DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP 25 1997

Mr. J. Jackson
President
S. Jackson, Inc.
15 Roth Street, PO Box 4487
Alexandria, Virginia 22303

Re: K973379
Trade Name: Sterile SupraFOIL Smooth Nylon Foil Sheets
Regulatory Class: II
Product Code: FTM
Dated: September 5, 1997
Received: September 8, 1997

Dear Mr. Jackson:

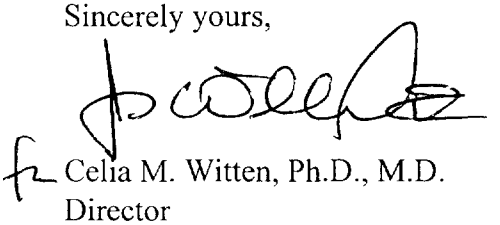
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

510(k) Number (if known): K831725

Device Name: Sterile SupraFOIL Smooth Nylon Foil Sheets

Indications For Use:

The indications for use for sterile SupraFOIL Smooth Nylon Foil Sheets are consistent with the indications for use approved by the August 16, 1983 approval letter, Ref. K831725, for nylon foil in three forms, namely, non-sterile nylon sheets, sterile textured nylon foil, and sterile nylon pre-punched foil, as:

"The Foil is intended for use by surgeons only where indicated for plastic and reconstructive surgery. The most widespread and standard use presently is for repair of orbital floor blow-out fractures in the eye. Its use is detailed in articles by Orkan Stasior, M.D., Merrill J. Reeh and James Tsujimura, M.D., J. Emery, M.D., G. von Noorden, M.D., and Donald Schlernitzauer, M.D. The foil is also used in Tympanoplasty in the middle ear as reference in...(the) article by James L. Sheehy, M.D. It has also been used to separate nerves and tendons from surrounding tissue to prevent adhesions during healing and then removed after healing is complete. It has been used to repair or replace dura matter in the skull, and in heavier thicknesses it has been attched to bones to give added strength where necessary."

(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 K973379

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)