K971479

Allied Biomedical Corporation
3850 Ramada Drive
Paso Robles, CA 93446

JUL 18 1997

TAB H

510(k) SUMMARY

PRODUCT DESCRIPTION

Duralastic Malar implants are crescent shaped concave convex silicone elastomer rubber implants made from specially formulated silicone elastomers designed for implantation. They are manufactured in pairs with a mirror image left and right. The LSR 30 Implant Grade elastomer is Masterfiled at FDA and has been thoroughly tested for biocompatibility, mutagenicity, carcinogenicity, and cytotoxicity. These referenced material characterizations are found in Applied Silicone's Master File MAF-562. The Duralastic Malar Implants will be provided sterile and nonsterile.

SUBSTANTIAL EQUIVALENCE

Under it original 510(k) K952707, Duralastic Malar implants were found SE to the Applied Biomedical malar implants. In fact the very same molds and materials used to produce the Duralastic Malar implants in the sterile form, because these molds were sold to Allied and Allied has not changed raw material suppliers.

INTENDED USE

Duralastic Malr implants are intended for use in augmentation and reconstruction of the cheek. They are intended for insertion via an intraoral or cilliary incision.

PHYSICAL AND CHEMICAL PROPERTIES

The Duralastic Malar implants are manufactured from Applied Silicone's LSR-30 part # 40029 which is a platinum cured dimethyl polysiloxane system. All chemical characterizations are found in Applied Masterfile MAF-562.

The physical properties are: Durometer 30 Shore A, Elongation 650%, Tensile Strength 950 PSI, tear strength Tear Die C 150 PSI, Specific Gravity 1.12, Modulus 300 PSI at 200% Elongation, Surface Smooth and Textured.

STERILIZATION CYCLE

Duralastic Malar Implants are sterilized via gamma radiation cycles of 2.5 - 4.2 Megarads. The validation of this cycle was designed and performed by STI of Brea, California. Sterigenics Corporation is the contract gamma sterilizer. The validation used Method i Testing as defined in the ANSI/AAMI/ISO 1137-1994 "Sterilization of

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gerald Hanson
Regulatory Affairs
Allied Biomedical Corporation
3850 Ramada Drive
Paso Robles, California 93446

JUL 18 1997

Re: K971478
Trade Name: Duralastic Anatomical Chin Implants
Product Code: FWP

K971479
Trade Name: Duralastic Anatomical Malar Implants
Product Code: LZK

K971481
Trade Name: Duralastic Anatomical Nasal Implants
Product Code: ESR

Regulatory Class: II
Dated: April 15, 1997
Received: April 23, 1997

Dear Mr. Hanson:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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). You may, therefore, market the devices, 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.

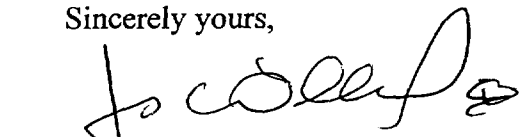
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the

current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

Enclosure

510(k) Number K971479

Device Name: Duralastic Anatomical Malar Implants

Indications For Use:

The Duralastic Anatomical Chin Implants are intended to be used to augment or reconstruct the maxilla for cosmetic or reconstructive surgery.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971479

Prescription Use X OR Over-The Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)