K083087

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Attachment I

510(k) Summary

Trade Name: **Ecocel®**

Sponsor: Polichem S.A.
50 Val Fleuri
Luxembourg 1526

AUG 07 2009

Contact: Hari Nagaradona, PhD
Kendle International Inc.
Rockville, MD 2-855
Phone: 301-295-1370

Device Generic Name: **Liquid Bandage**

Classification: CFR 880.5090 Class I

Product Code: KMF

Product Description:
Ecocel® is a water-soluble lacquer contained in a glass bottle (1.5 or 3.3 mL) with a nylon brush fitted on the polypropylene screw cap.

Indications for Use:
Ecocel® is a hydrosoluble lacquer indicated to protect intact or damaged nails from the effects of moisture, friction (rubbing) or shear (tearing), relieving symptoms and signs of nail dystrophy (i.e. nail splitting and fragility).

Predicate Devices:
Ecocel is substantially equivalent to predicate devices, Liquiderm, Closure Medical Corp. (K002338) and LiquiShield S, MedLogic Global Ltd. (K023163).

Technological Characteristics
Polichem has submitted summaries of preclinical studies, including biocompatibility and laboratory studies, and the reports from clinical studies as well as the post market experience in Europe that substantiate Ecocel's performance both in vitro as well as its in vivo use.

Conclusion
Polichem believes the preclinical lab test results, clinical studies and information comparing Ecocel's technological features provided in the application demonstrate that Ecocel® is substantially equivalent to predicate Liquid Bandage devices legally marketed in the U.S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

PolichemS.A
% Kendle International, Inc.
Hari Nagaradone, Ph.D.
Associate Director
7361 Calhoun Place, Suite 500
Rockville, Maryland 20855

AUG 07 2009

Re: K083087
Trade/Device Name: Ecocel®
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: July 10, 2009
Received: July 14, 2009

Dear Dr. Nagaradone:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083087

510(k) Number (if known): K083087

Device Name: Ecocel®

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Prescription Use X AND / OR Over-the -Counter Use X
(PART 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083087