K103114

MAR 14 2011

SECTION E
510(k) SUMMARY

1. SUBMITTER INFORMATION:

Name: OSspray Ltd.
Address: Hodgkin Building
King's College London
Guys Hospital Campus
London
SE1 1UL

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

Contact: Ian Thompson, Ph.D.

Preparation Date: September 2010

2. DEVICE NOMENCLATURE:

Trade Name: OSspray Sylc CR
Common Name: Calcium Phosphosilicate
Classification Name: (EJR) Agent, Polishing, Abrasive, Oral Cavity

3. LEGALLY MARKETED PREDICATE DEVICE:

Device Name: OSspray Cleaning Compound
510(k) Number: K062502
Applicant: OSspray Ltd, Hodgkin Building, King's College London, Guys Hospital Campus, London, SE1 1UL

4. DEVICE DESCRIPTION:

OSspray Sylc CR is a biologically-compatible device designed to selectively remove weakened or decayed carious enamel without damaging underlying healthy enamel in addition to cleaning tooth surfaces and closing exposed dentine tubules.

The device when applied as a dry powder via an air polishing or air abrasion delivery system to a decayed enamel surface will abrade away the decayed tissue.

The process of cleaning the tooth surface physically occludes exposed dentin tubules for the management of sensitive teeth.

OSspray caries removal powder is a dry inorganic particulate, (calcium phosphosilicate), composed of elements that occur naturally in the body's hard tissues (Ca, Na, Si, P, and O). To aid powder flow less than 2% by weight of silicon dioxide (Aerosil R972 Pharma) is added to the calcium phosphosilicate.

Bench testing has shown that Sylc CR is a more accurate method for selectively removing decayed dental tissue than traditional dental burs and aluminum oxide air abrasion

5. INTENDED USE:

OSspray Sylc CR compound is a single-phase calcium phosphosilicate ceramic product intended for the removal of weakened or decayed small enamel lesions, in addition to the cleaning of enamel surfaces and providing relief of hypersensitivity associated with exposed dentin and open dentinal tubules.

6. TECHNOLOGICAL CHARACTERISTICS:

The technological characteristics of OSspray Sylc CR and FDA cleared OSspray Cleaning Compound (K062502) are identical, except for particle size and the addition of up to 2 wt% silicon dioxide flow aid (Aerosil R972 Pharma). Both devices clean tooth enamel, desensitize exposed dentine and are a single-phase dry powder.

The primary difference between the two devices is that OSspray Sylc CR has a smaller particle size distribution of 5-50 microns. Sylc CR is designed to selectively remove weakened enamel or caries decay. This process requires the particle flow, delivered via an air polishing or abrasion unit, to be focused onto the weakened enamel site for a short period of time. The kinetic energy of the particles is such that it is able to selectively remove any weakened or infected enamel and leave healthy or affected enamel intact. The OSspray Cleaning Compound has a mean particle size distribution of 55-75 microns and is designed to remove heavy stain and plaque.
Neither OSspray Cleaning Compound nor Sylc CR is suitable for the removal of bulk healthy enamel.

The OSspray Sylc CR is a bioactive glass intended to remove decayed enamel by abrasion of weakened enamel when the powder is directed at the tooth surface in a compressed air stream.

7. SAFETY AND PERFORMANCE DATA:

The biocompatibility of OSspray Sylc CR, with 2% by weight silicon dioxide flow aid (Aerosil R972 Pharma) was evaluated for cytotoxicity (L-929), intracutaneous irritation, maximization sensitization. The results of these tests indicate that there is no evidence of any hazardous effects to the patient if the product is used as directed.

The tubule occlusion efficacy of OSspray Sylc CR was evaluated using an *in vitro* dentin block model. The results indicate that OSspray Sylc CR compound occludes a statistically equivalent number of tubules when compared with OSspray Cleaning Compound.

8. CONCLUSIONS:

OSspray Sylc CR compound is considered to be equivalent in cleaning and desensitization properties to that of OSspray Cleaning Compound. The provided *in vitro* performance and biocompatibility data demonstrate the substantial equivalence of OSspray Sylc CR compound for the intended uses.

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

Dr. Ian Thompson
Technical Director
OSspray, Limited
Hodgkin Building, Kings College London
London, United Kingdom SE1 1UL

MAR 14 2011

Re: K103114
Trade/Device Name: OSspray Sylc CR
Regulation Number: 21 CFR 872.6030
Regulation Name: Oral Cavity Abrasive Polishing Agent
Regulatory Class: I
Product Code: EJR
Dated: December 12, 2010
Received: February 2, 2011

Dear Dr. Thompson:

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,

Anthony D. Watson

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

SECTION D
STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K103114

Device Name: ___OSspray Sylc CR

INDICATIONS FOR USE:
OSspray Sylc CR compound is a single-phase calcium phosphosilicate ceramic product intended for the removal of weakened or decayed small enamel lesions, in addition to the cleaning of enamel surfaces and providing relief of hypersensitivity associated with exposed dentin and open dentinal tubules.

(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 (Per 21 CFR 801.109) Over-The-Counter Use ____

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

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