K033215

JAN - 9 2004

510(k) Summary of Safety and Effectiveness
(As Required by 21 C.F.R. §807.92)

Applicant:	Danville Materials, Inc. 2021 Omega Dr. San Ramon, CA 94583
Contact Person:	Craig R. Bruns Phone 925 838-7940 Fax 925 838-0944 e-mail: cbruns@daneng.com
Date of summary	September 29, 2003
Device name	PrepAir
Common name	Airbrush

Classification names	Regulation Number	Product Code
	21 CFR 872.6080	KOJ

Device Description	The PrepAir is a dental airbrush using aluminum oxide to prepare all classes of caivty prior to restoration.
Predicate Device	The device is substantially equivalent to other legally marketed devices in the United States including PrepStart by Danville Engineering (K970589), PrepTech by Prep Technology Corp (K974655), AirDent by Air Techniques (K981564) and Rondoflex by Kavo America (K002708).
Intended Use	The PrepAir is intended for the cutting and preparation of all classes of cavity restorations; removal of composite resin fillings; surface roughening of enamel, dentin, metals and composite surfaces prior to adhesive resin bonding; preparation of pits and fissures prior to sealing; cleaning and removal of cements and adhesives from bridges and crowns prior to re-cementation; and preparation of adhesive surfaces of orthodontic bands and brackets to increase retention.

Enclosure 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2004

Mr. Craig R. Bruns
Danville Materials Incorporated
2021 Omega Road
San Ramon, California 94583-1229

Re: K033215
Trade/Device Name: PrepAir
Regulation Number: 872.6080
Regulation Name: Airbrush
Regulatory Class: KOJ
Product Code: II
Dated: December 30, 2003
Received: January 2, 2004

Dear Mr. Bruns:

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.

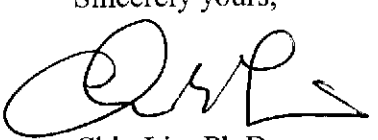
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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,



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

K033215

Indications for Use

510(k) Number (if known): K033215

Device Name PrepAir

Indications For Use:

The PrepAir is intended for the cutting and preparation of all classes of cavity restorations; removal of composite resin fillings; surface roughening of enamel, dentin, metals and composite surfaces prior to adhesive resin bonding; preparation of pits and fissures prior to sealing; cleaning and removal of cements and adhesives from bridges and crowns prior to re-cementation; and preparation of adhesive surfaces of orthodontic bands and brackets to increase retention.

Prescription Use ✓ 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)

for MSR

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

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