DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JAN 10 2017

Aesthetic and Reconstructive Technologies, Inc.
% Ms. Catherine Riple
5871 Lone Pine Place
Paso Robles, California 93446

Re: K021337
Trade/Device Name: AART Pectoralis Implant
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose and Throat synthetic polymer material
Regulatory Class: Class II
Product Code: MIC
Dated: April 15, 2002
Received: April 26, 2002

Dear Ms. Riple:

This letter corrects our substantially equivalent letter of July 3 2002.

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 Parts 801 and 809); 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 Parts 801 and 809), please contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

AMENDMENT 1

510(k) NUMBER (IF KNOWN): K021337

DEVICE NAME: AART Pectoralis Implant

INDICATIONS FOR USE:

The intended use for the AART Pectoralis Implant is augmentation of the chest to add definition to the pectoralis muscle by placing submuscular. It may also be used for reconstruction of the pectoralis depression caused by Poland's Syndrome (congenitally absent pectoralis muscle).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-9)

MRO for cmw
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021337

K021337

JUL 3 2002

ATTACHMENT 5

510(k) Summary

April 15,2002

Contact Information: Aesthetic and Reconstructive Technologies, Inc. (AART)
3545 Airway Drive, Suite 108
Reno, NV 89511
(775) 853-6800 / FAX (775) 853-6805
Winston A. Andrews

Proprietary Name: AART Pectoralis Implant
Common Name: Silicone Elastomer Pectoralis Implant
Classification Name: Implant, Muscle, Pectoralis

Substantial Equivalence: The AART Pectoralis Implant is substantially equivalent in function, design, performance and materials to the Pectoralis Implant marketed by Allied Biomedical Corporation of Ventura, CA and the Seare Biomedical Pectoralis Implant marketed by Seare Biomedical Corp. of Salt Lake City, Utah.

Device Description: The AART Pectoralis Implants are manufactured from a medical grade silicone elastomer that has been molded into various convex oval shapes. They are provided in three styles, each with a right and left mirror image. Dimensions of the implants will range from 14.4 cm to 17.6 cm in length with widths from 10.0 cm to 13.5 cm and projection (height) from 1.6 cm to 3.2 cm. The AART Pectoralis Implants are intended to be used for augmentation of the chest by placing the implant submuscular of the pectoralis muscle. They can also be used to reconstruct the pectoralis depression caused by Poland's Syndrome (congenitally absent pectoralis muscle). The surface characteristic of the implants is smooth. The AART Pectoralis Implants will be offered non-sterile.

Intended Use: The intended use for the AART Pectoralis Implant is augmentation of the chest to add definition to the pectoralis muscle by placing submuscular. It may also be used for reconstruction of the pectoralis depression caused by Poland's Syndrome (congenitally absent pectoralis muscle).

Predicate Device: The AART Pectoralis Implant is substantially equivalent in material, design, function, and performance to the Pectoralis Implant marketed by Allied Biomedical Corp. and the Pectoralis Implant marketed by ~~Seare Biomedical Corp.~~ All products have identical intended uses and are offered in similar shapes and sizes.