

K10 2827

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## 510(k) Summary

Date Prepared: September 14, 2010, updated January 28, 2011.

### 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. Accessories: MDT dressings; maggot confinement dressings; maggot cage dressings.
- c) **"Proprietary" name:** Medical Maggots; to be used with Creature Comforts or LeSoc (the latter being the new accessory featured in this Special PMN)
- d) **Name and 510(k) number of legally marketed device:**
- Medical Maggots and associated dressings (including Creature Comforts & Creature Comforts Nylon Stockings); K033391.
- Medical Maggots and associated dressings (including LeFlap dual-layered dressing); K072438.
- e) **Classification:** This is a pre-amendment device, still unclassified. Product Code: NQK

### 2. Sponsor / Manufacturer identification:

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Phone: 949-679-3000  
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### 3. Discussion of Legally Marketed Device, including safety and efficacy data

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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. The most common complaint is late delivery by express couriers. Since medicinal maggots are highly perishable, they must be delivered immediately before the patient's procedure or appointment; late deliveries by even a few hours can be a significant inconvenience. Rarely, maggots escape through the stretchable weave of the nylon stocking dressings. This occurs during the first few minutes after application, when the maggots are still small and exploring the wound. Because the maggots are so small and difficult to see, it may be under-reported.

#### **4. Description of Modifications & Comparison to the cleared device**

The proposed modified accessory ("*LeSoc*") has the same basic structure and use as the previously approved "Sterile Nylon Stocking," with the exception that we will make the stocking out of a different polyester fabric: the same polyester monofilament fabric that we currently use in the production of our approved Creature Comforts dressing (our flat, non-stocking dressing). This means that the stocking weave will be fixed, not free to move or stretch.

The structure, function, technology and indications are the same as in the currently marketed products. The only difference will be the offering of a hybrid dressing accessory to create a stocking-like dressing out of our currently used fixed-weave polyester net instead of the stretch-weave polyester of our Sterile Nylon Stockings. By substituting this fixed-weave fabric (the same fabric used in our Creature Comforts flat fabric dressings), the maggots will not be able to escape through the pores of the stocking dressing, as they occasionally do now. Consequently, the new accessory should increase safety by decreasing the opportunity for escaping maggots. There is no change in efficacy as the underlying technology (debridement by medical grade larvae) remains unchanged.

#### **5. Studies demonstrating substantial equivalence**

Evidence of substantial equivalence was based on results of the following evaluations:

Penetration & Durability Feasibility Study, which demonstrated that maggots would not escape during normal operation.

Sterilization validation, which demonstrated steam sterilization to be an adequate method of sterilization.

Biocompatibility testing (data supplied by manufacturer), which demonstrated the material not to be toxic nor to induce contact hypersensitivity in mice.

In summary, these evaluations demonstrate that the polyester net fabric used for many years in our other maggot dressings should be more effective in preventing maggots from escaping from our sock-like dressings, too.

#### 6. Intended use of the device (Indications: unchanged)

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 LeFlap™ and LeSoc™, are indicated for confining the medicinal maggots on the area of treatment during debridement therapy for the conditions mentioned above.

#### 7. 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 new dressing accessory (*LeSoc*). As described in its labeling, this accessory has not changed the indicated use of the product, nor the method of operation.

#### 8. 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 Hygiene, 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. Medical Maggots are chemically disinfected in-house, and each batch is tested. No changes in these procedures are proposed.

Creature Comfort dressing accessories are constructed from fixed-weave polyester netting. Standard, flat fabric Creature Comforts are cut to standard or custom sizes (some in-house, some by subcontractor), and steam sterilized (autoclaved) in-house, incorporating validation and verification quality controls along the way. Currently marketed Sterile Nylon Stockings are manufactured by outside manufacturer as stockings, and specially packaged and sterilized by Monarch Labs in-house.

The new accessory, *LeSoc*, is a hybrid dressing, combining the fixed-weave polyester monofilament fabric of standard Creature Comforts with the tubular design of Creature Comforts Sterile Nylon Stockings, to create a fixed-weave tubular or stocking-like dressing, from which the maggots can not as easily escape. The fabric will be the same type of fixed-weave polyester fabric as we currently use in Creature Comforts Dressings, produced by the same manufacturer. It will be ultrasonically sealed into tubes by the manufacturer/subcontractor, or heat-sealed by us, in-house (depending on size). It will then be steam sterilized in-house, in the same manner as is currently done for our Creature Comforts and Creature Comforts Sterile Nylon Stockings.

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. 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

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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.



Food and Drug Administration  
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Silver Spring, MD 20993-0002

Monarch Labs, LLC  
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Co-Founder & Laboratory Director  
17875 Sky Park Circle, Suite K  
Irvine, California 92614

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Re: K102827  
Trade/Device Name: Medical Maggots and maggot confinement dressings  
Regulatory Class: Unclassified  
Product Code: NQK  
Dated: October 7, 2011  
Received: October 11, 2011

Dear Dr. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

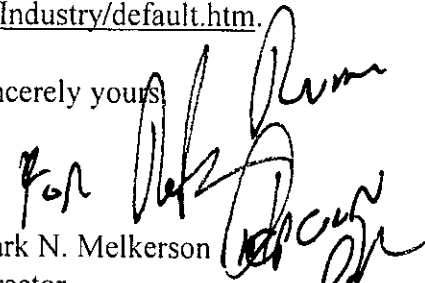
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21 CFR 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 (301) 796-7100 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

Statement of Indications for Use

510(k) Number (if known): K102827

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 LeFlap™ and LeSoc™, are indicated for confining the medicinal maggots on the area of treatment during debridement therapy for the conditions mentioned above.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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