

**510(K) SUMMARY****1 Submitter Information**

- A. Company Name: Synovis Orthopedic and Woundcare, Inc.
- B. Company Address: 6 Jenner, Suite 150  
Irvine, CA 92618
- C. Company Phone: (949) 502-3240
- D. Company Facsimile: (949) 502-3241
- E. Contact Person: Amy Boucly  
Manager, Regulatory Affairs  
amy.boucly@synovisorthowound.com
- F. Date: August 18, 2011

**2 Device Identification**

- A. Device Trade Name: Unite® Biomatrix
- B. Common Name: Animal-derived extracellular matrix  
(xenograft) wound care product
- C. Classification Name(s): Unclassified
- D. Classification Regulation: Unclassified
- E. Device Class: Unclassified
- F. Product Code(s): KGN
- G. Advisory Panel: General and Plastic Surgery

**3 Identification of Predicate Devices**

The Unite™ Biomatrix is substantially equivalent to the following devices, which are cleared for commercial distribution in the United States:

- Unite® Biomatrix, Pegasus Biologics (K071425)
- Oasis® Wound Matrix, Cook Biotech Incorporated (K061711)

**4 Device Description**

The Unite® Biomatrix is a decellularized equine pericardial extracellular matrix (xenograft) which 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. The device is for single use, single patient application only.

## **5 Indications for Use**

The Synovis Orthopedic and Woundcare Unite® Biomatrix is an animal-derived extracellular matrix (xenograft) intended for the management of moderately to severely exudating 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 [second-degree] burns, skin tears)
- Surgical wounds (e.g., donor sites/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, dehisced surgical incisions)

## **6 Substantial Equivalence**

The Unite® Biomatrix is identical to the predicate device (Unite® Biomatrix, Pegasus Biologics) in terms of intended use, technology, design, materials and performance and is equivalent to the Oasis Wound Matrix in terms of intended use, technology, and design.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -W066-G609  
Silver Spring, MD 20993-0002

Synovis Orthopedic and Woundcare, Inc.  
% Ms. Amy Boucly  
Manager, Regulatory Affairs  
6 Jenner Street, Suite 150  
Irvine, California 92618

Re: K112399  
Trade/Device Name: Unite<sup>®</sup> Biomatrix  
Regulatory Class: Unclassified  
Product Code: KGN  
Dated: August 18, 2011  
Received: August 19, 2011

SEP - 7 2011

Dear Ms. Boucly:

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

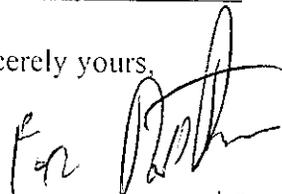
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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,



For Mark N. Melkerson

Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K112399

Device Name: Unite® Biomatrix

### Indications For Use:

The Synovis Orthopedic and Woundcare Unite® Biomatrix is an animal-derived extracellular matrix (xenograft) intended for the management of moderately to severely exudating wounds, including:

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Prescription Use   X    
(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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number   K112399