K131760

MAR 2 6 2014

510(K) SUMMARY

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

Date Prepared: 05/24/2013

1. **APPLICANT**

Whip Mix Corporation
361 Farmington Avenue
Louisville, KY 40217

PHONE: 502-634-5357
FAX: 502-634-4512
EMAIL: jwaters@whipmix.com

2. **SUBMITTER and CONTACT**

John P. Waters
Regulatory Compliance Officer & Official Correspondent for
Whip Mix Corporation
361 Farmington Avenue
Louisville, KY 40217

PHONE: 502-634-5357
FAX: 502-634-4512
EMAIL: jwaters@whipmix.com
DATE: 05/24/2013

3. **DEVICE NAME**

Preppies Plus®

4. **COMMON OR USUAL NAME AND CLASSIFICATION**

Oral Cavity Abrasive Polishing Agent
Regulation Number: **872.6030**
Product Code: **EJR**
Classification: **Class I**

5. **PREDICATE DEVICE INFORMATION**

Preppies flour of pumice (**Whip Mix product 510(k) exempt**)

Bisco Cavity Cleanser (**K915668**)
Ultradent Consepsis Scrub **(K925375)**

DEVICE DESCRIPTION

Whip Mix Preppies Plus is an innovative blend of polishing and cleaning agents including 2% Chlorhexidine Gluconate (CHG) relative to liquid component and is in a paste form. Each cup provides enough flour of pumice paste for a single use. Preppies Plus has no fluoride, oils, or added flavoring agents.

6. INTENDED USE

Whip Mix Preppies Plus ® is a device used as part of a professionally administered prophylaxis treatment. It is used on the tooth surface prior to;

- Restoration cementation.
- Acid etching procedures:
  - Sealants
  - Orthodontic brackets
  - Composite restorations

SUBSTANTIAL EQUIVALENCE WITH PREDICATE DEVICES

(new) Preppies Plus	**Whip Mix Preppies flour of Pumice**	**Bisco Cavity Cleanser**	**Ultradent Consepsis Scrub**
Class I Device	Class I device	Class II device	Class II device
510(k) Pending	510(k) Exempt	K915668	K925375

Whip Mix **Preppies Plus ®** Pumice Paste is a device specifically formulated with 2.0% Chlorhexidine Gluconate. Each cup provides enough Preppies Plus for a single patient.
• Contains no fluoride, oils, or added flavoring agents.
• For use on tooth surface prior to restoration cementation
• For use prior to acid etching procedures
  ○ Sealants
  ○ Composite restorations
**Minimizes the potential for post-op sensitivity
	Cleans the tooth surface prior to acid etching procedures;
	-sealants
	-orthodontic brackets
	-composite restorations
	Cleans the tooth surface prior to restoration cementation.
	Polishing amalgam or composite restorations.
		Used to clean and moisten tooth structure	Used for removal of residual temporary cement prior to permanent cementation and/or for cleaning debris while disinfecting.

	Prophylaxis of heavily stained teeth. Prepping the tooth surface prior to bleaching procedures.		
Paste solution	Paste solution	Aqueous solution	Slurry
Contains 2% (relative to liquid component) Chlorhexidine Gluconate	Contains no Chlorhexidine	Contains 2% Chlorhexidine Digluconate (CHD)	Contains 2% (relative to liquid component) Chlorhexidine Gluconate

7. SAFETY AND EFFECTIVNESS

The use of chlorhexidine in medical device applications have been cleared since the 1970's and is used in many dental applications as well. A thorough search for known risks associated with chlorhexidine in the FDA database was performed. This information was an input to our risk management process. In accordance with ISO 14971 our risk management process has identified the known hazards associated with our new product and all have been mitigated to an acceptable level. Whip Mix's new device, Preppies Plus, is exactly the same as our 510(k) exempt device, Preppies Flour of Pumice except for the addition of 2% Chlorhexidine Gluconate (CHG). Based on the acceptable results of the non-clinical tests for bio-compatibility performed and comparison to the predicates Whip Mix Preppies Plus ® device introduces no new risks and is considered substantially equivalent.

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

March 26, 2014

Whip Mix Corporation
Mr. John P. Waters
Regulatory Compliance Officer & Official Correspondent
361 Farmington Avenue
Louisville, KY 40217

Re: K131760
Trade/Device Name: Preppies Plus®
Regulation Number: 21 CFR 872.6030
Regulation Name: Oral Cavity Abrasive Polishing Agent
Regulatory Class: I
Product Code: EJR
Dated: December 20, 2013
Received: December 30, 2013

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 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 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. 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Division 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 (IF KNOWN) K131760

DEVICE NAME: **PREPPIES PLUS®**

INDICATIONS FOR USE:

Whip Mix Preppies Plus ® is a device used as part of a professionally administered prophylaxis treatment. It is used on the tooth surface prior to;

- Restoration cementation.
- Acid etching procedures:
  - Sealants
  - Orthodontic brackets
  - Composite restorations

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over-The-Counter Use ____

Sheena A. Green -S
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