K022223

AUG 0 8 2002

ATTACHMENT 7

510(k) Summary

July 2, 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 Silicone Sheeting
Common Name: Silicone Carving Block
Classification Name: Elastomer, Silicone Block

Substantial Equivalence: The AART Silicone Sheeting is substantially equivalent in function, design, performance and materials to the Seare Biomedical Silicone Sheeting marketed by Seare Biomedical Corporation of Salt Lake City, Utah.

Device Description: The AART Silicone Sheeting is manufactured from a medical grade silicone elastomer intended for long term implantation. The sheeting will be provided reinforced or non-reinforced in three sizes of varying thicknesses. The AART Silicone Sheeting is intended to be used for various surgical and non-surgical applications and may be trimmed by scalpel or scissors where additional shaping by the surgeon may be necessary.

Intended Use: The intended use for the AART Silicone Sheeting is for various surgical and non-surgical applications. The silicone sheeting is intended for short term and long term applications.

Predicate Device: The AART Silicone Sheeting is substantially equivalent in material, design, function, and performance to the Seare Biomedical Silicone Sheeting marketed by Seare Biomedical Corporation of Salt Lake City, Utah. All products have virtually identical intended uses and are offered in similar sizes, thicknesses, and options of reinforcement or non-reinforcement.

Packaging: The AART Silicone Sheeting will be offered sterile. The sheeting will be packaged individually in a double Tyvek® pouch configuration. One size of sheeting will be offered both individually or in boxes of ten. Once sterilized the individual sheeting will then be packaged in a protective plastic bag along with a package insert for inventory and shipping. Sheeting sold in boxes of ten wil be boxed after sterilization along with a package insert.

Sterilization: The AART Silicone Sheeting is offered sterile. Sheeting will be sterilized by Gamma Radiation. The radiation dose level will be a minimum of 25kGy or as determined by the validation studies. The sterility assurance level (SAL) for the AART Silicone Sheeting will be 10^{-6}.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 8 2002

Aesthetic and Reconstructive Technologies, Inc.
c/o Catherine Riple
5871 Lone Pine Place
Paso Robles, California 93446

Re: K022223
Trade/Device Name: AART Silicone Sheeting
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, and Throat
Synthetic Polymer Material
Regulatory Class: Class II
Product Code: MIB
Dated: July 2, 2002
Received: July 9, 2002

Dear Ms. Riple:

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.

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" (21 CFR 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

510(k) NUMBER (IF KNOWN): K022223

DEVICE NAME: AART Silicone Sheeting

INDICATIONS FOR USE:

The AART Silicone Sheeting has a variety of intended uses. The silicone sheeting is intended for short term and long term applications.

Short term indications for use:

- Nasal splinting
- Wound dressing
- Management of keloid or hypertrophic scarring
- Temporary use in TMJ disease
- Temporary joint shims
- Laboratory uses

Long term indications for use:

- Nasal septal repair
- Orbital floor reconstruction
- Tympanic membrane repair
- Dialysis shunt anchoring
- Durameter repair
- Staged repair of omphalocoel
- Lengthening of extraocular muscles
- As a protective sheathing to help facilitate neural regeneration and tendon anastomosis
- As a protective sheathing to help facilitate osteogenesis
- Other uses deemed appropriate by the using surgeon

Caution: The American Academy of Oral Maxillofacial Surgeons recommends against the use of silicone products for permanent treatment of Temporo Mandibular Joint Disease.

(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 1-2-96)

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

510(k) Number K022223