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

May,11,2016

Whip Mix Corporation
c/o John P. Waters, Regulatory Compliance Officer
361 Farmington Avenue
Louisville, KY 40217

Re: K152443/S002
Trade/Device Name: Vericore® Gradient Temporary Disc
Regulation Number: 21 CFR 872.3770
Regulation Name: Crown and Bridge, Temporary, Resin
Regulatory Class: Class II
Product Code: EGB
Dated: April 14, 2016
Received: April 14, 2106

Dear Mr. Waters:

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 801and 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,

Erin 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

Indications for Use

510(k) Number (if known): K152443

Indications for Use:

Vericore ® Gradient Temporary discs is a device made from Polymethylmethacrlate. It is used to mill/fabricate temporary crown or bridge for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Restorations are designed virtually by a dental professional/technician then manufactured (milled) using CAD technology.

Prescription Use____X_____ (21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use_____ (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) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92

Date Prepared: May 10, 2016

1. APPLICANT

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2. SUBMITTER and CONTACT

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3. DEVICE NAME

Vericore® Gradient Temporary Disc

4. COMMON OR USUAL NAME AND CLASSIFICATION

Crown and Bridge, Temporary, Resin
Regulation Number: **872.3770**
Product Code: **EBG**
Classification: **Class II**

5. PREDICATE DEVICE COMPARISON

Whip Mix claims three predicates for our Vericore ® Gradient Temporary Discs. The primary predicate is to Copra-Temp discs manufactured by White Peaks Dental Systems (K131664). The Indications for Use are similar and both devices use Evonik as the supplier of the PMMA raw material supplier. Both devices are similar in regards to flexural strength, chemical solubility, and sorption. Both devices are biocompatible and there are no new risks introduced in regards to substantial equivalence when used in accordance with the Instructions For Use. The secondary and reference predicates are to demonstrate substantial equivalence with the shade materials. Whip Mix K142670 and Jensen Dental K111743 are referenced. Whip Mix claims these predicates for the shading ingredient of red, yellow, and blue. The rest of the information provided for K142670 and K111743 are for informational purposes only.

6. DEVICE DESCRIPTION

Vericore ® Gradient Temporary Discs is a device made from high quality PMMA (polymethylmethacrylate) that is >98%. It is intended for use in the oral cavity as a temporary restoration up to six (6) months while awaiting a permanent restoration. Two (2) pontics are allowed between two (2) abutment teeth. Restorations are designed by the dental technician using CAD technology and uses scans or models from the basis of the restoration to be milled. Vericore ® Gradient Temporary Discs are circular in form and available in a variety of thicknesses for different milling systems and are also available in Vita shades of A1, A2, A3, B1, B2, and Bleach. The device is fabricated in the standard dental laboratory environment. The intended patient population is for anyone needing a temporary crown or bridge while awaiting a permanent restoration.

7. INDICATIONS FOR USE

- Vericore ® Gradient Temporary discs is a device made from Polymethylmethacrlate. . It is used to mill/fabricate temporary crown or bridge for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Restorations are designed virtually by a dental professional/technician then manufactured (milled) using CAD technology.

8. SUBSTANTIAL EQUIVALENCE WITH PREDICATE DEVICES

Item	**(NEW) Whip Mix Device**	**White Peaks (K131664) Copra-Temp Primary Predicate**	**Whip Mix (K142670) Vericore Zirconia Blanks Secondary Predicate**	**Jensen Dental (K111743) InSync Ceramic System Reference Predicate**
Class	Class II device	Class II device	Class II device	Class II device
510K number	K152433	K131664	K142670	K111743
Classification Code	EBG	EBG	EIH	EIH
Shade Ingredient	CAS 1309-37-1 CAS 51274-00-1 CAS 68187-11-1	CAS 12035-39-1	CAS 1309-37-1 CAS 51274-00-1	CAS 68187-11-1
Ingredient	PMMA ≥ 98%	PMMA 100%	Zirconia	Porcelain Powder
Shades	Vita Shades A1, A2, A3, B1 B2, BL	Vita shades A1, A2, A3, B1	Vita Shades A1, A2, A3, A4, B0, B1, B2	Ancillary InSync pastes available in all 16 Vita shades
Diameter	98.5mm	98.0mm	98.5mm	Pellets
Thickness	12, 16, & 20mm	15, 16, and 20mm	10, 12, 14, 16, 20, and 25mm	Pellets
Milling Technology	Milled using CAD technology	Machined using any milling system	Milled using CAD technology	Pressable Silica pellets
Raw Material Supplier	Evonik ® PMMA beads	Evonik ® PMMA beads	Zirconia Powder from Tosoh	Not specified
Flexural Strength	82 MPa	113 MPa	533	Not specified
Regards to sterility	Sold non-sterile	Sold non-sterile	Sold non-sterile	Sold non-sterile
Chemical Solubility	-0.2 µg/mm ^{3}	0.2 µg/mm ^{3}	≤ 18 µg/cm ^{2}	Not Specified
Water Sorption	22 µg/mm ^{3}	20.3 µg/mm ^{3}	NA	Not Specified
Indications For Use	Vericore ® Gradient Temporary discs is a device made from Polymethylmethacrylate. It is used to mill/fabricate temporary crown	White Peaks Copra Temp is a device made from high quality 100% PMMA (polymethylmethacrylate) for the fabrication of temporary crowns	Indications for Use: Vericore zirconia blanks are made from pre-sintered zirconium dioxide intended to be used with many CAD/CAM or	The pressable ceramic pellets are pressed onto zirconia frames by dental technicians to

	or bridge for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Restorations are designed virtually by a dental professional/technician then manufactured (milled) using CAD technology.	and bridges and is intended for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Restorations are designed and manufactured by a dental Professional (Technician) using CAD technology	manual milling machines. Vericore zirconia blanks are biocompatible and designed to fabricate; - Zirconia Substructures - Restorations (Including inlays, onlays, and veneers) - Crown Framework in the Anterior and Posterior regions - Bridge Framework in the Anterior and Posterior regions	fabricate full ceramic crowns and the ceramic layering porcelain and liquids are used to build up the pressed ceramic to final tooth morphology and shade. The ceramic layering porcelain and liquids are also used in building ceramic crowns and bridges on titanium and titanium alloy substructures. Both applications are to provide prostheses for missing/damaged teeth.

9. PERFORMANCE TESTING

Testing according to ISO 10477 was conducted for Flexural Strength, Water Sorption, and chemical Solubility (same tests as performed on the predicate K131664) and all tests passed the requirements.

10. BIOCOMPATIBILITY

Whip Mix' Vericore ® Gradient Temporary Discs use the same source for the PMMA as White Peaks and that is Evonik ®. White Peaks performed biocompatibility tests in regards to ISO:10993-3, ISO:10993-5, and ISO:10993-10. Whip Mix listed different shading ingredients than claimed by the predicate from White Peaks. To ensure this did not alter the equivalence claim Whip Mix performed biocompatibility test for the oral mucosa and subject device did not demonstrate any irritation effects on the test subjects.

11. PREDICATE DIFFERENCE DISCUSSION

Whip Mix claims three predicates to substantiate substantial equivalence. Whip Mix Vericore ® Gradient Temporary Discs is substantially equivalent to Whip Mix Vericore Zirconia Blanks (K142670) and Jensen Dental InSync Ceramic Systems (K111743 for the shade ingredients only). The other differences between the new device and the predicates are shown for information only.

Whip Mix Vericore ® Gradient Temporary Discs claims substantial equivalence in performance and technological characteristics to White Peaks Copra-Temp K131664. The amount of PMMA claimed, while different, is very similar in the amount of PMMA used. The flexural strength while less than the predicate is similar and passes the minimum requirement which is 50mPA per ISO 10477. There is no correlation between the claimed PMMA percentage and lesser flexural strength. Lastly, the subject device did not demonstrate any irritation effects on the test subjects.

12. CONCLUSION

Vericore ® Gradient Temporary Discs demonstrate substantial equivalence to Copra-Temp K131664, Whip Mix K142670, and K111743 when used in accordance with the Instructions For Use. Compared to the predicate devices our new device is similar in flexural strength, chemical solubility, sorption tests, shading ingredients, and passed biocompatibility tests.