K080868 page 1/2

510(k) Summary

MAY 14 2009

Submitter Name and Address:

Aeon Astron Europe B.V.
Niels Bohrweg 11-13, 2333 CA Leiden,
The Netherlands

Contact Person:

Horng Ji Lai
C.E.O.
Tel : +31.71.332.2280
Fax : +31.71.332.2281

Date Prepared:

February 18, 2008

Device Information:

Proprietary Name:	Aongen™ Collagen Matrix
Common Name:	Wound dressing
Classification Name:	Dressing, wound, collagen
Product Code:	KGN
Device Class:	Unclassified
Review Panel:	General & plastic surgery

Predicate Device:

Predicate #1

Proprietary Name:	ACell™ Powder Wound Dressing
Common Name:	Topical Wound Dressing
Product Code:	KGN
510(k) Number:	K060888
510(k) Submitter:	ACell, Incorporated

Predicate #2

Proprietary Name:	To be determined
Common Name:	Collagen Topical Wound Dressing
Product Code:	KGN

510(k) Number:	K030921
510(k) Submitter:	Collagen Matrix, Inc.

Predicate #3

Proprietary Name:	To be determined
Common Name:	Collagen Topical Wound Dressing – Oral
Product Code:	KGN
510(k) Number:	K040403
510(k) Submitter:	Collagen Matrix, Inc.

Device Description:

The Aongen™ Collagen Matrix is a biodegradable material composed of collagen. It is indicated for the management of wounds. The device is supplied sterile and for single use only.

Indications for Use:

The Aongen™ Collagen Matrix is intended for the management of wounds including:

- surgical wounds
- trauma wounds
- draining wounds
- second degree burns
- partial and full-thickness wounds
- pressure ulcers
- venous ulcers
- vascular ulcers
- diabetic ulcers
- oral wounds and sores

Summary of Tests:

Tests were conducted to evaluate the biocompatibility of the Aongen™ Collagen Matrix. The results of these tests demonstrate that the Aongen™ Collagen Matrix meets the requirements of ISO 10993.

Conclusion of Tests:

The results of the product characterization studies and biocompatibility studies demonstrate that the Aongen™ Collagen Matrix is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2009

Aeon Astron Europe B.V.
% Horng Ji Lai
C.E.O.
Niels Bohrweg 11-13
Leiden 2333 CA
The Netherlands

Re: K080868
Trade/Device Name: Aongen™ Collagen Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: April 27, 2009
Received: May 1, 2009

Dear Horng Ji Lai:

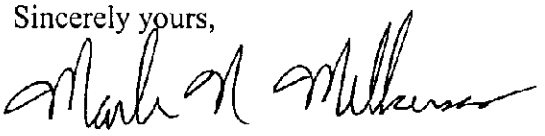
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080868

Indications for Use

510(k) Number (if known): K080868

Device Name: Aongen™ Collagen Matrix

Indications for Use:

The Aongen™ Collagen Matrix is intended for the management of wounds including:

- surgical wounds
- trauma wounds
- draining wounds
- second degree burns
- partial and full-thickness wounds
- pressure ulcers
- venous ulcers
- vascular ulcers
- diabetic ulcers
- oral wounds and sores

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K080868