K062502

510(k) SUMMARY

1. SUBMITTER INFORMATION:

DEC 15 2006

Name: OSspray Ltd.
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London
SW13 0PT

Phone: +44 (0)207 188 4341
Facsimile: +44 (0)207 188 4360

Contact: Ian Thompson, Ph.D.

Preparation Date: August 2006

2. DEVICE NOMENCLATURE:

Trade Name: OSspray Cleaning Compound
Common Name: Dental Prophylaxis Powder
Classification Name: Oral Cavity Abrasive Polishing Agent

3. LEGALLY MARKETED PREDICATE DEVICES:

Device Name: Prophy Powder
510(k) Number: Exempt
Applicant: PAC-Dent INTL. Inc (Owner Number 9029860)

Device Name: BUTLER NUCARE PROPHYLAXIS PASTE WITH NOVAMIN
510(k) Number: K041371
Applicant: NOVAMIN TECHNOLOGY, INC., 13709 Progress Blvd., Suite. 23, Alachua, FL 32615

4. DEVICE DESCRIPTION:

The OSspray Cleaning Compound is a biocompatible calcium sodium phosphosilicate compound in powder form intended for cleaning and polishing procedures as part of a dental prophylaxis treatment to remove debris from tooth surfaces. The OSspray Cleaning Compound is also intended to physically occlude dentin tubules to provide relief from tooth sensitivity during the prophylaxis treatment. The process of cleaning the tooth surface with the OSspray Cleaning Compound physically occludes dentin tubules for the management of sensitive teeth.

The OSspray Cleaning Compound is a dry inorganic particulate (calcium sodium phosphosilicate) composed of elements that occur naturally in the body's hard tissues (Ca, Na, Si, P, and O). When exposed to an aqueous environment, the OSspray Cleaning Compound undergoes a rapid surface reaction, allowing it to physically adhere to exposed root dentin and to physically occlude tubules. Within a short period of time, essentially all of the particles of the compound react to form hydroxycarbonate apatite (HCA), which is chemically similar to natural tooth mineral.

5. INTENDED USE:

The OSspray Cleaning Compound is intended for cleaning and polishing procedures as part of a professionally administered dental prophylaxis treatment. The OSspray Cleaning Compound is also intended to provide relief from tooth sensitivity during the prophylaxis treatment.

6. TECHNOLOGICAL CHARACTERISTICS:

The technological characteristics of the OSspray Cleaning Compound and the Prophy Powder are substantially equivalent in that they are both abrasive compounds in powder form designed to polish and clean tooth enamel. The OSspray Cleaning Compound supplies calcium and phosphate ions in the form of a bioactive glass, and the Prophy Powder supplies sodium bicarbonate.

The OSspray Cleaning Compound and the BUTLER NUCARE PROPHYLAXIS PASTE WITH NOVAMIN are both composed of bioactive glass particles. Both devices are intended to polish and clean the tooth surface during a prophylaxis treatment. The bioglass component of the Butler predicate device is suspended in glycerin and comes in the form of a paste. The bioglass component of the OSspray Cleaning Compound comes in the form of a dry powder to be applied by a compressed air system (i.e., air polishing). Both devices are also intended for use during a prophylaxis treatment to occlude dentinal tubules and block hydrodynamic flow.

7. SAFETY AND PERFORMANCE DATA:

The biocompatibility of the OSspray Cleaning Compound was evaluated by performing cytotoxicity (L-929), intracutaneous irritation, and maximization sensitization tests according to ISO 10993. The results of these tests indicate that this device is biocompatible and safe if used as directed.

The tubule occlusion efficacy of OSspray Cleaning Compound was evaluated using an *in vitro* dentin block model. The results indicate that the OSspray Cleaning Compound occludes a statistically significant number of tubules when compared with both positive and negative controls.

8. CONCLUSION:

The OSspray Cleaning Compound is substantially equivalent to the Prophy Powder (510(k) exempt) and the BUTLER NUCARE PROPHYLAXIS PASTE WITH NOVAMIN (K041371). The *in vitro* performance and biocompatibility data demonstrate that the OSspray Cleaning Compound is substantially equivalent to, and as safe and effective as, the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2006

OSspray, Limited
C/O Ms. Carmelina G. Allis, Esq
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street NW, Suite 1200
Washington, DC 20005

Re: K062502
Trade/Device Name: OSspray Cleaning Compound
Regulation Number: 872.6030
Regulation Name: Oral Cavity Abrasive Polishing Agent
Regulatory Class: I
Product Code: EJR
Dated: December 1, 2006
Received: December 4, 2006

Dear Ms. Allis:

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.

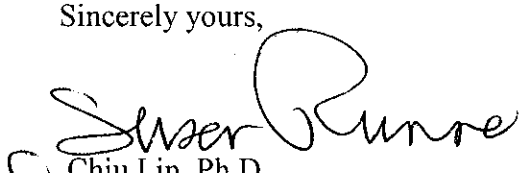
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION C

INDICATIONS FOR USE

510(k) Number (if known): K062502

Device Name: OSspray Cleaning Compound

INDICATIONS FOR USE:

The OSspray Cleaning Compound is intended for cleaning and polishing procedures as part of a professionally administered dental prophylaxis treatment. The OSspray Cleaning Compound is also intended to provide relief from tooth sensitivity during the prophylaxis treatment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ (Part 21 C.F.R. 801 Subpart D) OR Over-The-Counter Use ____ (21 C.F.R. 801 Subpart C)

Susan Runner

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

(510(k) Number: K062502