AUG 27 1999

K992516

DENTSPLY

510(k) SUMMARY

NAME & ADDRESS:

DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
~~Fax (717) 854-2343~~

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

CONTACT: P. Jeffery Lehn

DATE PREPARED:

TRADE OR PROPRIETARY NAME: DYRACT® SEAL COMPOMER PIT & FISSURE SEALANT

CLASSIFICATION NAME: Pit and fissure sealant and conditioner 872.3765

PREDICATE DEVICES:

Delton® FS Direct Delivery System	K982564
Dyract® Flow Restorative	K982395

DEVICE DESCRIPTION: DYRACT® SEAL COMPOMER PIT & FISSURE SEALANT is a light curing pit and fissure sealant containing releasable fluoride. The fluoride offers an additional protection of the sealed pits and fissures.

The physical properties of DYRACT® SEAL COMPOMER PIT & FISSURE SEALANT meet ISO Standard 6874.

INTENDED USE: DYRACT® SEAL COMPOMER PIT & FISSURE SEALANT is used for preventive sealing of pits and fissures in the primary and secondary dentition.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in DYRACT® SEAL COMPOMER PIT & FISSURE SEALANT have been used in legally marketed devices.

The results of Ames testing on the main components were negative.

We believe that biocompatibility studies with the final formulation are not necessary, due to the prior use of all components in DENTSPLY legally marketed devices.

Therefore, we believe that the prior use of the components of DYRACT® SEAL COMPOMER PIT & FISSURE SEALANT in legally marketed devices, the similarity in composition to the predicate device, the performance data, and the results of Ames and previous biocompatibility testing support the safety and effectiveness of DYRACT® SEAL COMPOMER PIT & FISSURE SEALANT for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1999

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: K992516
Trade Name: Dyract® Seal Composer Pit & Fissure Sealant
Regulatory Class: II
Product Code: EBC and EBF
Dated: July 27, 1999
Received: July 28, 1999

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

K992516

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 801.109)

510(K) Number: K992516

Device Name: DYRACT® SEAL COMPOMER PIT & FISSURE SEALANT

Used for preventive sealing of pits and fissures in the primary and secondary dentition.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992516