K973730

HANSON MEDICAL INC.
19325 58TH PL. NE.
Seattle WA 98155
(425) 481 2185

DEC 24 1997

510(k) Submission
Durasil Sheeting

TAB H

510(K) SUMMARY

PRODUCT DESCRIPTION

Durasil I and Durasil II Silicone Elastomer Sheeting are made from a biocompatible silicone high consistency rubber, HCRP-50 made by Applied Silicone and Nusil Technologies' MED 4750. There is essentially no difference between these two products saving for the short term and long term indications which are for marketing considerations only. Durasil I and II are available in polyester mesh reinforced and nonreinforced in a variety of thicknesses. The silicone elastomer used to make this product have met all Biocompatibility Guidelines set for by FDA for the replacement of Dow Corning Products. These biomaterial standards exceed or meet Class VI USP Standards in that they include Teratogenicity, Mutagenicity, Carcinogenicity and Toxicity Testing. These referenced material characterizations are found in Applied Master File - MAF 607.

SUBSTANTIAL EQUIVALENCE

These products are substantially equivalent to Duralastic I and II made by Allied Biomedical's Sheeting (K971480). Because Durasil Sheeting is made from the same materials using the same processes and made in the same sizes and thicknesses for the same intended use, it is SE to the predicate devices.

INTENDED USES

Durasil I and II are intended for a variety of medical purposes both in short term and long term applications. For short term application this list includes nasal splinting, wound dressings, scar coverings, temporary joint shims, and laboratory uses. For long term use this list includes nasal septal repair, orbital floor reconstruction, tympanic membrane repair, dialysis shunt anchoring, duramater repair, staged repair of omphalocoel, lengthening of extraocular muscles, tendon and nerve anastomosis, facilitation of osteogenesis or guided tissue regeneration, and other uses deemed appropriate by the using surgeon. Silicone sheeting has been in use for over 30 years and the uses are myriad. Hanson Medical Inc. advises surgeons to consult the literature before utilizing

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Durasil Sheeting for any purpose in the package inserts.

PHYSICAL AND CHEMICAL PROPERTIES

Durasil Sheeting is a vulcanized calendared cured rubber of a 45 - 55

Durometer hardness (Shore A). It has an elongation of 800 percent with a tensile strength of 1600 psi and a tear strength of 190 psi (Tear Die C). The elasticity is greatly reduced in the polyester reinforced sheets. The specific gravity is 1.16. Chemically Durasil I and II are made from HCRA-50, an Applied Silicone dimethylpolysiloxane and from Nusil Technologies MED 4750. For details on the foregoing chemical and physical properties consult Masterfile MAF 607 of Applied Silicone and MAF 500 of Nusil Technologies.

STERILIZATION CYCLE

Durasil I and II sheeting are sterilized via gamma radiation 2.5 - 4.2 Megarads. The validation of this cycle was performed by STI Corporation of Brea California. STI uses Sterigenics Inc. as the contract gamma radiation sterilizer. The validation uses Method 1 Testing as defined in the ANSI/AAMI/ISO 11137-1994 "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

DEC 24 1997

Mr. Gerald Hanson
Regulatory Affairs
HANSON MEDICAL INC.
19325 58th Place NE
Seattle, Washington 98155

Re: K973730
Trade Name: Durasil I and Durasil II
Regulatory Class: Unclassified
Product Code: MIB
Dated: September 27, 1997
Received: September 30, 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.

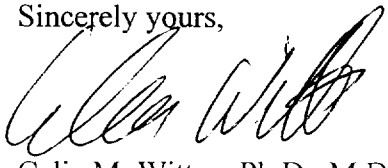
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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. Failure to comply with the GMP regulation may result in regulatory action. 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,



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

K 973730

INTENDED USE FORM

510(k) Number(if known) K973730

Device Name: Silicone Elastomer Sheeting Durasil I and II

Indications For Use:

Durasil I (Short Term) nasal splinting, wound dressings, wound drains, covering for gastroschisis, suture bolsters, scar coverings, laboratory uses, temporary facilitation of osteogenesis, and guided tissue regeneration between the teeth and gingival margin, or external ear canal for example, temporary joint spacers, and other short term uses according to the surgeon's determination.

Durasil II (Long Term) **Nonreinforced** - Tympanic membrane repair, dural covering .005 inch, nasal septal repair, tendon anastomosis, neural repair - .007 inch. correction of strabismus .010 inch, galea repair - .020 inch, orbital floor repair .040inch, hemodialysis shunt anchors .060. **Reinforced** - Facilitation of osteogenesis .007inch, repair of urethral strictures .007inch, staged repair of omphalocoel .020inch, repair of orbital floor fractures .040inch.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use

(Optional Format 1-2-96)

(Division Sign 658)
Division of General, Restorative Devices
510(k) Number K973730