JUN 20 2007

# 510(K) SUMMARY

## 11.1 SUBMITTER INFORMATION

| | | |
|---|---|---|
| A. | Company Name: | Pegasus Biologics, Inc. |
| B. | Company Address: | 6 Jenner, Suite 150<br>Irvine, CA 92618 |
| C. | Company Phone: | (949) 502-3240 |
| D. | Company Facsimile: | (949) 502-3241 |
| E. | Contact Person: | Pamela Misajon<br>Vice President, RA/CA<br>pmisajon@pegasusbio.com |

## 11.2 DEVICE IDENTIFICATION

| | | |
|---|---|---|
| A. | Device Trade Name: | Unite™ Biomatrix |
| B. | Common Name: | Dressing, Wound, Collagen |
| C. | Classification Name(s): | Unclassified |
| D. | Classification Regulation: | Unclassified |
| E. | Regulatory Class: | Unclassified |
| F. | Product Code: | KGN |
| G. | Advisory Panel: | General and Plastic Surgery |

## 11.3 IDENTIFICATION OF PREDICATE DEVICE

The Unite™ Biomatrix is substantially equivalent to the DermADAPT™ Wound Dressing manufactured by Pegasus Biologics, Inc. and cleared for commercial distribution under 510(k) K061494.

## 11.4 DEVICE DESCRIPTION

The Pegasus Biologics Unite™ Biomatrix is decellularized, equine pericardium. The Unite™ Biomatrix has been crosslinked and exposed to a liquid chemical sterilant. The product has passed the USP sterility test and satisfies FDA requirements for LAL endotoxin limit for a medical device. The product must be rinsed prior to use.

## 11.5 INDICATIONS FOR USE

The Pegasus Biologics Unite™ Biomatrix is a collagen-based wound dressing for the local management of moderately to heavy exuding wounds, including:

- Partial and full thickness wounds,
- Draining wounds,
- Pressure sores/ulcers,
- Venous ulcers,
- Chronic vascular ulcers,
- Diabetic ulcers,
- Trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears),
- Surgical wounds (e.g., donor sites/grafts, post-laser surgery, post-Mohs' surgery, podiatric wounds, dehisced surgical incisions)

## 11.6 SUBSTANTIAL EQUIVALENCE

Supplier qualification activities, receiving controls, and design verification testing demonstrate that the Unite™ Biomatrix device is equivalent to the predicate device in terms of design, performance and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pegasus Biologics, Inc.
% Ms. Pamela Misajon
Vice President, RA/CA
6 Jenner, Suite 105
Irvine, California 92618

JUN 20 2007

Re: K071425
Trade/Device Name: Unite™ Biomatrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: May 15, 2007
Received: May 23, 2007

Dear Ms. Misajon:

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

# Indications for Use

510(k) Number (if known):

Device Name: **Unite™ Biomatrix**

Indications for Use:

**The Pegasus Biologics Unite™ Biomatrix is a collagen-based wound dressing for the local management of moderately to heavy exuding wounds, including:**

- **Partial and full thickness wounds,**
- **Draining wounds,**
- **Pressure sores/ulcers,**
- **Venous ulcers,**
- **Chronic vascular ulcers,**
- **Diabetic ulcers,**
- **Trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears),**
- **Surgical wounds (e.g., donor sites/grafts, post-laser surgery, post-Mohs' surgery, podiatric wounds, dehisced surgical incisions)**

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

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

(Division Sign-Off)
Concurrence of CDRH, Office of Device Evaluation (ODE)
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** k071428