April 2, 2024

American Medical Disposables, Inc.
Win Hirsch
President
81 Essex Street, Third Floor
Boston, Massachusetts 02111

Re: K803116
Trade/Device Name: Heavy Drainage Pack
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: KDD

Dear Win Hirsch:

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 January 28, 1981. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code KDD.

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 Infection Control
and Plastic 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
3757 Georgia Avenue
Silver Spring MD 20910

JAN 28 1981

Mr. Win Hirsch
President
American Medical Disposables, Inc.
81 Essex Street, Third Floor
Boston, Massachusetts 02111

Ref: K803116
Heavy Drainage Pack

Dear Mr. Hirsch:

We have reviewed your Section 510(k) notification of intent to market the above device, and we have determined the device to be substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Premarket Approval), it would be subject to additional controls.

However, we have determined that your product contains the following components which are subject to regulation as drugs: iodine (swabs and ointment), acetone swabs, and benzoine sticks. Our "substantially equivalent" determination does not apply to these drug components of your product. For information on the applicable Agency requirements for marketing the drug components of your product, we suggest you contact Rudolf Apodaca at the following address:

Rudolf Apodaca
Bureau of Drugs (HFD-310)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

General controls for devices presently include regulations on annual registration, listing of devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will be broadened to include additional regulations relating to restricted devices, records and reports, and others.

All applications and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the FEDERAL REGISTER. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the FEDERAL REGISTER will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S.

Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Bureau of Medical Devices, Division of Compliance Operations, 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Carl W. Druck /for/

Robert S. Kennedy, Ph.D.
Associate Director for
Device Evaluation
Bureau of Medical Devices