Attachment 18

K090894
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COLLAMATRIX Co. Ltd.

510(k) summary

Summary information

1. **Date Prepared**

March 15, 2009

JUN 25 2009

2. **Submitter name and address**

Collamatrix Inc.
1st floor, No.50-1, Keyan Road, Jhunan Township
Miaoli County, 350, Taiwan

3. **Contact person**

Name:	Dennis J. N. Seah
Tel:	+ 886 2 7711 3299
Fax:	+ 886 2 7711 5299

4. **Device names**

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

5. **Device classification**

Regulatory class:	Class II
Product code:	KGN

6. **Device description**

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COLLAMATRIX Co. Ltd.

CollaWound wound dressing is a sterile, single use, disposable wound dressing comprised of cross-linked porous collagen matrix with yellow to off-yellow appearance and is supplied in sponge configuration. It forms a layer of thin film at the wound site and provides a biodegradable scaffold for the cell invasion and capillary growth.

7. Intended use

CollaWound wound 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, draining wounds and trauma wounds.

8. Statement of Substantial equivalence

CollaWound wound dressing is a collagen wound dressing device similar to predicate collagen-based devices that are previously approved by the agency and allowed for marketing towards the management of wounds.

Predicate devices are listed below

Trade name:	CollaWound dressing (K061474)
Company:	Collamatrix Inc.
Trade name:	Bilayer Matrix Wound Dressing (K021792)
Company:	Integra Lifescience Corporation
Trade name:	AVAGEN Wound Dressing (K022127)
Company:	Integra Lifescience Corporation
Trade name:	Oasis SIS Wound Dressing (K993948)
Company:	COOK Biotech

The proposed device, CollaWound wound dressing, is another collagen wound dressing that is quite similar with respect to the indication for use, technological characteristics and material to the above devices in terms of the substantial equivalency under the 510(k) regulations.

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9. Safety

Biocompatibility tests have confirmed that CollaWound wound dressing meets the requirements stated in the FDA Blue book memorandum G95-1 and ISO 10993.

10. Conclusion

CollaWound wound dressing is essentially equivalent in indication for use, technological characteristics and material to the commercially available predicate devices, and therefore meets the requirements as defined in 21 CFR § 807.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2009

Collamatrix Co., Inc.
% Mr. Dennis J.N. Seah
Manager
26F, No. 105, Section 2
DunHua South Road
Daan district, Taipei 106
Taiwan

Re: K090894
Trade/Device Name: CollaWound wound dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 25, 2009
Received: March 31, 2009

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 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/cdrh/mdr/ 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 (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 Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090894

3 Statement of indications for use

Device Name: To be determined

Indications for Use:

CollaWound wound dressing is intended for the management of wounds including:

- partial and full-thickness wounds
- diabetic ulcers
- venous ulcers
- pressure ulcers
- chronic vascular ulcers
- tunneled/undermined wounds
- surgical wounds (donor site/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- trauma wounds (abrasions, lacerations, secondary-degree burns, and skin tears)
- draining wounds

Prescription Use____X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090894