K082198

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OCT 29 2008

DENTSPLY

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510(k) SUMMARY
for
DURASHIELD® PLUS

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: July 31, 2008

2. Device Name:

- Proprietary Name: DURASHIELD® PLUS
- Classification Name: Cavity Varnish
- CFR Number: 872.3260
- Device Class: II
- Product Code: LBH

3. Predicate Device:

Company	Device	510(k) Number	Date Cleared
Scientific Pharmaceuticals, Inc.	Sci-Pharm DFV Varnish	K982915	02/12/1999
NovaMin Technology, Inc.	Sultan Tooth Root Desensitizer	K072342	10/03/2007

4. Description of Device:

DURASHIELD® PLUS is a topically applied, flavored cavity varnish containing sodium fluoride and NovaMin. The varnish is a viscous liquid and is insoluble in water and saliva. NovaMin is a bio-available calcium phosphosilicate that releases calcium and phosphorous when exposed to moisture.

5. Indications for Use:

DURASHIELD® PLUS is indicated for the relief of dental hypersensitivity where dentin and cementum are exposed.

6. Substantial Equivalence:

Technological Characteristics.

The technological characteristics (i.e., chemical composition and device function) of DURASHIELD® PLUS are similar to that of Sci-Pharm DFV Varnish and other cavity varnishes that have been in widespread use for many decades. The only difference is that DURASHIELD® PLUS contains NovaMin, which naturally remineralizes teeth.

Non-Clinical Performance Data.

Prior use of the components of DURASHIELD® PLUS have been evaluated and passed biocompatibility testing for oral toxicity. Therefore, no additional biocompatibility tests were conducted.

Conclusion as to Substantial Equivalence

DURASHIELD® PLUS with NovaMin is substantially equivalent to the current Sci-Pharm DFV Varnish in terms of intended use, physical properties and materials. The purpose of this submission is to introduce a cavity varnish with NovaMin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 2008

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International, Incorporated
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K082198
Trade/Device Name: Durashield® Plus
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: July 31, 2008
Received: August 4, 2008

Dear Ms. Lewis:

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.

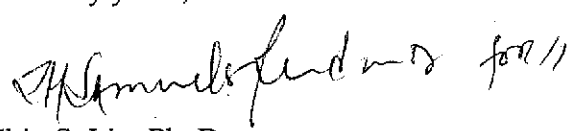
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, Ph. D
Division 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 STATEMENT

K082198

510(k) Number (if known): _____

Device Name: DURASHIELD® PLUS

Indications for Use:

DURASHIELD® PLUS is indicated for the relief of dental hypersensitivity where dentin and cementum are exposed.

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: K082198