March 2, 2018

Aeon Astron Europe B.V.
Horng Lai
C.E.O.
J.H. Oortweg 19
Leiden, 2333 CH Nl

Re: K173223
Trade/Device Name: ologen Collagen Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: January 25, 2018
Received: February 2, 2018

Dear Horng 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 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173223

Device Name
ologen™ Collagen Matrix

Indications for Use *(Describe)*
ologen™ 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.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared: January, 29, 2018

The 510(k) owner
Aeon Astron Europe B.V.
J.H. Oortweg 19, 2333 CH, Leiden, The Netherlands
Contact Person:
Horng Ji Lai, C.E.O.
Tel: +31.71.332.2280
Fax: +31.71.332.2281
E-mail: michael.lai@aeonastron.com

Device Information
Proprietary Name: ologen™ Collagen Matrix
Common name: Wound dressing
Classification Name: Dressing, wound, collagen
Product Code: KGN
Device Class: Unclassified
Review Panel: General & plastic surgery
510(k) Number: K173223

Predicate Device
Proprietary Name: Aongen™ Collagen Matrix; ologen™ Collagen Matrix
Common name: Wound dressing
Classification Name: Dressing, wound, collagen
Product Code: KGN
Device Class: Unclassified
Review Panel: General & plastic surgery
510(k) Number: K080868
510(k) Submitter: Aeon Astron Europe B.V.

Device Description
Device Identification:
ologen™ Collagen Matrix (K173223) proposed device has 9 models which differ in sizes and shapes but with the same composition. Different specifications are all intended for wound dressing. Which specification should be applied is determined by the physician according to the size, depth, location, type of wound and his/hers preference. The lists the specifications and shapes of all 9 models refer to Instruction for Use.

Device Characteristics

■ single-use

■ sterile

Environment of Use:

■ healthcare facility/hospital

Description of the Device:

ologen™ Collagen Matrix is a biodegradable material composed of collagen. It is indicated for the management of wounds. ologen™ Collagen Matrix is obtained from porcine hide and the matrix structure has a porous configuration made of ≥90% cross-linked lyophilized porcine collagen and ≤10% glycosaminoglycans (GAG).

This device is sterile (gamma sterilization) and for single use only. ologen™ Collagen Matrix should only be opened under sterile conditions and handled using standard aseptic techniques.

Materials of Use

■ General type of material used : porcine collagen

Indications for Use

ologen™ 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.

Comparison of Technological Characteristics with The Predicate Device

ologen™ Collagen Matrix and the predicate devices are intended for the same use in wound management. The fundamental technology of both devices is using porcine collagen, a biocompatible and biodegradable material. Predicate device has the same intended use as the new device.

All the techniques and chemicals used in the production have not changed. Please note that the water purification system, which was not shown in the new flow chart, was the same as the previous flow chart displayed. All the water used during the manufacturing was processed through the same procedures.

The following technological differences exist between the subject and predicate devices:
*ologen™ Collagen Matrix in “Precipitation” step, pH value was adjusted from 7.0 to 5.8. This manufacturing improvement was the only step that the pH value was changed.
*ologen™ Collagen Matrix used molding to take shape of the final form whereas the previous manufacturing used laser-cutting (Trimming) after freeze-dry.
*ologen™ Collagen Matrix used new labeling.

Performance Data

Product characteristics tests and biocompatibility tests of ologen™ Collagen Matrix were performed. The biocompatibility evaluation for the ologen™ Collagen Matrix was conducted in accordance with the FDA Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff. Document issued on: June 16, 2016 as recognized by FDA. The Product Characteristics testing included the following tests:

Product Characteristics tests:

Hydroxyproline assay

pH value test

Stability test

Hydroxyproline assay

This test was performed for detect the concentration of collagen concentration. The result showed that the device met our acceptance criterion of total protein concentration >90% collagen same as predicate device.

pH value test

pH value test was performed for semi-product inspection. The result showed that the device met our acceptance criterion of pH value 7.0±0.5. Please note that semi-product is the unsterilized final product.

Stability test

The stability test was performed by placing samples at real time aging stability temperature limitation storage conditions (40 $\pm$ 2 °C). For the real time aging stability test, the quantity of samples was randomly withdrawn for inspection at 3 time points: 0, 6 and 36 months. The results of microstructure, optical, pH value, water absorption ratio and sterility tests were recorded to determine whether the acceptability criteria were met. The results of both real time aging stability test showed that, there were no significant difference between samples, which were stored under 40 $\pm$ 2 °C.

Biocompatibility tests & Animal Study

Pyrogen Test Collagen matrix

Implantation Study in Rabbits-Muscle-12 weeks Collagen Matrix

Hemolytic Properties Study Collagen Matrix

Cytotoxicity study for biocompatibility Collagen Matrix

Acute Systemic toxicity study in Mice Collagen Matrix

Skin sensitization

Skin irritation (Intradermal reaction)

Subchronic Systemic Toxicity

Pyrogen test Collagen matrix

The pyrogen test was performed in accordance with the USP35 – NF30 (2012), Biological Tests: <151> PYROGEN TEST. Based on the finding of the test, it was concluded that the proposed device was non-pyrogenic.

Implantation Study in Rabbits-Muscle-12 weeks Collagen Matrix

This test was conducted in accordance with ISO 10993-6. After 12-week of implantation, the device was degraded and the histopathological evaluation of the implantation site showed no irratation reaction was observed.

Hemolytic Properties Study Collagen Matrix

This test was conducted in accordance with ISO 10993-4. ologen™ Collagen Matrix extract had non-hemolytic potential in rabbit blood *in vitro.*

Cytotoxicity study for biocompatibility Collagen Matrix

This test was conducted in accordance with ISO 10993-5. ologen™ Collagen Matrix had no cytotoxic effect on L929 cells under the testing condition employed.

Acute Systemic toxicity study in Mice Collagen Matrix

This test was conducted in accordance with ISO 10993-11. ologen™ Collagen Matrix had no significant evidences of systemic toxicity from the test article extracts injected into ICR mice. All data generated from this study will provide as safety information for human exposure.

Skin Sensitization Study Guinea Pig Maximization Test Collagen Matrix

This test was conducted in accordance with ISO 10993-10. The sensitization rate in each group was calculated and determined. Collagen Matrix, was classified as a non-sensitizer.

Skin irritation (Intradermal reaction)

This test was conducted in accordance with ISO 10993-10. The irritation rate in each group was calculated and determined. Collagen Matrix, was classified as a non-irritative.

Subchronic Systemic Toxicity

This test was conducted in accordance with ISO 10993-11. The test sample exhibited no subchronic systemic toxicity.

Summary

Based on the Biocompatibility tests & Animal Study, the ologen™ Collagen Matrix was found to have a safety and effectiveness profile that is similar to the predicate device.

Conclusions

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