K030488

MAY - 2 2003

Pascal
Company, Inc.
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VII. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (AS REQUIRED BY SECTION 807.92C)

1) Submitted by: Vincent M. Tentarelli
Pascal Company, Inc.
2929 NE Northup Way
Bellevue, WA 98004
USA

2) Establishment Registration No.: 3011632

3) Date Prepared: March 1, 2003

4) Device Trade Name: Fluorilaq Fluoride Varnish

5) Device Common Name: Dental Varnish

6) Device Classification Name: Cavity Varnish

7) Device Class: Class II

8) Substantial equivalence: **Fluorilaq** is substantially equivalent to the originally classified device described in CFR 872.3260 "Varnish, cavity." It is also substantially equivalent and nearly identical to (for example) the following products that are currently on the market, having been cleared by 510(k)s:

510(k) Number	Name of Device	Company
K982915	Sci-Pharm DVF Varnish	Scientific Pharmaceuticals, Inc.
K945794	Duraphat	Inpharma
K961893	Duraflor	Pharmascience, Inc.

9) The document, "Guidance on the CDRH Premarket Notification Review Program, June 30, 1986 (K86-3)" was used to determine substantial equivalence:
   a) Fluorilaq has the same intended use, as a varnish on sensitive teeth over exposed dentin under temporary restoratives and cements and exposed dentin on roots, as many cleared by the 510(k) process as shown above.

b) The technological characteristics for this product are the same as those for the predicate devices and other resinous products currently on the market except for minor variations in the same or similar components.

c) Descriptive information provided shows that the materials from which Pascal Co., Inc.'s **Fluorilaq** is made are substantially equivalent to (nearly identical with some) those of similar products, used for identical purposes, currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Vincent M. Tentarelli
Quality Assurance Manager
Pascal Company, Incorporated
2929 NE Northup Way
Bellevue, Washington 98004

Re: K030488
Trade/Device Name: FLUORILAQ
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity varnish
Regulatory Class: II
Product Code: LBH
Dated: February 13, 2003
Received: February 14, 2003

Dear Mr. Tentarelli:

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 (301) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030488

V. STATEMENT OF INDICATIONS FOR USE

INDICATIONS

Intended for use as a varnish on sensitive teeth over exposed dentin under temporary restoratives and cements where post-operative sensitivity is a concern and to improve quality and functionality of restorations when used in conjunction with dental restoratives and cements. To seal dentinal tubules in cavity preparations or on sensitive root surfaces.

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

510(k) Number: K030488