

OCT 6 1999

K 992956



510(k) SUMMARY

DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
NAME & ADDRESS: (717) 845-7511
~~Fax (717) 854-2343~~

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

CONTACT: P. Jeffery Lehn

DATE PREPARED: August 31, 1999

TRADE OR PROPRIETARY NAME: LUCITONE® FRS™ FLEXIBLE DENTAL RESIN

COMMON OR USUAL NAME: Denture material

CLASSIFICATION NAME: Denture relining, repairing or rebasing resin 872.3760

PREDICATE DEVICE: Valplast® Resin Material Pre-1976 Device

DEVICE DESCRIPTION: LUCITONE® FRS™ FLEXIBLE DENTAL RESIN is an injection moldable, flexible thermoplastic resin designed for fabricating removable dental appliances.

Physical property testing indicates that LUCITONE® FRS™ FLEXIBLE DENTAL RESIN performs equal to or better than the predicate device.

INTENDED USE: LUCITONE® FRS™ FLEXIBLE DENTAL RESIN is used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in LUCITONE® FRS™ FLEXIBLE DENTAL RESIN have been used in legally marketed devices or have been found to be safe for dental use.

LUCITONE® FRS™ FLEXIBLE DENTAL RESIN was evaluated as follows:

MEM Elution Test	Non-cytotoxic
Ames Mutagenicity Test	Non-mutagenic
Mucous Membrane Irritation	Non-irritant
Hamster Cheek Pouch Irritation Test, Repeated Dose	Non-irritant
Kligman Maximization Study (NaCl)	Non-sensitizer
Kligman Maximization Study (Cottonseed oil)	Non-sensitizer

We believe that the similarity in composition of LUCITONE® FRS™ FLEXIBLE DENTAL RESIN to the predicate device, the performance data, and the results of biocompatibility testing support the safety and effectiveness of LUCITONE® FRS™ FLEXIBLE DENTAL RESIN for the indicated uses.

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Substantial Equivalence Comparison:

ID of Predicate Device:

Valplast® Resin Material, manufactured and distributed by Valplast International, is the predicate device for LUCITONE® FRS™ FLEXIBLE DENTAL RESIN.

Valplast Resin Material was labeled and promoted prior to May 28, 1976. The attached literature indicates the predicate device was marketed in 1954. The FDA establishment registration information for Valplast International is also attached.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 1999

Mr. P. Jeffrey Lehn
Director, Corporate Compliance
and Regulatory Affairs
DENTSPLY International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K992956

Trade Name: Lucitone® FRS™ Flexibel Dental Resin
Regulatory Class: II
Product Code: EBI
Dated: August 31, 1999
Received: September 2, 1999

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.

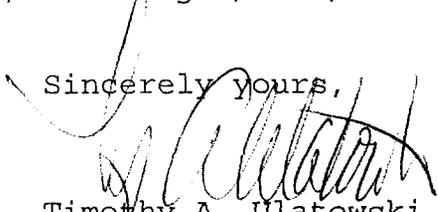
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

K992956

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 801.109)

510(K) Number: K992956

Device Name: LUCITONE® FRS™ FLEXIBLE DENTAL RESIN

Used for fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use

Susan Runnu
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992956

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