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WARNING LETTERFood and Drug Administration
2098 Gaither Road
Rockville MD 20850**VIA FEDERAL EXPRESS**
VIA FACSIMILEAlfred C. Coats, M.D.
President and CEO
Life-Tech, Inc.
4235 Greenbriar Drive
Stafford, Texas 77477-3995

Re: Iontophoresis Applicators and Meditrode Kit

Dear Dr. Coats:

The Food and Drug Administration (FDA) has reviewed promotional materials, including information from your website at <http://www.life-tech.com>, for the NeedleBuster NB-1, Iontophor PM/DX, and Microphor Iontophoresis Applicators and Meditrode Kit. These products are manufactured by Life-Tech, Inc., and are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

These devices have been cleared under section 510(k) of the Act. Iontophoresis drug delivery systems are indicated for the local administration of ionic drug solutions into the body for medical purposes and can be used as an alternative to injections. These delivery systems were not cleared for use with a specific drug or class of drugs or to treat specific conditions.

Our office received promotional literature that includes a "Needle Buster" promotional brochure, "The Iontophoresis Connection" flyer, and a Life-Tech Price List (June 1, 1998). Two additional pieces of literature entitled "NeedleBuster Pain-Free Local Anesthetization" and "Iontophoresis," which contain similar information found in the materials noted above, were reportedly distributed at a meeting of the American Pain Society during the week of October 15, 1999. Most of these items were also included in the documents that you submitted in followup to our request for promotional materials.

The promotional materials for the NeedleBuster (including the Operating Manual) make claims that include "Indications: The NeedleBuster...is indicated for the administration of water-soluble anesthetics (e.g., lidocaine hydrochloride) for local anesthesia," "Some drugs (e.g., Lidocaine) when administered alone..." "Needleless Local Anesthetization Iontophoretically," "Pain-free Local Anesthetization," "...NeedleBuster Model NB-1 utilizes iontophoretic drug delivery technology to deliver enough local anesthetics to anesthetize a local area...". These same claims can also be found in the Microphor Operating Manual.

The Model 6111PM/DX Iontophor-II Operating Manual, General Description, states "Usually, these substances consist of medications such as anti-inflammatory steroids and local anesthetics," and "For instance, Lidocaine Hydrochloride... separates into the Lidocaine ion... Only the positive Lidocaine ion has a therapeutic effect. Driving the Lidocaine ion through the skin into the tissue below has a therapeutic effect....".

All three Operating Manuals have warnings not to use the device in the presence of flammable anesthetics.

The Iontophoresis material states "In Physical Medicine and Pain Management, iontophoresis is used to deliver anti-inflammatory drugs and local anesthetics to localized areas of inflammation." The Price List, under "Iontophoretic Applicators," contains statements such as "For use with anti-inflammatory

medications...For local anesthesia applications...,” and advertises a Reprint Book “Iontophoresis for Local Anesthesia” under the heading “Education and Instructional Material.” The website indicates that the NeedleBuster is a “Specialty design Iontophoretic Applicator for the delivery of local anesthesia,” “Pain-free Local Anesthetization with Life-Tech’s *NeedleBuster*,” “...utilizes iontophoretic drug delivery technology to deliver enough local anesthetics to anesthetize a local area...”.

In the various letters to your firm granting substantial equivalence to the Iontophoresis Systems and Meditrode Kit, including those for K863166, K871869, K882554, and the most recent clearance (K913601 July 15, 1994), the FDA states either (1) that a determination of substantial equivalence for your device does not affect the regulatory status of drugs used with the device. Any person who intends for a drug to be used with the iontophoretic applicator must assure that the drug is in compliance with all applicable requirements of the Act, or (2) that our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs or class of drugs, nor may you package drugs with your device prior to FDA having approved the drugs for iontophoretic administration with your specific device. Our office has verified with the Center for Drug Evaluation and Research (CDER) that your firm, in fact, does not have an approved New Drug Application (NDA) for the use of any drug, e.g., anesthetics (lidocaine) or anti-inflammatories, for iontophoresis use. Therefore, you can not make any claims related to the use of a specific drug or class of drugs, for use in the Iontophoresis Systems and Meditrode Kit unless the drug has been cleared for use in your devices by the FDA.

The promotional information also includes iontophoresis treatment for various conditions. The Generic Warranty Record (H1320) has a section entitled “Planned use of this product,” which lists TMJ, Hypersentivity (sic), and Bleaching. Other claims in the reviewed promotional materials include treatment of numerous specific ailments, including bursitis, neuralgia, sprains/strains, carpal tunnel syndrome, joint inflammation, TMJ, trigger points, epicondylitis, turf toe, and tendonitis, IV and catheter placement, phlebotomy, lumbar puncture and local surgical procedures. The FDA has not approved the use of your device for the treatment of specific conditions.

Marketing the Iontophoresis Systems and Meditrode Kit for treatment of the specific conditions listed above, or any other claims for uses which have not been cleared by FDA, and labeling or promoting your device for use with specific drugs without FDA approval of an NDA for such use, causes the device to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The Iontophoresis Systems and Meditrode Kit are also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device. Additionally, the promotion of these iontophoresis devices for use with a specific drug without an approved NDA is prohibited under section 505(a) of the Act.

There are also additional claims which our Office of Device Evaluation (ODE) has reviewed and does not believe are appropriate. The NeedleBuster literature states that “In less than 10 minutes, NeedleBuster Model NB-1 utilizes iontophoretic drug delivery technology to deliver enough local anesthetics to anesthetize a local area for 30 minutes to depths of 8-11mm.” The graph accompanying this statement indicates that the maximum penetration depth is 10mm. The predicate IOMED Phoresor II device is limited to a depth of 10mm over 10 minutes. Therefore, we believe that the claim of 11mm is not substantiated.

The claim that the device “ensures [a] clean and sterile application environment” is unsubstantiated. Eliminating the need for creams alone is not sufficient to ensure sterility, and it does not appear that the electrodes are sterile. The statement is misleading in that the iontophoresis is intended only to deliver soluble ions to the body. In addition, the statement that choosing the NeedleBuster will result in an “easily identifiable treatment area” has not been substantiated.

Claims that the NeedleBuster provides pain-free local anesthetization and results in painless needlesticks during routine medical and local surgical procedures imply that the device completely anesthetizes the skin surrounding the treatment area. ODE believes that these claims need to be substantiated through an NDA submission to CDER, in addition to the claim that the NeedleBuster provides for “even distribution of medication over a large tissue area.” The same is true for two “benefits” associated with the Microphor and Iontophor, that they have the ability to deliver a high concentration of medication into a localized area beneath the tissue surface without hypodermic injection and that they provide delivery of high concentrations of medication in the treated area with a relatively small proportion of the drug entering the system. It has not been demonstrated through an NDA that any drug used with the devices is safe and effective.

ODE has reviewed your premarket notifications, and could not find a controller device similar to the one described as the NeedleBuster, and noted that the electrodes pictured in the promotional materials appear modified from the original 510(k). In addition, the Iontophor model cleared by FDA was the Model 6110A, not 6111. Please provide us with the 510(k) numbers for the NeedleBuster, Iontophor II Model 6111PM/DX, and all electrodes.

Finally, you indicated that your firm, as the manufacturer for Dynatronics-distributed products, are responsible for placing a Dynatronics “DynaPak” flyer with the DynaPak product. This flyer includes a treatment chart with a heading “Drug for simple phase treatment (Dexamethasone).” There is a reference that indicates the chart information is taken from a protocol by Dr. Arthur Jeske, and states “See your Dynatronics representative for additional protocol information.” The protocol is for inflammation of the joints or soft tissue, and discusses the use of Lidocaine and Epinephrine.

These statements misbrand and adulterate the DynaPak for the same reasons discussed above regarding the Life-Tech devices. In addition, because the flyer directs customers to contact their Dynatronics representative for additional protocol information, this is considered to be promotion of the protocol. The protocol may only be provided to customers if it is in followup to completely unsolicited requests.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Iontophoresis Systems/Meditrode Kit. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

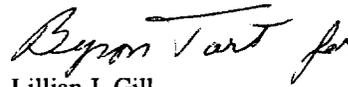
Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Page 4 – Dr. Alfred C. Coats, President and CEO

Your response should be sent to Ms. Patricia L. Jahnes, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Dallas District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Dallas District Office (HFR-SW100), 3310 Live Oak Street, Dallas, Texas 75204.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Lillian J. Gill for". The signature is written in a cursive style with a horizontal line above the name.

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health