

K670306

SECTION 5: 510(k) SUMMARY

MAR 22 2007

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

CONTACT: Helen Lewis
DATE PREPARED: January 30, 2007
TRADE OR PROPRIETARY NAME: Paint-on Polish Agent
CLASSIFICATION NAME: Coating Material for Resin Fillings,
Class II per 21CFR872.3310
PREDICATE DEVICES: Biscover LV, K043168

DEVICE DESCRIPTION:

The Paint-on Polish Agent is liquid Polish agent designed eliminate the Polishing procedure by painting the formulation on the surface of restorations directly. It is indicated for use on both permanent and temporary restorations. Paint-on Polish can also be used as a sealant to decrease the micro-leakage at tooth-composite restoration interface. Due to the unique chemistry, Paint-on Polish formulation can be cured by both LED and halogen light. The addition of fillers provides excellent wear resistance for the formulation. The cured coating surface has a strong adhesion to restoration and excellent stain resistance to food and drinks. It also emits blue fluorescence close to enamel surface. Paint-on Polish formulation has a thin oxygen inhibited layer after curing, but it can be easily removed by ethanol or isopropanol without reducing the glossiness of coating.

INTENDED USE:

1. Surface and enamel margin treatment of Direct, light-cured composite restorations.
2. Surface treatment of Indirect restorations; composite resin or methacrylate veneers, inlays, onlays, crown and bridge retainers.

TECHNOLOGICAL CHARACTERISTICS:

All of the components found in Paint-on Polish Agent have been used in legally marketed devices and were found safe for dental use. Paint-on Polish has been evaluated and passed biocompatibility testing for cytotoxicity, genotoxicity, irritation and sensitization.

We believe that the prior use of the components of Paint-on Polish in legally marketed devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of Paint-on Polish for the indicated uses.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAR 22 2007

Re: K070306
Trade/Device Name: Paint-on Polish Agent
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material for Resin Fillings
Regulatory Class: II
Product Code: EBD
Dated: January 30, 2007
Received: February 09, 2007

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 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu S. Lin', with a stylized flourish at the end.

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

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K07 0306

Device Name: Paint-on Polish Agent

Indications for Use:

- Paint-on Polish Agent is indicated for
1. Surface and enamel margin treatment of Direct, light-cured composite restorations.
 2. Surface treatment of Indirect restorations; composite resin or methacrylate veneers, inlays, onlays, crown and bridge retainers.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)



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