K971572

NOV - 7 1997

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

TAB H

510(k) SUMMARY

PRODUCT DESCRIPTION

Duralastic Chin implants are crescent shaped concave convex silicone elastomer rubber implants 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' MAF 612. The Duralastic Chin Implants will be provided sterile and nonsterile.

SUBSTANTIAL EQUIVALENCE

Duralastic Chin implants are SE to the Allied Biomedical chin implants K971478. They are soft solid silicone implant grade cresent shaped implants in various sizes and styles.

INTENDED USE

Duralastic Chin implants are intended for use in augmentation and reconstruction of the chin. They are intended for insertion via an intraoral or submental incision.

PHYSICAL AND CHEMICAL PROPERTIES

The Duralastic Chin 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 and in Nusil Technologies 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 Chin Implants will be 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gerald Hanson
Regulatory Affairs
Hanson Medical Inc.
19325 58th Place NE
Seattle, Washington 98155

NOV - 7 1997

Re: K973575
Trade Name: Duralastic Anatomical Chin Implant
Regulatory Class: II
Product Code: FWP
Dated: September 18, 1997
Received: September 19, 1997

Dear Mr. Hanson:

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,

for 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 - ~~N/A~~ K973575

Device Name: Silicone Elastomer Chin Implant

Indications For Use: To augment or reconstruct the chin or anterior mandibular contour.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973575

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