K113146

JAN 2 3 2012

Chapter 6 510(k) Summary

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

1. Submitter Information

Ross Healthcare Inc.
1750 Grant Ave
Blaine, WA, 98230

Subject: Abbreviated 510(k) PCXX Fluoride Varnish

Contact Person

Marc N. Ross
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Date Prepared: October 5, 2011-10-05

2. Device Name

Trade Name: PCXX Varnish
Common Name: Cavity Varnish
Classification Name: Cavity Varnish (21 CFR 872.3260)

3. Predicated Devices

Device	Company	K Number
Duraflor	Pharmascience, Inc	K961893
Duraphat	Colgate	K945794
Fluorilaq	Pascal Co., Inc.	K030488

4.&5. Description and Intended Use

PCxx Varnish is 5% Sodium Fluoride Varnish that reduces tooth sensitivity by forming a film when topically applied to enamel and dentin surfaces.

The properties, intended use and composition are equivalent to the predicated devices and other current varnishes which are rosin based insoluble mixtures that form a film when applied to tooth surfaces.

6. Technological Characteristics

PCxx Varnish used the same rosin (colophony) and rosin derivatives that are used as adhesive agents in FDA approved cavity varnishes. Examples include but are not limited to Duraflor, Duraphat and Fluorilaq.

The product comes in a single unit dose package containing the varnish and separate applicator brush.

7. Performance and Comparison Data

The sealant used in predicate devises is the same material used in the submitted devices. The sealant used is a colophony, rosin or rosin derivative of CAS# 65997-06-0 in an ethanol solution. There are no performance standards established for this product but as the narrative comparison with predicate devices shows it to be substantially equivalent, performance will be the same.

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

JAN 23 2012

Mr. Marc N. Ross
President
Ross Healthcare, Inc.
1750 Grant Avenue
Blaine, WA 98230

Re: K113146
Trade/Device Name: PCXX Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: January 6, 2012
Received: January 17, 2012

Dear Mr. Ross:

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

Chapter 4.

Indications for Use

510(k) Number : ~~none~~ (K113146)

Device Name:

Trade Name:	PCXX Varnish
Common Name:	Cavity Varnish
Classification Name:	Cavity Varnish (21 CFR 872.3260)

Indications For Use:

- Treatment of hypersensitive teeth
- Use on exposed dentin and root sensitivity
- Under temporary restoratives and cements where post-operative sensitivity is of concern.

Prescription Use __X__. AND/OR Over-the-Counter Use _____.
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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