FEB 2 6 2013

510(k) SUMMARY
K122502
Harbor MedTech, Inc.
BriDGE Extracellular Collagen Matrix Wound Dressing

ADMINISTRATIVE INFORMATION:

Manufacturer Name:	Harbor MedTech, Inc. 4 Jenner, Suite 190 Irvine, CA 92618 Telephone: (949) 679-4800 Facsimile: (949) 679-1086 Email: jerrym@harbormedtech.com
Official Correspondent:	Jerry Mezger, Chief Executive Officer
Additional Correspondent:	Carol White, QA/RA Consultant 21521 Hummingbird Street Trabuco Canyon, CA 92679 Telephone: (949) 874-2024 Facsimile: (949) 589-0442 Email: carolwhite@cox.net

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	BriDGE Extracellular Collagen Matrix Wound Dressing
Common Name:	Dressing, Wound, Collagen
Classification Regulation:	Unclassified
Product Code:	KGN
Device Class:	Unclassified
Review Panel:	General & Plastic Surgery

INTENDED USE

The Harbor MedTech BriDGE Extracellular Collagen Matrix Wound Dressing is indicated 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)

DEVICE DESCRIPTION

The Harbor MedTech BriDGE Extracellular Collagen Matrix (ECM) Wound Dressing is a decellularized equine pericardial device that has been stabilized and radiation sterilized. The BriDGE ECM is non-pyrogenic and is provided sterile for single use only. The device must be rehydrated and rinsed prior to use following the procedure described in the Instructions for Use.

The BriDGE ECM is available in four sizes. The BriDGE ECM is available as a standard dressing and in a fenestrated model with pre-cut slits in the collagen matrix. A table of proposed model numbers and sizes is provided below:

Model Number	Dimensions	Description
HMT009	3 cm x 3 cm	Standard
HMT036	6 cm x 6 cm	Standard
HMT100	10 cm x 10 cm	Standard
HMT150	10 cm x 15 cm	Standard
HMT009F	3 cm x 3 cm	Fenestrated
HMT036F	6 cm x 6 cm	Fenestrated
HMT100F	10 cm x 10 cm	Fenestrated
HMT150F	10 cm x 15 cm	Fenestrated

EQUIVALENCE TO MARKETED PRODUCT

Harbor MedTech, Inc., demonstrated that, for purposes of FDA's regulation of medical devices, the BriDGE Extracellular Collagen matrix (ECM) Wound Dressing is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

The Harbor MedTech BriDGE ECM Wound Dressing is substantially equivalent to the following predicate devices: Pegasus Biologics Inc., Unite™ Biomatrix Collagen Wound Dressing K071425, and Cook Biotech, Inc., Oasis Wound Dressing K061711.

The BriDGE Extracellular Collagen Matrix Wound Dressing has the same intended use as the predicate devices and incorporates the same basic design. The proposed device and the predicate devices are available as sheets in multiple sizes and are either sold pre-fenestrated (Pegasus) or may be fenestrated by the physician (Oasis). The BriDGE ECM undergoes a lyophilization process during manufacturing as does the Oasis predicate device. Device stabilization of the BriDGE ECM is achieved by using BDDGE, whereas the Pegasus predicate device uses EDC and the Oasis predicate device process is unknown. The BriDGE ECM and the Pegasus predicate device utilize equine pericardium and the Oasis predicate device utilizes porcine SIS.

PERFORMANCE TESTING

A number of preclinical studies were conducted to assess the physical attributes of the collagen biomaterial and manufacturing processing. Complete biocompatibility studies were conducted on the material. Results of all performance tests were found to be acceptable. The BriDGE Extracellular Collagen Matrix Wound Dressing is as safe and as effective as the predicate devices.

Biocompatibility testing was performed under Good Laboratory Practices (GLP) by NAmSA in accordance with the relevant parts of ISO 10993 Biological Evaluation of Medical Devices. All GLP testing met the criteria for biocompatibility. The testing criteria followed were based on the following medical device categorization: surface device, breached or compromised surface, prolonged contact (>24h to ≤30 days).

The following table summarizes the material testing performed.

Biocompatibility Summary - BriDGE Extracellular Collagen Matrix		
Cytotoxicty ISO Elution Method	ISO 10993-5	Pass – non-toxic
Genotoxicity Mouse Lymphoma Assay	ISO 10993-3	Pass - non-mutagenic
Systemic Toxicity ISO Study in Mice	ISO 10993-11	Pass - non-toxic
Intracutaneous ISO Study in Rabbits	ISO 10993-10	Pass - non-irritant
Sensitization ISO Guinea Pig Maximization	ISO 10993-10	Pass – non-sensitizing
Mouse Peripheral Blood Micronucleus Study	OECD Test No. 474	Pass - no micronuclei in mice
Bacterial Reverse Mutation Study	ISO 10993-3	Pass - non-mutagenic
Rabbit Pyrogen USP Material Mediated	ISO 10993-11	Pass - non-pyrogen

Tensile Strength Testing

A study was conducted to compare the ultimate tensile strength of the BriDGE ECM to the predicate devices: Unite Biomatrix and Oasis Wound Matrix. Samples were rehydrated and pull tested for peak load (N). The tensile strength of the BriDGE ECM was equivalent to the Unite Biomatrix and significantly stronger than the Oasis Wound Matrix samples.

A study was conducted to determine the functional tensile strength characteristics of the fenestrated version of the BriDGE Extracellular Collagen Matrix. Samples were rehydrated and pull tested for peak load (N). The results were compared to the tensile strength data collected for the standard BriDGE Extracellular Collagen Matrix (non-fenestrated). The samples were pulled both vertically and horizontally. The results of the testing showed that the fenestrated

BriDGE ECM samples were comparable to the non-fenestrated BriDGE ECM samples and stronger than the Oasis Wound Matrix non-fenestrated samples.

Suture Pull-Out Testing

The BriDGE ECM was tested to characterize the device in terms of suture pull out resistance. The samples were hydrated and a 4-0 Prolene suture was attached and pull tested for peak load (N). Comparison testing was performed using samples of the predicate devices: Unite Biomatrix and Oasis Wound Dressing. The BriDGE ECM was found to be equivalent to the predicate devices in terms of suture pull-out strength.

Based on the results of the performance bench testing and comparison to predicate devices, Harbor MedTech has demonstrated that the BriDGE Extracellular Collagen Matrix Wound Dressing is equivalent to the predicate devices in terms of performance characteristics and will perform as intended for the application of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Harbor Medtech, Incorporated
% Mr. Jerry Mezger
Chief Executive Officer
4 Jenner, Suite 190
Irvine, California 92618

February 26, 2013

Re: K122502
Trade/Device Name: Bridge Extracellular Collagen Matrix
Regulation Number: Unclassified
Regulation Name: Dressing, Wound Collagen
Regulatory Class: Unclassified
Product Code: KGN
Dated: January 29, 2013
Received: February 25, 2013

Dear Mr. Mezger:

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 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" (21CFR 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

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122502

Device Name: BriDGE Extracellular Collagen Matrix Wound Dressing

Indications for Use:

The Harbor MedTech BriDGE Extracellular Collagen Matrix Wound Dressing is indicated 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
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K122502