JUL 10 2014

510(k) Summary

(K140976)

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

Date: ___07/08/2014___

1. Applicant / Submitter:

KM Corporation
727 , Seoun-ro, Miyang-myeon, Anseong-si,
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2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110,
Fullerton, CA 92831
Phone: 714-202-5789 Fax: 714-409-3357
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3. Device:

Proprietary Name:	Enaden Flow
Common Name:	Light-cured Flowable Restorative Material
Classification Name:	Tooth Shade Resin Material
Classification:	Class II, 21 CFR 872.3690
Classification Product Code:	EBF

4. Predicate Device:

Tetric Evocream by Ivoclar Vivadent, Inc. (K042819)
G-aenial Universal Flo (GCUC-505) by GC AMERICA, Inc. (K091388)
Denfil Flow by VERICOM Co., Ltd. (K060637)

5. Device Description:

Enaden Flow is a polymer-based restorative material. Enaden Flow is visible light-cured, radiopaque flowable composite and it is easy to handle, ready to be applied to restorations directly. The Enaden Flowl is available in 5 shades: A1, A2, A3, A3.5, and B2 (according to VITAPAN® classic shade guide). The device is used for the restorations of both anterior and posterior teeth. The device is contained in a plastic syringe and the system includes a plunger, disposable needle, protective cap, and a holder for direction control of the needle.

6. Intended Use:

The Enaden Flow is intended for use in:

1) Restoration of class I~V cavities
2) Blocking out of undercuts
3) Sealing hypersensitive areas

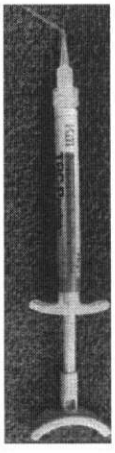
7. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

- ISO 4049 - Flexural Strength, Sensitivity to Ambient Light, Depth of polymerization, Water Absorption/Solubility, Radio-opacity, Color/ Color Stability
- ISO 9917 – Compressive Strength
- ISO 10993-5 - Cytotoxicity
- ISO 10993-10 - Skin sensitization test, Oral mucous irritation test
- ISO 10993-11 - Short term systemic toxicity test
- Other bench testing – Shelf life, Appearance, Volume, and Packaging tests

8. Substantial Equivalence

Enaden Flow is substantially equivalent to the predicate devices described herein with respect to intended use, device design, main raw material, accessory components, and delivery method. Also the curing mechanism of the subject device and the predicate devices is substantially equivalent in principle.
The difference is the compositions of some additives; however, the biocompatibility and the performance testing results show that this difference does not raise issues in safety and effectiveness.

	Subject Device	Predicate Devices		
510(K) Number	K140976	K042819	K091388	K060637
Device Name	Enaden Flow	Tetric Evocream	G-aenial Universal Flo (GCUC-505)	Denfil Flow
Manufacturer	KM Corporation	Ivoclar Vivadent, Inc	GC AMERICA, INC	VERICOM Co., Ltd.
Product Code	EBF	EBF	EBF	EBF
Design				
Intended Use	The Enaden Flow is intended for use in : 1) Restoration of class I~V cavities. 2) Blocking out of undercuts. 3) Sealing hypersensitive areas	1) Anterior restorations (Class III, IV) 2) Class V restorations 3) Restorations in the posterior region(Class I, II) 4) Veneering of discolored anterior teeth 5) Splinting of mobile teeth 6) Repair of composite and ceramic veneers.	1) Restoration of class I~V cavities. 2) Restoration of root surface caries. 3) Restoration of deciduous teeth. 4) Filling tunnel shaped cavities. 5) Sealing hypersensitive areas 6) Liner/base/filling in cavity undercuts 7) Sealant 8) Splinting mobile teeth 9) Additions to composite restorations.	1) Class V restorations 2) Anterior restorations(Class III,IV) 3) Small posterior restorations 4) Restorative therapy for mini-cavities of all types. 5) Extended fissures sealing in molars and premolars. 6) Repair of composite/ceramic veneers. 7) Blocking out of undercuts
Material Composition	Barium Glass, Urethane Dimethacrylate(UDMA), Triethylene Glycol Dimethacrylate(TEGDMA) , Bis-GMA, etc	Barium Glass, Dimethacrylates(UDMA), etc	Triethylene Glycol Dimethacrylate(TEGDMA), Urethane Dimethacrylate(UDMA), etc	Bis-GMA, Barium aluminosilicate. Triethylene Glycol Dimethacrylate(TEGDMA, etc
Human Factors	Ready to use dispensing system	Ready to use dispensing system	Ready to use dispensing system	Ready to use dispensing system

Biocompatibility	Biocompatible, conforming to ISO 10993	Biocompatible, conforming to ISO 10993	Biocompatible, conforming to ISO 10993	Biocompatible, conforming to ISO 10993
Physical Properties	Meets IS0 4049 specifications	Meets IS0 4049 specifications	Meets IS0 4049 specifications	Meets IS0 4049 specifications

9. Conclusion:

Based on the testing results, KM Corporation concludes that the Enaden Flow is substantially equivalent to the predicate devices.

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

July 10, 2014

KM Corporation
C/O Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA Incorporated
2651 E Chapman Avenue
Suite 110
Fullerton, CA 92831

Re: K140976
Trade/Device Name: Enaden Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: April 7, 2014
Received: April 16, 2014

Dear Ms. Chung:

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,

FDA Digitally signed by Richard C. Chapman -S Date: 2014.07.10 14:08:37 -04'00' 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K140976

Device Name
Enaden Flow

Indications for Use *(Describe)*
The Enaden Flow is intended for use in :

1) Restoration of class I~V cavities
2) Blocking out of undercuts
3) Sealing hypersensitive areas

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sheena A. Green -S
2014.07.10 11:35:45 -04'00'

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