K050880

APR 2 2 2005

510(k) SUMMARY

DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, PA 17405-0872

CONTACT:	Helen Lewis
DATE PREPARED:	April 1, 2005
TRADE OR PROPRIETARY NAME:	DYRACT® EXTRA RESTORATIVE
CLASSIFICATION NAME:	Tooth shade resin material, 872.3690
PREDICATE DEVICES:	Dyract® AP Restorative, K973235 Quixx® Posterior Restorative, K040144

DEVICE DESCRIPTION: DYRACT® EXTRA RESTORATIVE is a hybrid resin-composite restorative material for use in filling all dental cavity classes. The direct restorative consists of a single paste that is filled into a cavity in increments up to 2 mm before visible light curing.

INTENDED USE: DYRACT® EXTRA RESTORATIVE is indicated for Cavity Classes III, IV, V, and VI, and Cavity Classes I and II where the cavity preparation is less than ⅔ of the intercuspal distance.

TECHNOLOGICAL CHARACTERISTICS: All of the components in DYRACT® EXTRA RESTORATIVE have been used in legally marketed devices and found to be safe for dental use. We believe that the prior use of the components of DYRACT® EXTRA RESTORATIVE in the legally marketed predicate devices support the safety and effectiveness of DYRACT® EXTRA RESTORATIVE for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2005

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

Re: K050880
Trade/Device Name: Dyract® eXtra Restorative
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: April 04, 2005
Received: April 06, 2005

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
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

510(K) Number (if known): K050880

Device Name: DYRACT® EXTRA RESTORATIVE

Indications for Use:

Indicated for

- Cavity Classes III, IV, V, and VI
- Cavity Classes I and II where the cavity preparation is less than ⅔ of the intercuspal distance

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)

[signature]

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

(510(k) Number: K050880