JUL 16 2002

ATTACHMENT 7

510(k) Summary K02 1839

May 31, 2002

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

Contact Person: Catherine Riple
Consultant for AART, Inc.
(805) 239-1059

Proprietary Name: AART Gluteal Implant
Common Name: Silicone Carving Block
Classification Name: Elastomer, Silicone Block

Substantial Equivalence: The AART Gluteal Implant (Silicone Carving Block) is substantially equivalent in function, design, performance and materials to the Silimed Gluteal Implant marketed by Silimed LLC.

Device Description: The AART Gluteal Implants (Silicone Carving Blocks) are manufactured from a medical grade silicone elastomer that has been molded into various convex oval or round shapes. They are provided in four styles with dimensions varying in length, width, height and initial shape. The AART Gluteal Implant (Silicone Carving Block) is intended to be used for augmentation and reconstructive surgery where additional shaping by the surgeon may be necessary.

Intended Use: The intended use for the AART Gluteal Implant (Silicone Carving Block) is for augmentation and reconstructive surgery where additional shaping by the surgeon may be necessary. It may be used in body contouring to minimize muscular defects.

Predicate Device: The AART Gluteal Implant (Silicone Carving Block) is substantially equivalent in material, design, function, and performance to the Silimed Gluteal Implant marketed by Silimed LLC. of Crofton, MD. All products have identical intended uses and are offered in similar shapes and sizes.

Packaging: The AART Gluteal Implant (Silicone Carving Block) will be offered non-sterile. The implants will be individually packaged in an autoclavable peel pouch and labeled on the plastic side with appropriate identification for traceability. They will then be boxed in a SSB chipboard box along with a package insert and labeled for inventory and shipment.

Sterilization: The AART Gluteal Implants (Silicone Carving Blocks) are offered non-sterile. Recommended autoclave cycles are stated in the Package Insert which is included with each product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2002

Aesthetic and Reconstructive Technologies, Inc.
c/o Ms. Catherine Riple
3545 Airway Drive, Suite 108
Reno, Nevada 89511

Re: K021839
Trade Name: AART Gluteal Implant
Regulation Number: 874.3620
Regulation Name: Ear, nose and throat synthetic polymer material
Regulatory Class: II
Product Code: MIB
Dated: May 31, 2002
Received: June 4, 2002

Dear Ms. Riple:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 1

AART Gluteal Implant (Silicone Carving Block)

510(k) NUMBER (IF KNOWN): K021839

DEVICE NAME: _____

INDICATIONS FOR USE:

The intended use of the AART Gluteal Implant (Silicone Carving Block) is for augmentation and reconstructive surgery where additional shaping by the surgeon may be necessary. It may be used in body contouring to minimize muscular defects.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number K021839