Attachment 2

K071557

page 1/2

COLLAMATRIX Inc.

510(k) summary

1. **Date Prepared**

   January 28, 2008

2. **Submitter name and address**

   Collamatrix Inc.

   26th F, 105, section 2, DunHua South Road, Da-an District, Taipei, 106, Taiwan

3. **Contact person**

Name:	Dennis J. N. Seah
Tel:	+ 886 2 7711 3299
Fax:	+ 886 2 7711 3599

4. **Device names**

Propriety name:	CollaWound™ Hydrogel
Common name:	Collagen hydrogel wound dressing
Classification name:	Dressing, wound and burn, hydrogel w/drug and/or biologic

5. **Device classification**

Regulatory class:	Unclassified
Product code:	~~MGQ~~ FRO

6. **Device description**

   CollaWound™ Hydrogel is a collagen-based emulsion/liquid formulation comprising collagen derived from porcine hides. It is intended for the management of partial and full thickness wounds, pressure ulcers, diabetic ulcers, venous ulcers, surgical wounds, first and second degree burns, superficial injuries, cuts and abrasions.

7. **Intended use**

   CollaWound™ Hydrogel is intended for the management of partial and full thickness wounds, pressure ulcers, diabetic ulcers, venous ulcers, surgical wounds, first and second degree burns, superficial injuries, cuts and abrasions.

26F, 105, Section 2 DunHua South Road., Da-an, Taipei 106, Taiwan
Tel: +886 2 7711 3299 Fax: +886 2 7711 3599

COLLAMATRIX Inc.

8. **Statement of Substantial equivalence**

   CollaWound™ Hydrogel is substantially equivalent in material, function, technological characteristics and intended use to its predicate.

9. **Safety**

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

10. **Conclusion**

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

26F, 105, Section 2 DunHua South Road., Da-an, Taipei 106, Taiwan
Tel: +886 2 7711 3299 Fax: +886 2 7711 3599

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2008

Collamatrix Co., Inc.
% Mr. Dennis J.N. Seah
Quality Assurance
No. 360 Ruiguang Road, 2nd Floor
Neihu District, Taipei
Taiwan

Re: K071557
Trade/Device Name: Collawound Hydrogel
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 3, 2008
Received: February 5, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

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

Enclosure

Attachment 7 K071557

3 Statement of indications for use

CollaWound™ Hydrogel is intended for the management of:

- Partial and full thickness wounds
- Pressure ulcers, diabetic ulcers, venous ulcers
- Surgical wounds
- First and second degree burns
- Superficial injuries, cuts, abrasions

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)

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

510(k) Number K071557

2/7/08