510(k) Summary
for the SurgiSil™
Perma Facial Implants

SEP 19 2007

1. SUBMITTER/510(K) HOLDER

SurgiSil™
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Date Prepared: September 10, 2007

2. DEVICE NAME

Proprietary Name: Perma Facial Implants
Common/Usual Name: Silicone block
Classification Name: Ear, nose, and throat synthetic polymer material

3. PREDICATE DEVICES

- Spectrum Designs Pre-Form Contour Silicone Carving Block, Spectrum Designs (K982688)
- AART Silicone Carving Block, Aesthetic and Reconstructive Technologies, Inc. (K021820)
- Seare Biomedical Silicone Sheeting, Seare Biomedical Corporation (K983041)
- AART Silicone Sheeting, Aesthetic and Reconstructive Technologies, Inc. (K022223)

4. DEVICE DESCRIPTION

The SurgiSil™ Perma Facial Implants are injection-molded (pre-formed) silicone implants with a hardness of 40 on the shore "00" scale. The SurgiSil™ Perma Facial Implants have a cylindrical shape with tapered ends. The implants will be provided in various sizes, with diameters of 2-6 mm and lengths of 50-75 mm.

The Perma Facial Implants are individually packaged and sterilized by gamma irradiation and are labeled for single use.

The Perma Facial Implants are designed with tapered ends to reduce visibility of the implant ends following implantation. The smooth surface of the implant prevents tissue ingrowth permitting easy removal and/or exchange of the implant. The Perma Facial Implants are ideal for use in soft tissue augmentation anywhere in the face where, in the physician's experience, use of a soft silicone elastomer is appropriate.

5. INTENDED USE

The Perma Facial Implants are solid silicone implants that are intended for use in plastic and reconstructive surgery. The devices can be used for cosmetic augmentation and corrections in the face, including areas such as the nose, chin, and cheeks.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Perma Facial Implants and the predicate devices are manufactured from medical grade silicone elastomer and are indicated for implantation in the facial region for various surgical applications. Differences between the proposed Perma Facial Implants and the predicate silicone implants are limited to design differences, including the range of sizes and shapes available. Testing was conducted that confirms that the Perma Facial Implants are biocompatible and safe for the intended use.

The similarities in intended use and material composition between the proposed Perma Facial Implants and the predicate Spectrum Designs Pre-Form Contour Silicone Carving Block, AART Silicone Carving Block, Seare Biomedical Silicone Sheeting, and AART Silicone Sheeting, leads to a conclusion of substantial equivalence between the proposed and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Surgisil
% Medical Device Consultants, Inc.
Cynthia J.M. Nolte, Ph.D., RAC
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49 Plain Street
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Re: K071823
Trade/Device Name: Perma Facial Implants
Regulation Number: 21 CFR 878.3500
Regulation Name: Polytetrafluoroethylene with carbon fibers composite implant material
Regulatory Class: II
Product Code: ODU
Dated: August 28, 2007
Received: August 29, 2007

Dear Dr. Nolte:

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K071823

Device Name: Perma Facial Implants

Indications for Use:

The Perma Facial Implants are solid silicone implants that are intended for use in plastic and reconstructive surgery. The devices can be used for cosmetic augmentation and corrections in the face, including areas such as the nose, chin, and cheeks.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K071823