Hanson Medical Inc.
19325 58th PL NE
Seattle WA 98155
(425) 481 2185

DEC 24 1997

K973729

TAB G

510(k) Summary

Substantial Equivalence

The Hanson Medical Pectoralis implant is Substantially Equivalent to the Allied Biomedical Pectoralis Implant. The Hanson Pectoralis Implant is made from the same Silicone liquid elastomer materials and manufacturing processes as the predicate device.

Intended Use

The intended use of the Hanson Pectoralis Implant is augment or reconstruct the male chest by inserting the implant under the pectoralis muscle usually through a transaxillary incision. The proposed device can also be used for the correction of surface defects resulting from congenital anomalies such as depressions secondary to Poland's Syndrome. This product will be delivered non sterile.

Labeling

The labeling for this device will comprise a label for the inner package and a label for the outer box. Catalog numbers and sizes will be depicted on the labels. The package insert will contain instructions for use and sterilization. Product promotional literature will merely depict the sizes shapes and material hardness.

Physical and Chemical Properties

The physical properties of this device are the same as the predicate device in that the same materials or equivalent materials will be used. These raw materials are the LSR 30 of Applied Silicone and the MED 4211 unrestricted silicone fluid of Nusil Technologies. The durometers or hardness (Shore A) will range from 5 to 30. The appearance is described as clear to slightly opaque. The raw materials for these blocks will be Applied Silicone's LSR series and Nusil Unrestricted MED 4211. Tensile strength from lot to lot average 600 PSI or greater. The percent elongation is over 400 percent. Each lot is certified and tested for compliance to the parameters set for in the raw material certifications for each lot tested by the manufacturer.

The Chemical components of this device are polysiloxanes catalyzed by a two part system. Refer to master files MAF 562 of Applied and MAF 612 of Nusil for complete material characterizations.

Package Description

The implants will be packaged in a tyvec pouch and labeled with the size, catalogue number and dimensions. This inner package will be placed into a white thin paper box. This package will contain an outer label. This box will be properly cushion with bubble wrap and shipped in a corrugated box. Package inserts will be placed into the inner box and a packing slip will be placed in the shipping box.

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 N.E.
Seattle, Washington 98155

DEC 24 1997

Re: K973729
Trade Name: Powerflex Pec Implant
Regulatory Class: II
Product Code: MIC
Dated: September 27, 1997
Received: September 30, 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(if known)_____

Device Name: Silicone Pectoralis Implant

Indications For Use:

Silicone Carving Blocks are to be used for augmenting the chest by placing the implant in the submuscular space via a trans-axillary incision. They can also be used to reconstruct the pectoralis depression of Poland's Syndrome (Congenitally Absent Pectoralis Muscle)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973729