K100539

510(k) SUMMARY

(21 C.F.R.§ 807.87(a), 807.92)

JUN 17 2010

1. **Applicants Information/Address:**
Preventive Technologies, Inc
4330 Matthews-Indian Trail Road
Indian Trail, North Carolina 28079

2. **Establishment Registration Number:**
1061053

3. **Contact Person/Telephone:**
Kenneth S. Peterson
704-849-2416 (Phone)
704-849-2417 (Fax)

4. **Date Summary was Prepared:**
February 18, 2010

5. **Device Identification:**

A. Panel:
DENTAL

B. Proprietary Name:
PREVENTECH Prophylaxis Paste with Fluoride

C. Common Name:
Dental Prophylaxis Paste

D. Classification Name:
Oral Cavity Abrasive Polishing Agent (21§ CFR 872.6030)

E. Classification:
Class I

F. Product Code:
EJR

6. **Legally Marketed Predicate Device(s):**

A. ENAMEL PRO™ Professional Prophylaxis Paste with ACP (Amorphous Calcium Phosphate), Premier Dental (K062166)
B. NUPRO® (Satin) Prophylaxis Paste with Fluoride, Dentsply International,

(K912945)

Proposed Labeling Sufficient to Describe the Device, Its Intended Use, and the Directions for Its Use: (807.87(e)), (continued);

7. Description of the Device:

PREVENTECH Prophylaxis Paste with Fluoride is an oral cavity abrasive polishing agent containing sodium fluoride in a blend of enamel polishing and cleaning abrasive agents in a paste form designed for professional application to the teeth during the course of standard dental hygiene procedures. *PREVENTECH* Prophylaxis Paste with Fluoride is sweetened with Xylitol® and offered in various grit levels and various flavors.

The standard mode of application for *PREVENTECH* Prophylaxis Paste with Fluoride is by use of a low speed Dental Handpiece and accessories, (21§ CFR 872.4200) and a Prophylaxis Cup, (21§ CFR 872.6290).

8. Statement of Intended Use:

PREVENTECH Prophylaxis Paste with Fluoride is intended to be used for cleaning and polishing procedures as part of a professionally administered prophylaxis treatment. (21§ CFR 872.6030),

9. Technological Characteristics and Comparison of Devices

A. The technological characteristics of the Proposed device, *PREVENTECH* Prophylaxis Paste with Fluoride is substantially equivalent to the Predicate devices, ENAMEL PRO Professional Prophylaxis Paste with ACP, (K062166) and NUPRO (Satin) Prophylaxis Paste with Fluoride, (K912945) in;

i.) Intended Use: The Proposed device, *PREVENTECH* Prophylaxis Paste with Fluoride and Predicate devices, ENAMEL PRO Professional Prophylaxis Paste with ACP, (K062166) and NUPRO (Satin) Prophylaxis Paste with Fluoride, (K912945) have the same Intended Use;
   a. For cleaning and polishing procedures as part of a professionally administered prophylaxis treatment (21§ 872.6030),

ii.) Composition; The Proposed device, *PREVENTECH* Prophylaxis Paste with Fluoride and Predicate devices, ENAMEL PRO Professional Prophylaxis Paste with ACP, (K062166) and NUPRO (Satin) Prophylaxis Paste with Fluoride, (K912945) are similar in components used;
   a. Sodium fluoride, 1.23% Fluoride ion,
   b. Pumice as the abrasive agents at various grit levels for cleaning, polishing, stain and plaque removal,
   c. Glycerin and/or other humectants polyols for moisture control, viscosity and lubrication during use,
   d. Xylitol® or sodium saccharin as sweetening agents,

e. Flavoring and color agents.

Proposed Labeling Sufficient to Describe the Device, Its Intended Use, and the Directions for Its Use: (807.87(e)), (continued);

iii.) Shelflife/Expiration Dating: The Proposed device, *PREVENTECH* Prophylaxis Paste with Fluoride will be labeled with an expiration date of two (2) years from date of manufacture. This statements is similar to the Predicate devices, ENAMEL PRO Professional Prophylaxis Paste with ACP, (K062166) and NUPRO (Satin) Prophylaxis Paste with Fluoride, (K912945).

iv.) Method of application; Prophylaxis Paste is applied to teeth during a routine dental hygiene procedure via the use of a low speed Dental Handpiece and accessories, (21§ 872.4200) and a Prophylaxis Cup, 21§872.6290) at RPM of less than 5000.

v.) Primary Package; The Proposed device, *PREVENTECH* Prophylaxis Paste with Fluoride and Predicate devices, ENAMEL PRO Professional Prophylaxis Paste with ACP, (K062166) and NUPRO (Satin) Prophylaxis Paste with Fluoride, (K912945) are packaged into 2 gram Individual Use cups,

vi.) Relative Enamel Abrasion (REA); The Proposed device, *PREVENTECH* Prophylaxis Paste with Fluoride and Predicate device, ENAMEL PRO Professional Prophylaxis Paste with ACP, (K062166) demonstrate similar performance for enamel abrasion. The Proposed device, *PREVENTECH* Prophylaxis Paste with Fluoride is identified as Prophy Paste C and Predicate device, ENAMEL PRO Professional Prophylaxis Paste with ACP, (K062166) is identified as Prophy Paste B as referenced in Final Report, Relative Enamel Abrasion (REA) Study, REA09-284.

10. Substantial Equivalence (SE) Summary Statement

In summary, we believe the Proposed device, *PREVENTECH* Prophylaxis Paste with Fluoride is substantially equivalent in composition and performance to the Predicate devices ENAMEL PRO Professional Prophylaxis Paste with ACP, (K062166) and NUPRO (Satin) Prophylaxis Paste with Fluoride, (K912945) as referenced in this submission. The components used in the Proposed device, *PREVENTECH* Prophylaxis Paste with Fluoride are similar to those components used in the Predicate devices described within this submission as well as other dental prophylaxis products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Kenneth S. Peterson
Vice President, Research and Development
Preventitive Technologies, Incorporated
4330 Mathews-Indian Trail Road
Indian Trail, North Carolina 28079

JUN 17 2010

Re: K100539
Trade/Device Name: PREVENTECH Prophylaxis Paste with Flouride
Regulation Number: 21 CFR 872.6030
Regulation Name: Oral Cavity Abrasive Polishing Agent
Regulatory Class: I
Product Code: EJR
Dated: May 27, 2010
Received: June 4, 2010

Dear Mr. Peterson:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(21 CFR §§ 807.87(h), 807.92)

510(K) Number (if known): K

Device Name: **PREVENTECH Prophylaxis Paste with Fluoride.**

Indications for Use:

For cleaning and polishing procedures as part of a professionally administered prophylaxis treatment.

Prescription Use X AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulay for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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