510(k) SUMMARY

K041272

OCT 18 2004

DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, PA 17404
P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: May 11, 2004

TRADE OR PROPRIETARY NAME: DYRACT® CEM PLUS CEMENT

CLASSIFICATION NAME: Dental Cement (872.3275)

PREDICATE DEVICES:

RelyX Luting Cement	K933139
Dyract® Flow Restorative	K982395

DEVICE DESCRIPTION: DYRACT® CEM PLUS CEMENT is a dental luting cement (powder/liquid system) that combines the major benefits of glass ionomer cements--adhesion to tooth substance and fluoride release--with the mechanical strength of a luting composite.

INTENDED USE: DYRACT® CEM PLUS CEMENT is indicated for: 1) Cementation of conventional metal or porcelain-fused-to-metal inlays, onlays, crowns, bridges, posts and post-core units; 2) Adhesive cementation of porcelain, composite, or all-ceramic inlays, onlays and crowns; and 3) Cementation of all-zirconia bridges.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in DYRACT® CEM PLUS CEMENT have been used in legally marketed devices or were found safe for dental use.

DYRACT® CEM PLUS CEMENT was evaluated for biocompatibility. The cured material was tested for cytotoxicity and found to be acceptable.

We believe that the prior use of the components of DYRACT® CEM PLUS CEMENT in legally marketed devices, the performance data, and the biocompatibility data provided support the safety and effectiveness of DYRACT® CEM PLUS CEMENT for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2004

DENTSPLY International
C/O Mr. P. Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
World Headquarters Susquehanna Commerce Center
221 West Philadelphia Street
York, Pensylvania 17405-0872

Re: K041272
Trade/Device Name: DYRACT® CEM PLUS CEMENT
Regulation Number: 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: September 29, 2004
Received: September 30, 2004

Dear Mr. Lehn:

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" (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,

for Chiu Lin, Ph.D.
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

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K041272

Device Name: **DYRACT® CEM PLUS CEMENT**

Indications for Use:

1. Cementation of conventional metal or porcelain-fused-to-metal inlays, onlays, crowns, bridges, posts and post-core units
2. Adhesive cementation of porcelain, composite, or all-ceramic inlays, onlays and crowns
3. Cementation of all-zirconia bridges

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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: K041272