DEC 10 1999

510(k) Summary

H-1. ADMINSTRATIVE INFORMATION

H-1.1 Name and address

Submitted by: Survivalink Corporation
5430 Feltl Road
Minneapolis, MN 55343

Contact Person: Sew-Wah Tay, Ph.D.
Telephone No.: 612-939-2942
Facsimile No.: 612-939-4191
Email address: stay@survivalink.com

Date Prepared: September 8, 1999

H-1.2 Device Name

Common or Usual Name: Disposable Polymer (Hydrogel) Multifunctional Electrode
Device Name: SVL-9630
Trade Name: SVL-9630

H-1.3 Classification Name

Disposable Single Use Accessory (Electrode) to:
a) Semi-automatic low energy DC defibrillator 21CFR§870.5300; Class II
b) Cardiac Monitor (Cardiotachometer and Rate Alarm) 21CFR§870.2300; Class II

H-1.4 Applicant

Applicant's Name: Survivalink, Corporation
5430 Feltl Road
Minneapolis, MN 55343

H-2. PREDICATE DEVICE

1. Survivalink Model 9130 electrodes (K971149)
2. Katecho KDP-60 electrodes (K981737)

H-3. INDICATION FOR USE

The SVL-9630 electrodes are single use, non sterile, and intended to be used in conjunction with low energy semi-automatic external defibrillators (AED) and/or external transcutaneous pacemakers to monitor, defibrillate or pace the adult patient. The electrodes meet AAMI DF-39 performance standards. The electrodes can be used with external defibrillators/pacing devices that had been tested for compatibility with the proper electrode connector or adapter.

The electrodes are intended for short-term use (<8 hours) and must be used before the expiration date listed on the packaging. These electrodes provide the conductive interface between the defibrillator and/or the external transcutaneous cardiac pacemaker and the patient skin.

H-4 DEVICE DESCRIPTION

The SVL-9630 electrodes consists of a pair of non sterile, hydrogel polymeric self-adhesive electrode pads of equal dimension. The electrode are packaged in such a way that the two conductive areas are in electrical contact.

H-5 SUBSTANTIAL EQUIVALENCE

The Company's SVL-9630 electrodes covered by this submission are substantially equivalent to other legally marketed electrodes for semi-automatic low power DC defibrillators. Specifically, the SVL-9130 electrode is substantially equivalent to SVL-9130 electrodes (K971146) and Katecho's D-Defib/Pace electrodes (K 981737).

H-6. PERFORMANCE DATA

The SVL-9630 electrodes meet all the specifications for single use hydrogel electrodes of the AAMI DF-39 specifications and Survivalink's internal specifications. In all instances, the SVL-9630 electrodes functioned as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 1999

Sew-Wah Tay, Ph.D.
Survivalink Corporation
5420 Feltl Road
Minneapolis, MN 55343

Re: K993072
Survivalink 9630 Defibrillation Electrode
Regulatory Class: III (three)
Product Code: 74 MLN
Dated: September 13, 1999
Received: September 14, 1999

Dear Dr. Tay:

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 legally marketed predicate 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4648. 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 (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) K993072 Amendment 1

Indication for Use

510(k) Number: K993072
Device Name: Survivalink Multifunctional Electrode (SVL-9630).

1. INDICATION FOR USE

The SVL-9630 electrodes are single use, non sterile, and intended to be used in conjunction with low energy semi-automatic external defibrillators (AED) and/or external transcutaneous pacemakers to monitor, defibrillate or pace the adult patient. The electrodes meet AAMI DF-39 performance standards. The electrodes can be used with external defibrillators/pacing devices that had been tested for compatibility with the proper electrode connector or adapter.

The electrodes are intended for short-term use (<8 hours) and must be used before the expiration date listed on the packaging. These electrodes provide the conductive interface between the defibrillator and/or the external transcutaneous cardiac pacemaker and the patient skin.

for Carol C. Cary
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993072

PRESCRIPTION USE ✓
(PER 21 CFR 801.109)

C. Cary
12/6/99