SEP - 7 2004

K033164

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: Dr Len's Medical Products LLC
2-Address: 555 Andorra Glen Ct. Suite #7. Lafayette Hill, PA 19444
3-Phone: (484) 530- 0557
4-Fax: (484) 530- 0559
5-Contact Person: Marc Swartz
6-Date summary prepared: August 30th, 2004 by Jay Mansour, Mansour Consulting LLC
7-Device Trade or Proprietary Name: ABRAM'S MULTI-DENSITY POLYURETHANE FOAM WOUND DRESSING SYSTEM
8-Device Common or usual name: Dressing
9-Device Classification Name: Dressing
10-Substantial Equivalency is claimed against the following device:

- Ferris Polymem Sterile Wound Dressing with Collagen from Ferris Manufacturing Corporation, 510k #K002129
- Contreet Foam Adhesive/Non-Adhesive from Coloplast Corporation, 510k #K 022416

11-Description of the Device:

The patented Abrams Multi-Density Polyurethane Foam Wound Dressing System is a single-patient use sterile medical device that contains silver based anti-microbial agent, effective as antibacterial barrier in the dressing.
The dressing is available in different configurations:

- 4x4" and 4x8" sizes with adhesive backing, sterile.
- 4x4" and 4x8" sizes without adhesive backing, sterile.
- 4x11" size without adhesive backing, sterile, attached to 11x38" cotton bandage.

12-Intended use of the device: (refer to FDA form attached)

The patented Abrams Multi-Density Polyurethane Foam Wound Dressing System is indicated for use for the treatment of pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds, trauma wounds (abrasions, lacerations, second degree burns) and draining wounds.

13-Safety and Effectiveness of the device:

This device is safe and effective as the predicate device cited above.

The main submission includes a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2004

Dr. Len's Medical Products, LLC
c/o Mr. Jay Mansour
Mansour Consulting LLC
1308 Morningside Park Drive
Alpharetta, Georgia 30022

Re: K033164
Trade/Device Name: Abrams Multi-Density Polyurethane Foam Wound Dressing System
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 3, 2004
Received: August 9, 2004

Dear Mr. Mansour:

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (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

Indications for Use

510(k) Number (if known): K033164

Device Name: Abrams Multi-Density Polyurethane Foam Wound Dressing system

Indications For Use:

This device is indicated for use for the treatment of pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds, trauma wounds (abrasions, lacerations, second degree burns) and draining wounds.

Prescription Use ✔ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(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 K033164