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OCT 5

510(k) Summary

1. **Product name and description**

a) Scientific name: *Phaenicia sericata* larvae (see Figure 1)

b) Common names: Maggot dressings; green blow fly maggots; disinfected maggots; sterile maggots; therapeutic maggots; debriding maggots; maggot debridement therapy; MDT dressings

c) "Proprietary" name: Medical Maggots; to be used with Creature Comforts or Creature Comforts II

d) Name and 510(k) number of legally marketed device:

Medical Maggots; K033391

The dressings used to confine them on the wound are called "Creature Comforts."

e) Classification: This is a pre-amendment device, still unclassified. Product Code: NQK

2. **Sponsor / Manufacturer identification:**

Monarch Labs, LLC
17875 Sky Park Circle, Suite K
Irvine, CA 92614
Phone: 949-679-3000
Fax: 949-679-3001
E-mail: rsherman@MonarchLabs.com
Registration Number: 3005735989

3. **Description of Modifications & Comparison to the cleared device**

The proposed modified accessory is a pre-assembled version of the hydrocolloid-netting cage that is commonly assembled at the bedside by end-users.

The structure, function, technology and indications are the same as in the currently marketed product. The differences resulting from this accessory will simplify application of the device, and consequently reduce the opportunity for user error. The accessory should increase safety by decreasing the opportunity for escaping maggots. There should be no change in efficacy as the underlying technology (debridement by medical grade larvae) remain unchanged.

4. **Intended use of the device (Indications: unchanged)**

The indications for using Medical Maggots and their confinement dressings remain unchanged: To debride non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post surgical-wounds.

5. Discussion of Legally Marketed Device, including safety and efficacy data

Maggot therapy is essentially a controlled wound myiasis (maggot infestation). The maggots macerate their food with their mouth hooks, release their digestive enzymes into the local environment, and ingest the liquefying and semi-solid tissue. As they grow, they molt twice. When satiated, the maggots leave their food source, burry themselves in a suitably protected area, and pupate. Adult flies emerge (eclose) approximately 1-3 weeks later. Maggot therapy dressings contain the medical grade larvae on the wound during the period of debridement, and facilitate easy and controlled removal when the patient and therapist determine they have completed their work.

All complaints and adverse events are collected and reviewed (phase 4 post-marketing study), along with solicited and unsolicited client comments. Analysis of this data recently revealed that there were 43 complaints and adverse events (AE) reported over the prior 2 years in association with 4,506 vials of maggots(250-1,000 larvae in each vial), making an AE rate of about 0.95% of vials distributed. The vast majority (69%) of those complaints concerned transportation problems (late or lost shipments by FedEx), or viability problems resulting from extreme temperature exposure during delayed transportation. An additional concern has been identified by clients: Obtaining some of the dressing components locally has been difficult for some; and the substitutions they have made has resulted in dressings which break down at the bedside and could potentially lead to escaping maggots.

6. Proposed labeling

No changes are proposed for the labeling or package inserts on any of the currently manufactured and legally marketed items. A new label and package insert is proposed for the pre-assembled version of the confinement dressings (accessory: "Creature Comforts II"). As described in its labeling, this accessory has not changed the indicated use of the product.

7. Design & Manufacturing Information

Design and production controls are in place. *Phaenicia sericata* larvae are grown and harvested according to previously published methods (Sherman & Wyle; Am J Trop Med Hygeine, 1996), now the standard around the world. The species was specifically tested for safety and efficacy in laboratory and clinical trials 1990-1995, and has not been mixed with other genetic material, even from blowflies of the same species.

Creature Comfort dressings are constructed from polyester netting. Original Creature Comforts are simply cut to standard or custom sizes that match other commercially available components (i.e., hydrocolloid dressings indicated for wound care) with which they can be assembled. These pieces of fabric are assembled (with glues and tapes) by the end user at the bedside, along with other dressing components (most commonly they are affixed to a hydrocolloid pad) to create a confining "cage dressing." Creature Comforts II dual layered dressings are constructed by affixing the same polyester netting to one edge of a hydrocolloid pad (hinge-like), with an adhesive strip along the other three sides so that the fabric can be sealed completely to its matching hydrocolloid pad simply by removing the protective liner on the adhesive strip and pressing down on the netted polyester fabric.

Medical Maggots are chemically disinfected in-house, and each batch is tested. Components that can withstand autoclaving are also sterilized in-house, and each batch is tested. Creature Comforts II require chemical sterilization, which is done by a subcontractor, with validation & verification. Each batch is tested.

The disinfected fly eggs are placed in the sterile vials that provide air for the maggots but prevent microbial entry. Minimally nutritious fluid keeps the larvae alive during transportation but prevents them from maturing before they reach the bedside. 250-500 larvae are packed in each standard shipping vial; 500-1,000 in "large" sized vials. Vials are shipped in protective packaging to prevent damage and to maintain optimal temperature during transit.

Medical Maggots should not be stored as they are highly perishable. They are sent out within 48 hours of production and should be used within 24 hours of arrival. Creature Comfort dressings can be stored for up to 6 months.

Medical Maggots are applied directly to the wound surface in a dose of 5-8 per square cm, and the confinement dressings are affixed to the skin surrounding the wound. The dressings are left in place on the wound for a "cycle" of 48 hours (24-72 hours). One to 3 cycles are applied weekly. Most wounds require 2-6 cycles for complete debridement. Methods of handling --- including application, removal, and disposal --- are described in detail in the Package Insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 2007

Monarch Labs, LLC
% Mr. Ronald S. Sherman
Co-Founder and Laboratory Director
17875 Sky Park Circle, Suite K
Irvine, California 92614

Re: K072438
Trade/Device Name: Medical Maggots and maggot confinement dressings
Regulatory Class: Unclassified
Product Code: NQK
Dated: September 24, 2007
Received: September 29, 2007

Dear Mr. Sherman:

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.

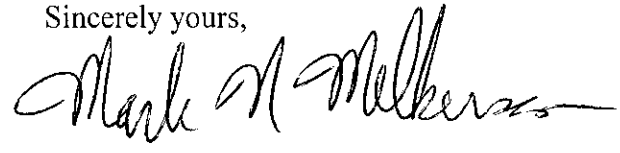
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND/PRSB
D.O.
f/t:CMD:kxl:10-3-07

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices Br	240-276-0120

Statement of Indications for Use

K072438

510(k) Number (if known): ~~K033391~~

Device Name: Medical Maggots and maggot confinement dressings

Indications for Use:

Medical Maggots are indicated for debriding non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post surgical -wounds.

The accessory maggot confinement dressings, Creature Comforts and Creature Comforts II, are indicated for confining the medicinal maggots on the area of treatment during debridement therapy for the conditions mentioned above.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Milhous

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

510(k) Number K072438