K061474 page 1/2

Attachment 26

COLLAMATRIX Inc.

510(k) summary

1. **Date Prepared**

May 8, 2006

JUL - 5 2006

2. **Submitter name and address**

Collamatrix Inc.
2nd floor, N360, RuiGuang Road,
Neihu, Taipei, 114, Taiwan

3. **Contact person**

Name:	Dennis J. N. Seah
Tel:	+ 886 2 7720 9988
Fax:	+ 886 2 7720 9900

4. **Device names**

Propriety name:	CollaWound™ dressing
Common name:	Wound dressing
Classification name:	Collagen wound dressing

5. **Device classification**

Regulatory class: ~~Class II~~ Unclassified
Product code: ~~KME~~ KGN

6. **Device description**

CollaWound™ dressing is a sterile, single use, disposable wound dressing device for the management of exudating wounds. It comprises insoluble fibrous collagen derived from porcine with white to off-white appearance, which forms a layer of thin film by maintaining a moist environment at the wound site.

7. **Intended use**

CollaWound™ dressing will be used for the management of partial and full thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds, first and second degree burns, surgical wounds and superficial injuries.

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COLLAMATRIX Inc.

8. Statement of Substantial equivalence

CollaWound™ dressing is substantially equivalent in material, function, technological characteristics and intended use to predicate collagen-based devices that are previously approved by the agency: ACell UBM Lyophilized wound dressing (K021637), Fortaderm (K011026), SS Matrix (K020732), Collagen topical wound dressing (K030921), Collatek powder (K012990) and Medifil (K910944).

9. Safety

Biocompatibility tests have confirmed that CollaWound™ dressing meets the requirements stated in ISO 10993/G95-1.

10. Conclusion

The product characterization studies and biocompatibility studies show that the CollaWound™ dressing is safe and substantially equivalent to its predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2006

Collamatrix Co., LTD.
% Quality Assurance
Mr. Dennis J. N. Seah, Manager
2nd Floor, No. 360 RuiGang Road
NeiHu District
Taipei
China (Taiwan) 114

Re: K061474
Trade/Device Name: CollaWound™ dressing
Regulation Class: Unclassified
Product Code: KGN
Dated: May 26, 2006
Received: May 30, 2006

Dear Mr. Seah:

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,

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

Enclosure

3 Statement of indications for use

510(k) Number (if known): K061474

Device Name: CollaWound™ dressing

Indications for Use:

CollaWound™ dressing is intended for the management of partial and full-thickness exudating wounds including:

- Pressure ulcers
- Venous ulcers
- Vascular ulcers
- Diabetic ulcers
- Trauma wounds (abrasions, lacerations, skin tears)
- First and second degree burns
- Surgical wounds

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)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K061474