

K9771480

Allied Biomedical Corporation  
3850 Ramada Drive  
Paso Robles, CA 93446

MAY 28 1997

TAB H

510(K) SUMMARY

PRODUCT DESCRIPTION

Duralastic I and II Silicone Elastomer Sheeting is made from a biocompatible silicone high consistency rubber, HCRP-50 made by Applied Silicone. It is 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 704.

SUBSTANTIAL EQUIVALENCE

Under it's original 510k K955368 and K955370 Duralastic I and II was found to be SE to Applied Biomaterial Technologies Duralastic Sheeting and Dow Corning's Silastic Sheeting in the Premarket Notification for the nonsterile Duralastic Sheeting. Because Duralastic Sheeting is made from Dow Corning Analogs and made in the same sizes and thicknesses for the same intended use it has been found SE to the predicate devices.

INTENDED USES

Duralastic 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 use in TMJ disease, 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 omphaloceol, 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. Allied Biomedical advises surgeons to consult the literature before utilizing Duralastic Sheeting for any purpose in the package inserts.

PHYSICAL AND CHEMICAL PROPERTIES

Duralastic Sheeting is a peroxide cured rubber of a 45 - 55

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Durometer hardness (Shore A). It has an elasticity of 700 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 Duralastic I and II are made from HCRA-50, an Applied Silicone dimethylpolysiloxane. For details on the foregoing chemical and physical properties consult Masterfile MAF 704.

#### STERILIZATION CYCLE

Duralastic 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."



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 28 1997

Mr. Gerald Hanson  
Regulatory Affairs  
Allied Biomedical Corporation .....  
3850 Ramada Drive  
Paso Robles, California 93446

Re: K971480  
Trade Name: Duralastic I and Duralastic II Silicone Sheeting  
Regulatory Class: Unclassified  
Product Code: MIB  
Dated: April 15, 1997  
Received: April 23, 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.

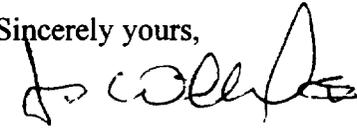
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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,



fx 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

510(k) Number (if known): K971480

Device Name: Duralastic I and Duralastic II Silicone Sheeting

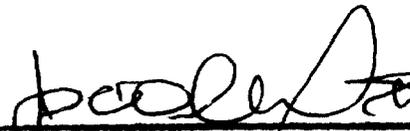
Indications For Use:

Duralastic 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.

Duralastic II (Long Term) Nonreinforced - Tympanic Membrane Repair, Dural Covering .005inch, Nasal Septal Repair, Tendon Anastomosis, neural repair - .007inch. Correction of Strabismus .010inch, Galea Repair- .020inch, Orbital Floor Repair .040inch., Hemodialysis Shunt Anchors .060inch. Reinforced - Facilitation of Osteogenesis .02inch, repair of urethral strictures .007inch, Staged Repair of Omphalocele .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)



(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K971480

Prescription Use /

OR Over-The-Counter Use     

(Optional Format 1-2-96)