C. 510(k) Summary

Submitter: Dow Pharmaceutical Sciences
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On Behalf of:
L.A.M. Pharmaceutical Corp.
755 Center Street, Unit 5
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Contact: Alan Drizen
C.E.O., L.A.M. Pharmaceutical, Corp.

Date: January 30, 2002

Device Name: L.A.M. IPM™ Wound Gel

Classification Name: Hydrogel Wound and Burn Dressing

Predicate Device: Bioneet® Hydrogel (K984413) (Fidia Pharmaceutical Corp.)
IIA Absorbent Wound Dressing (K984388) (ConvaTec)

Description:

L.A.M. IPM™ Wound Gel is a clear viscous, odorless, aqueous gel composed principally of sodium hyaluronate, a derivative salt of Hyaluronic acid. Over-the-counter use of L.A.M. IPM™ Wound Gel is suitable for minor abrasions and minor cuts. Under the supervision of a healthcare professional, L.A.M. IPM™ Wound Gel is suitable for exuding wounds such as leg ulcers, pressure ulcers, diabetic ulcers, and for the management of mechanically or surgically debrided wounds.

L.A.M. IPM™ Wound Gel has been subject to *in vitro* and *in vivo* biocompatibility testing (cytotoxicity, dermal irritation, dermal sensitization, hemolyisis, and acute toxicity tests). These tests were negative and support the safe use of L.A.M. IPM™ Wound Gel as a hydrogel temporary dressing in contact with breached or compromised skin.

Clinical experience in 27 patients with various types of non-healing ulcers indicates that L.A.M. IPM™ Wound Gel is safe for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 5 2002

L.A.M. Pharmaceutical Corporation
c/o Mr. Clawson Bowman, JD, RAC
Dow Pharmaceutical Sciences
1330A Redwood Way
Petaluma, CA 94954

Re: K020325
Trade/Device Name: L.A.M. IPM Wound Gel
Regulatory Class: Unclassified
Product Code: MGQ
Dated: January 30, 2002
Received: January 31, 2002

Dear Mr. Bowman:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020325

Device Name: L.A.M. IPM Wound Gel

Indications For Use:

Over-the-counter use of L.A.M. IPM Wound Gel is suitable for minor abrasions and minor cuts. Under the supervision of a healthcare professional, L.A.M. IPM Wound Gel is suitable for exuding wounds such as leg ulcers, pressure ulcers, diabetic ulcers, and for the management of mechanically or surgically debrided wounds.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020325

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)