

Allied Biomedical Corporation  
3850 Ramada Drive  
Paso Robles, CA 93446

K97/481

JUL 18 1997

TAB H

## 510(k) SUMMARY

### PRODUCT DESCRIPTION

Duralastic Nasal implants are "L" shaped or straight with concave convex dorsal aspect which reached from the alar cartilage to the radix. These silicone elastomer rubber implants are made from specially formulated silicone elastomers designed for implantation. 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 Nasal Implants will be provided sterile and nonsterile. Several biocompatible pigments are used to make the white and flesh tone versions of these implants.

### SUBSTANTIAL EQUIVALENCE

Under its original 510(k) K952705, Duralastic Nasal implants were found SE to the Applied Biomedical nasal implants. In fact the very same molds and materials are used to produce the Duralastic nasal implants in the sterile form, because these molds were sold to Allied and Allied has not changed raw material suppliers.

### INTENDED USE

Duralastic Nasal implants are intended for use in augmentation and reconstruction of the nasal contour during rhinoplasty. They are intended for insertion via an intraoral or nasal sill incision.

### PHYSICAL AND CHEMICAL PROPERTIES

The Duralastic Nasal 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. Titanium Oxide and Iron Oxide pigments are added to these implants when ordered by the physician. These pigments are tested for cytotoxicity.

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 Nasal Implants are sterilized via gamma radiation cycles of 2.5 - 4.2 Megarads. The validation of this cycle was designed

510(k) Summary Continued

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 Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization."



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.

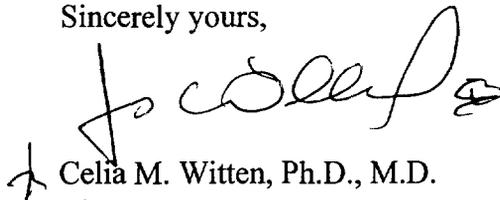
If your devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and a small "M" and "W".

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 K971481

Device Name: Duralastic Anatomical Nasal Implants

Indications For Use:

The Duralastic Anatomical Nasal Implants are intended to be used to augment or reconstruct the nasal bridge and nasal profile for cosmetic or reconstructive surgery.

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)

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