K960756

AUG 29

X. SAFE MEDICAL DEVICES ACT OF 1990 SUMMARY OF SAFETY AND EFFECTIVENESS. [Separate page].

A. Submitted by: Lifetech Systems, Inc.

B. Contact: John Oberst, Vice President, 11350 Random Hills Rd., Fairfax, VA 22030

I. Classification Names and numbers:

Oxygen Chamber, Topical, Extremity, 79KPJ (CFR 878.5650, Class III)

II. Common/Usual Names:

Topical Oxygen Chamber.

III. Proprietary Names:

Lifetech Cassette

IV. Establishment Registration Number: In process

V. Classification:

Topical oxygen chambers were classified in CFR 878.5650, Class III, by the General and Plastic Surgery Panel. They were proposed for Class II by this panel (FR Jan. 10, 1982) but this proposed rule apparently has not been acted upon.

VI. Performance Standard:

None established under section 514.

VII. Description of the Device:

The purpose of the LIFETECH CASSETTE is to serve as an adjuvant to normally accepted methods of wound and ulcer treatment and to prevent airborne organisms from landing on the site. The device may be indicated for non-healing surgical wounds, burns, and pressure ulcers.

VII.1 Sterilization Cleaning, and Packaging Procedures

Lifetech Cassettes are sterilized using gamma radiation or gas sterilization with Ethylene Oxide. When sterilized with radiation, the AAMI guideline "Process Control Guidelines for Gamma Radiation Sterilization of Medical Devices," is followed for this process. Sterilization cycles are validated to provide a minimum sterility assurance level of 10^{-6} (10 to the minus 6th). Validation is established by the overkill method. The specified dosage range is from 2.5 to 4.0 MRads.

VIII. Labels and Labeling:

Labels and labelling for the Lifetech Cassettes and competitive products were provided and compared.

IX. Substantial Equivalence Statement:

The Lifetech Cassette is substantially equivalent to the generic devices which were proposed for classification under CFR 878.5650 under "Topical Oxygen Chamber for Extremities".

The device is also substantially equivalent to several oxygen chambers used for topical purposes, for example that cleared by K920948.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from

ODE Guidance Memorandum #86-3 was followed as described below:

1. The Cassettes have the same intended use as an aid in healing as described in the topical oxygen chamber.
2. The technological characteristics for the new product are substantially equivalent to those of the generic devices and particularly close to the previously cleared predicate devices, currently on the market.
3. Descriptive information provided shows that the materials from which the Lifetech Cassette are made (polyvinyl chloride or polyethylene) are equivalent to and nearly identical with those of similar products used for medical purposes currently on the market.
4. Sufficiently precise specifications for the materials from which the Lifetech Cassettes are constructed, have been supplied.

(End)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Oberst
LifeTech Systems, Inc.
11350 Random Hills Road, Suite 800
Fairfax, Virginia 22030

AUG 29

Re: K960756
Trade Name: Lifetech Cassette
Regulatory Class: III
Product Code: KPJ
Dated: May 29, 1996
Received: May 31, 1996

Dear Mr. Oberst:

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 (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, 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. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under

sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K960756

VII.1 INDICATIONS FOR USE
(Separate Page)

510(k) Number: 960765

Device Name: Lifetech Cassettes

1. Surgical wounds, non-healing
2. Burns,
3. Pressure Ulcers

DO NOT WRITE BELOW THIS LINE –CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use____
(Optional Format 1-2-96)

repl. p. 9a

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____