

510(k) SUMMARY

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DENTSPLY

NAME & ADDRESS:

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York, PA 17405-0872
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SEP 16 1997

K972573

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

CONTACT: P. Jeffery Lehn

DATE PREPARED: July 9, 1997

TRADE OR PROPRIETARY NAME: LIQCRYLIC™ PRO DENTAL RESIN

CLASSIFICATION NAME: Denture relining, repairing or rebasing resin 872.3760

PREDICATE DEVICE: Palapress Vario Resin K902115

DEVICE DESCRIPTION: LIQCRYLIC™ PRO DENTAL RESIN is a pourable, cold-curing powder and liquid polymethyl methacrylate denture base material. It is color stable due to the fact that it utilizes a barbituric acid based catalyst system in lieu of the conventional benzoyl peroxide/amine catalyst system. It will be marketed in the popular Lucitone® 199 denture base shades. LIQCRYLIC™ PRO DENTAL RESIN mixes more quickly, has a shorter cure cycle and can be finished easier than the conventional pour resins currently available in the U.S. market.

INTENDED USE: LIQCRYLIC™ PRO DENTAL RESIN is used in the fabrication, repair or rebasing of complete or partial removable dentures and other removal dental appliances.

TECHNOLOGICAL CHARACTERISTICS: LIQCRYLIC™ PRO DENTAL RESIN is substantially equivalent to Palapress Vario (K902115) by Kulzer.

Kulzer has marketed the predicate device, Palapress Vario, in the United States since 1992 (K902115), and DENTSPLY has marketed this device (as Selecta-plus® Material and Trevapress® Material) in Europe and South America for over 25 years. The technology is over 30 years old and has a long clinical history. Therefore, we believe that biocompatibility studies are not necessary to prove the safety and efficacy of this formulation.

We believe that the substantial equivalence of LIQCRYLIC™ PRO DENTAL RESIN to the predicate device (K902115) marketed in the U.S., the long market history of the device outside of the U.S., and the performance data support the safety and effectiveness of LIQCRYLIC™ PRO DENTAL RESIN for the intended use.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 1997

Mr. P. Jeffrey Lehn
Director, Corporate Compliance and Regulatory Affairs
DENTSPLY International
570 West College Avenue
York, Pennsylvania 17405

Re: K972573
Trade Name: Liqcrylic™ Pro Dental Resin
Regulatory Class: II
Product Code: EBI
Dated: July 9, 1997
Received: July 10, 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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

Please also be advised that FDA is examining whether the Modified Human Draize Test, as it is currently conducted on medical gloves, is a valid means of predicting the sensitization potential of latex or synthetic materials. If FDA finds that the test is not a scientifically sound means to predict latex or synthetic materials hypersensitivity reactions in users, then hypoallergenic claims included in labeling for medical gloves may be considered misleading, and we will move to have the claim removed from labeling for all medical gloves.

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) 594-4618. 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: K972573

Device Name: LIQCRYLIC™ PRO DENTAL RESIN

Indications for Use:

Used in the fabrication, repair or rebasing of complete or partial removable dentures and other removable dental appliances.

Susan Rynn
(Division Sign-Off) _____
Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972573 OR Over-The-Counter Use _____
Prescription Use

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