December 11, 2024

Medtrax Industries, Inc.
Juan Alana
President
1372 Bennett Drive, Suite 156
Longwood, Florida 32750

Re: K940694
Trade/Device Name: Xeroform Petrolatum Dressing
Regulatory Class: Unclassified
Product Code: FRO

Dear Juan Alana:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 30, 1994. Specifically, FDA is updating this SE because FDA has better categorized your device technology under product code FRO.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yu-Chieh Chiu, OHT4: Office of Surgical and Infection Control Devices, 301-796-6196, Yu-Chieh.Chiu@fda.hhs.gov.

Sincerely,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

MAR 30 1994

Mr. Juan Alana
President
Medtrax Industries, Inc.
1372 Bennett Drive, Suite 156
Longwood, Florida 32750

Re: K940693
Petrolatum Dressing
K940694
Xeroform Petrolatum Dressing
Regulatory Class: Unclassified
Dated: February 3, 1994
Received: February 16, 1994

Dear Mr. Alana:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined these devices are substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your devices subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. These devices may not be labeled for use on third degree burns.

2. These devices may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.

3. These devices may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.

4. These devices may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the devices and would require a premarket notification submission (21 CFR 807.81).

The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and 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. 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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your devices as described. An FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and permits your devices to proceed to the market, but it does not mean that FDA approves your devices. Therefore, you may not promote or in any way represent your devices or their labeling as being approved by FDA. If you desire specific advice on the labeling for your devices please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Marie A Schroeder, MS, PT

for Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

2