DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Norbert D. Thompson
President
Technical Products, Inc.
2416 Park Central Boulevard
Decatur, Georgia 30035

JUL 11 1997

Re: K971472
Trade Name: Sil-Tec Sheeting
Regulatory Class: II
Product Code: FTL
Dated: April 18, 1997
Received: April 23, 1997

Dear Mr. Thompson:

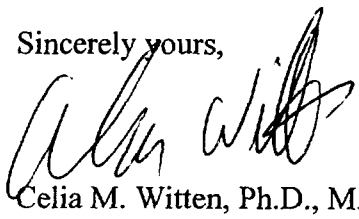
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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

510(k) Number (if known): K-971472

Device Name: Sil-Tec Sheeting

Indications For Use:

Sil-Tec Medical Grade Silicone Sheeting is suitable for external use or short-term implantation (30 days or less). Sil-Tec sheeting is intended for modification with a scalpel or scissors, by the surgeon or medical practitioner, for his/her own custom patient-specific applications. Patient selection and suitability is up to the surgeon/medical practitioner user. The surgeon/medical practitioner user must rely on his or her own best medical judgment and training as to the use of this device.

The following are some indications where silicone sheeting has been successfully employed. Surgical repairs; anchoring device for hemodialysis shunts; temporary covering for a prenatally ruptured omphalocele during staged repair; surgical repair of urethral strictures; protective sheathing to help facilitate neural regeneration and tendon healing; surgical repair of fractured orbital floors; to prevent soft tissue fibrosis or bony ankylosis following surgical correction of trismus (Warning Note: Not for permanent use in the presence of degenerative bone changes, chronic bruxism, or temporomandibular joint applications); other surgical procedures; and as insulating material for electrostimulation.

It is the surgeon/medical practitioner users responsibility to thoroughly test any products made in part or otherwise incorporating Sil-Tec medical grade sheeting to determine the acceptability of the products performance in a specific application.

(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 K971472

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)