April 26, 2022

Life-Tech Intl., Inc.
Alfred C. Coats, M.D.
P.O. Box 36221
Houston, TX 77236-6221

Re: K872077
Trade/Device Name: Model 1858 Cavro/pressure Module
Regulation Number: 21 CFR§ 876.1800
Regulation Name: Urine flow or volume measuring system
Regulatory Class: II
Product Code: EXY

Dear Alfred C. Coats:

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 August 27, 1987. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code EXY.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Mark Antonino, OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices, (240) 402-9980, Mark.Antonino@fda.hhs.gov.

Sincerely,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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
8757 Georgia Avenue
Silver Spring MD 20910

AUG 27 1987

Alfred C. Coats, M.D.
Life-Tech, Inc.
10920 Kinghurst
P. O. Box 36221
Houston, TX 77099

Re: K872077
Model 1858 Cavro/Pressure Module
Dated: May 29, 1987
Received: May 18, 1987
Regulatory Class: II

Dear Dr. Coats:

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 devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). This device has been placed into the regulatory class shown above, by a final regulation published in the Federal Register. All classes of devices are regulated by the general controls provisions of the Act applicable to all medical devices including annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act; class II devices must also meet present or future performance standards; class III devices will be required to undergo premarket approval at some time in the future. Please note: This action 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.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Section 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire and be notified 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 Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Halyna P. Breslawec

Halyna P. Breslawec, Ph.D.
Acting Director
Division of Gastroenterology-Urology
and General Use Devices (HFZ-420)
Office of Device Evaluation
Center for Devices and Radiological Health

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