K973573

NOV 13 1997

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

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 catilage 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 and Nusil Technologies's MAF 612 for their MED 4211 Silicone Rubber -Unrestricted. 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

Duralastic Nasal Implants are SE to Allied Biomedical Nasal Implants, K971481. They will be produced in the exact sizes and shapes as the Allied Predicate device.

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 proposed Duralastic Nasal Implants will also be manufactured utilizing Nusil Technologies' MED 4211 Unrestricted Silicone Rubber Masterfiled at FDA under Nusil 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.

STERILIZATION CYCLE

Duralastic Nasal Implants are sterilized via gamma radiation cycles of 2.5 - 4.2 Megarads. The validation of this cycle will be designed and validated by a private contractor. Sterigenics Corporation will be the contract gamma sterilizer. The validation will use Method 1 Testing as defined in the ANSI/AAMI/ISO 1137-1994 "Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization."
In the event the products are shipped nonsterile a validated heat cycle will be recommended to the user.

PACKAGE DESCRIPTION

The proposed Duralastic Nasal Implants will be double peel pouched in Tyvec pouches and provided sterile and non sterile. These pouches will be in turned packaged in corrugated boxes for shipping.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

NOV 13 1997

Re: K973573
Trade Name: Duralastic Anatomical Nasal Implants
Regulatory Class: II
Product Code: ESR
Dated: September 15, 1997
Received: September 19, 1997

Dear Ms. Richardson:

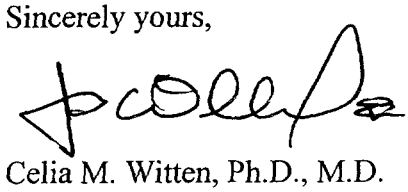
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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

510(k) Number - K973573

Device Name: Silicone Elastomer Nasal Implant

Indications For Use: To augment or reconstruct the nasal contour

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973573

Presecription Use X (Per 21 CFR 801.109) OR Over The Counter Use (Optional Format 1-2-96)