K 102053 FEB - 3 2011

Date of Summary	07/16/2010
Submitter/Contact Person	H. Carl Jenkins The **Wood Burditt** Group 10 E. Scranton Ave., Suite 201 Lake Bluff, IL 60044 (ph) (847) 234-7500 x 205 (fax) (847) 574-0728 (email) hcjenkins@woodburditt.com
Applicant	Sunstar Americas, Inc. 4635 W. Foster Ave. Chicago, IL 60630 (ph) 773-777-4000 (fax) 773-777-1417
Device Name	Butler® Calci-Flor Prophylaxis Paste
Common Name	Oral cavity abrasive polishing agent
Classification	Oral cavity abrasive polishing agent Regulation Number: 21 CFR 872.6030 Product Code: EJR Panel Code: Dental Device Class: I
Legally Marketed Predicate Devices	BUTLER G.U.M. WITH FLUORIDE JOHN O. BUTLER CO. K952091 ProCode: JES SATIN PROPHYLAXIS PASTE DENTSPLY INTL. K912945 ProCode: EJR ENAMEL PRO PREMIER DENTAL PRODUCTS CO. K062166 ProCode: EJR
Device Description	Butler® Calci-Flor Prophylaxis Paste is an oral cavity abrasive polishing agent that contains calcium and fluoride. This device is regulated by FDA as a Class I device. Butler® Calci-Flor Prophylaxis Paste is an abrasive oral prophylaxis paste (available in one of several levels of grit coarseness), which contains fluoride, calcium, humectants, bulking agents for proper paste formation, a sweetener, flavor, color, and preservatives. This device is intended for use by dental

	professionals, during professionally administered dental prophylaxis treatment (tooth-cleaning), to remove stain from and polish the teeth. Paste application is designed for use with a prophy angle with suitable cup. The device is to be limited to individuals who are professionally trained to perform dental prophylaxis.
Intended Use and Indications	Butler® Calci-Flor Prophylaxis Paste is designed to clean and polish teeth during professionally administered dental hygiene prophylaxis treatments.
Summary of technological characteristics compared to predicate devices	Butler® Calci-Flor Prophylaxis Paste is made of the same ingredient component materials that are used in lawfully marketed predicate devices, with the same type and durations of patient contact. Butler® Calci-Flor Prophylaxis Paste has the same indications for use and intended use as lawfully marketed predicate devices.
Performance Testing / Summary of Substantial Equivalence (SE)	Bench testing was performed on the Butler® Calci-Flor Prophylaxis Paste to ascertain fluoride release data. The results of this testing do not raise new questions of safety and effectiveness, and demonstrates that the device is at least as safe and effective as the legally marketed predicate device.

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

Sunstar Americas, Incorporated
C/O Mr. Carl Jenkins
The Wood Burditt Group
10 E. Scranton Avenue, Suite 201
Lake Bluff, Illinois 60044

FEB - 3 2011

Re: K102053
Trade/Device Name: Butler® Calci-Flor Prophylaxis Paste
Regulation Number: 21 CFR 872.6030
Regulation Name: Oral Cavity Abrasive Polishing Agent
Regulatory Class: I
Product Code: EJR
Dated: July 19, 2010
Received: July 22, 2010

Dear Mr. Jenkins:

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 Susan Runner

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

510(k) Number (if known): K102053

Device Name: Butler® Calci-Flor Prophylaxis Paste

Indications for Use:

Butler® Calci-Flor Prophylaxis Paste is intended for cleaning and polishing procedures as part of a professionally administered dental prophylaxis treatment.

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102053