April 26, 2022

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

Re: K931179
Trade/Device Name: Urolab Spectrum
Regulation Number: 21 CFR§ 876.1620
Regulation Name: Urodynamics measurement system
Regulatory Class: II
Product Code: FAP

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 November 18, 1993. Specifically, FDA is updating this SE Letter to remove the secondary product code LST.

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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

NOV 18 1993

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

Re: K931179/S1
Urolab Spectrum
Dated: July 20, 1993
Received: July 22, 1993
Regulatory class: II
21 CFR 876.1620

Dear Dr. Coats:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). General controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, 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. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification 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 device as described. An FDA finding of substantial equivalence for your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, 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 its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health