

JUL 22 1998

K982907

**DENTSPLY**

510(k) SUMMARY

**DENTSPLY International**

570 West College Avenue  
P.O. Box 872  
York, PA 17405-0872  
(717) 845-7511  
~~Box (717) 845-2345~~

NAME & ADDRESS:

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

CONTACT: P. Jeffery Lehn

DATE PREPARED: June 4, 1998

TRADE OR PROPRIETARY NAME: TRUBYTE® DENTURE BOND Denture Bonding Agent

CLASSIFICATION NAME: Resin tooth bonding agent 872.3200

PREDICATE DEVICES: Palabond® Adhesion Primer K924422

DEVICE DESCRIPTION: TRUBYTE® DENTURE BOND Denture Bonding Agent is a polymer/monomer liquid solution. It is compatible with both heat-cured and auto-polymerizable acrylic denture base resins.

INTENDED USE: TRUBYTE® DENTURE BOND Denture Bonding Agent is used to bond plastic denture teeth and denture relines materials to acrylic denture bases.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in TRUBYTE® DENTURE BOND Denture Bonding Agent have been used in legally marketed medical devices.

Gas chromatographic analysis of the residual methyl methacrylate monomer in denture samples was conducted to determine the effect that TRUBYTE® DENTURE BOND Denture Bonding Agent use would have on the residual monomer content in a denture. There is not a statistically significant difference in residual monomer between samples that utilized TRUBYTE® DENTURE BOND Denture Bonding Agent vs. those prepared without bonding agent. This analysis confirms that TRUBYTE® DENTURE BOND Denture Bonding Agent use does not affect the amount of residual monomer present in the denture base. Accordingly, no additional patient risk is associated with the use of TRUBYTE® DENTURE BOND Denture Bonding Agent on dentures properly processed with Lucitone® 199 or Lucitone® FasPor+™ pourable denture base.

We believe that the prior use of the components of TRUBYTE® DENTURE BOND Denture Bonding Agent in legally marketed predicate devices, and the performance and safety data provided, support the safety and effectiveness of TRUBYTE® DENTURE BOND Denture Bonding Agent for the indicated uses.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 22 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. P. Jeffrey Lehn  
Associate Director  
Corporate Compliance  
DENTSPLY International  
570 West College Avenue  
P.O. Box 872  
York, Pennsylvania 17404

Re: K982007  
Trade Name: TRUBYTE® DENTURE BOND Denture Bonding Agent  
Regulatory Class: II  
Product Code: EBI  
Dated: June 4, 1997  
Received: June 8, 1997

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.

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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

**PREMARKET NOTIFICATION**

**INDICATIONS FOR USE STATEMENT**

(As Required by 21 CFR 801.109)

510(K) Number: K982007

Device Name: TRUBYTE® DENTURE BOND Denture Bonding Agent

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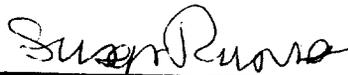
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-The-Counter Use



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

510(k) Number 7/20/17

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