comparison of technology and Indications for use, together with in vitro performance testing, the subject device of V-varnish™ Premium is substantially equivalent to the predicate of Enamel Pro Varnish.