

6973574

OCT 24 1997

Hanson Medical Inc.
19325 58th PL NE
Seattle WA 98155
(425) 481 2185
510(k) Submission
Malar Implants

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 its 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 Malar implants are intended for use in augmentation and reconstruction of the cheek. They are intended for insertion via an intraoral or ciliary incision.

PHYSICAL AND CHEMICAL PROPERTIES

The Duralastic Malar implants are manufactured from Applied Silicone's LSR-30 part # 40029 and Nusil Technologies' MED 4211 MAF 612 which are platinum cured dimethyl polysiloxane systems. All chemical characterizations are found in Applied Masterfile MAF-562 and Nusil's MAF 612

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.

TAB H Continued

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 Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization. SAL 10 to the minus 6th.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 1997

Ms. Kathy Hanson Richardson
Regulatory Affairs
Hanson Medical Inc.
19325 58th Place NE
Seattle, Washington 98155

Re: K973574
Trade Name: Duralastic Anatomical Malar Implants
Regulatory Class: II
Product Code: LZK
Dated: September 15, 1997
Received: September 19, 1997

Dear Ms. Richardson:

We have reviewed your Section 510(k) 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). 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.

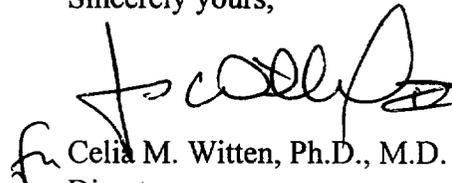
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission 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.

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This letter will allow you to begin marketing your device as described in your 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 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 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 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

INTENDED USE FORM

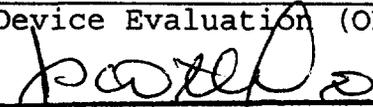
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510(k) Number - ~~N/A~~ K973574

Device Name: Silicone Elastomer Malar Implant

Indications For Use: To augment or reconstruct the malar cheek contour or the maxillary Zygoma.

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K973574

Precription Use
(Per 21 CFR 801.109)

OR

Over The Counter Use
(Optional Format 1-2-96)