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510(k) Summary

MAR - 1 2012

Submitter Name and Address:

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

Contact Person:

Horng Ji Lai
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Tel: +31-71-3322280
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Date Prepared:

February 23, 2012

Device Information:

Proprietary Name:	Aongen™ Dental Collagen Matrix
Product Code:	MGQ
Device Class:	Unclassified
Review Panel:	General & Plastic Surgery

Predicate Device:

Predicate #1

Proprietary Name:	OTA Collagen Biomaterial
Common Name:	Collagen dental membrane
Product Code:	NPL
510(k) Number:	K073685
510(k) Submitter:	Osseous Technologies of America, Inc.

Predicate #2

Proprietary Name:	Integra Meshed Bilayer Wound Matrix
Common Name:	N/A
Product Code:	FRO
510(k) Number:	K081635
510(k) Submitter:	Integra Lifesciences Corp.

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Device Description:

Aongen™ Dental Collagen Matrix is a white, resorbable matrix manufactured from porcine type I collagen and glycosaminoglycan. The function of glycosaminoglycan is water absorption. The device is supplied sterile and for single use only. Aongen™ Dental Collagen Matrix functions in a manner similar to the predicates.

Indications for Use:

Aongen™ Dental is intended for use in dental surgical procedures as a resorbable material for open wounds to aid in wound healing post surgery.

Summary of Tests:

Tests were conducted to evaluate the biocompatibility and performance of Aongen™ Dental Collagen Matrix. The results of these tests demonstrate that Aongen™ Dental Collagen Matrix is safe and biocompatible.

Biocompatibility Tests	Result
Agar Diffusion Test	Non-cytotoxic
Salmonella Typhimurium and *Escherichia Coli* Reverse Mutation Assay	Not mutagenic
Rodent Bone Marrow Micronucleus Assay	Non-clastogenic
Hemolysis – Rabbit Blood	Non-hemolytic
Intramuscular Implantation Test	No local toxic effects after implantation
Intracutaneous Injection Test	Negligible irritant
Kligman Maximization Test	No sensitization
Rabbit Pyrogen Test	Non-pyrogenic
Systemic Injection Test	No toxic effects
Heavy Metal Test	Within acceptance level
Sterility Test	Sterile
LAL Test	<0.5 EU/mL

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Comparison with the Predicates:

Device Name	Aongen™ Dental Collagen Matrix	Integra Meshed Bilayer Wound Matrix
Submitter	Aeon Astron Europe B.V.	Integra Lifesciences Corp.
510(k) No.		K081635
Similarities	Both devices are comprised of a Collagen-GAG matrix which creates a suitable environment for wound healing process.	
Differences	Integra Meshed Bilayer Wound Matrix has an extra layer of temporary semi-permeable silicone membrane.	

Device Name	Aongen™ Dental Collagen Matrix	OTA Collagen Biomaterial
Submitter	Aeon Astron Europe B.V.	Osseous Technologies of America, Inc.
510(k) No.		K073685
Similarities	Both devices are applied as an onlay to cover wound defects.	
Differences	The source of collagen is different in these two devices. Aongen™ Dental Collagen Matrix is sourced from porcine, and OTA Collagen Biomaterial is sourced from bovine.	

Conclusion of Tests:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 1 2012

Mr. Horng Ji Lai
CEO
Aeon Astron Europe B.V.
Niels Bohrweg 11-13
Leiden
NETHERLANDS 2333 CA

Re: K112568
Trade/Device Name: Aongen™ Dental Collagen Matrix
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MQN
Dated: February 23, 2012
Received: February 27, 2012

Dear Mr. 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.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: Aongen™ Dental Collagen Matrix

Indications for Use:

Aongen™ Dental is intended for use in dental surgical procedures as a resorbable material for open wounds to aid in wound healing post surgery.

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)

Susan Runner

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital

Infection Control, Dental Devices

510(k) Number: K112568