

K974097

SUMMARY OF SAFETY AND EFFECTIVENESS PERIACRYL™ APR - 9 1998

The Summary of Safety and Effectiveness of PERIACRYL™ dental cement reflects data available and presented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Intended Use

Periacryl™ is indicated for use as a dental cement for bonding dental materials such as crowns, caps and pins.

Caution

Federal law (U.S.A.) restricts this device to sale to and use by a qualified dental or medical practitioner.

Contraindications:

Periacryl™ must not come in contact with the conjunctival sac since conglutination may occur.

Identification of predicate devices:

Indermil™ Dental (Loctite, Rocky Hill, CT 06067)

Substantial Equivalency Information

The Blacklock Medical Product's Periacryl™ dental cement is similar to the Indermil™ Dental cement currently offered by Loctite. As a further note, Tissu-Glu is another cyanoacrylate that has been offered for sale in the United States by Ellman International, Hewlitt New York since prior to 1976. This product is sold non sterile as is Periacryl™.

	<u>Loctite</u>	<u>Blacklock</u>
Materials	N-Butyl 2 Cyanoacrylate	N-Butyl 2 Cyanoacrylate
Sterilization	Gamma Radiation SAL 10 ⁻⁶	Sterility is not claimed

The intended use and technological characteristics of these devices do not vary significantly. The safety and effectiveness of the Blacklock Medical Product's Periacryl™ dental cement are comparable to that of the Loctite's Indermil™ Dental cement.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 1998

Mr. Don Blacklock
President
Blacklock Medical Products, Incorporated
6671 London Court
Delta, British Columbia V4K 4W7
CANADA

Re: K974097
Trade Name: Periacryl
Regulatory Class: II
Product Code: EMA
Dated: January 13, 1998
Received: January 16, 1998

Dear Mr. Blacklock:

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

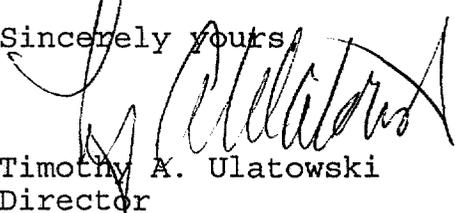
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

510(k) Number (if known): K9740 97

Device Name: PERI ACRYL

Indications For Use:

05/01/98

Periacryl™ is indicated for use as a dental cement for bonding dental materials such as crowns, caps, and pins.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

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

510(k) Number K974097

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

SK=65