

K982564



510(k) SUMMARY

DENTSPLY International
570 West College Avenue
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(717) 845-7511
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NAME & ADDRESS:

OCT 6 1998

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: July 22, 1998

TRADE OR PROPRIETARY NAME: ~~DELTON® FS DIRECT DELIVERY SYSTEM~~

CLASSIFICATION NAME: Pit and fissure sealant and conditioner 872.3765

PREDICATE DEVICES: DELTON® Plus Direct Delivery System K951296

DEVICE DESCRIPTION: DELTON® FS PIT & FISSURE SEALANT is a radiopaque, light-cured, resinous material designed for application to the occlusal surfaces of caries susceptible posterior teeth to seal irregularities and prevent ingress of oral fluids, food and debris.

DELTON® FS DIRECT DELIVERY SYSTEM also includes Delton® Etchant Gel, a DENTSPLY legally marketed device (K942031). The sealant is dispensed to the acid-etched tooth via an individually filled cartridge inserted into the applicator handle (Direct Delivery System).

The physical properties of DELTON® FS PIT & FISSURE SEALANT are equivalent or better than those of DELTON® Plus Pit & Fissure Sealant.

INTENDED USE: DELTON® FS DIRECT DELIVERY SYSTEM is used for preventive sealing of pits and fissures in the primary and secondary dentition in combination with the acid-etch technique.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in DELTON® FS PIT & FISSURE SEALANT have been used in the predicate dental device. Because of the nearly equivalent composition, no additional toxicity testing was necessary.

We believe that the prior use of the components of DELTON® FS DIRECT DELIVERY SYSTEM in the legally marketed predicate device, the nearly equivalent composition to the predicate device, and the performance data support the safety and effectiveness of DELTON® FS DIRECT DELIVERY SYSTEM for the indicated uses.

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OCT 6 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. P. Jeffrey Lehn
Director, Corporate Compliance
and Regulatory Affairs
DENTSPLY International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K982564
Trade Name: Delton® FS Director Delivery System
Regulatory Class: II
Product Code: EBC
Dated: July 22, 1998
Received: July 23, 1998

Dear Mr. Lehn:

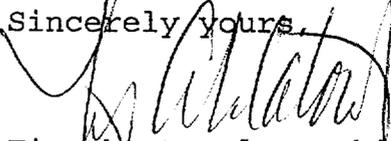
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 801.109)

510(K) Number: K982564

Device Name: ~~DELTON® FS DIRECT DELIVERY SYSTEM~~

The DELTON® FS DIRECT DELIVERY SYSTEM is used for preventive sealing of pits and fissures in the primary and secondary dentition in combination with the acid-etch technique.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use _____

[Signature]
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982564

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