

K971149

JUN 23 1997

**ATTACHMENT H: 510(K) SUMMARY**

# 510(k) Summary

## H-1. ADMINISTRATIVE 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.: 612-939-4181 ext. 142  
Facsimile No.: 612-939-4191

Date Prepared: March 26, 1997

### H-1.2 Device Name

Common or Usual Name: Disposable Polymer (Hydrogel) External Monitoring and  
Defibrillation Electrode

Device Name: SVL-9130

Trade Name: SVL-9130

### 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

Note: FDA has determined that Automatic External Defibrillators are currently classified as class III devices

### H-1.4 Applicant

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

## H-2. PREDICATE DEVICE

1. SurVivaLink Model 9010 (9010) electrodes manufactured for SurVivaLink Corporation by Katecho Inc. models (K940445)
2. Katecho K-Defib/Pace electrodes (K914955)

## H-3. INDICATION FOR USE

The SVL-9130 electrodes are single use and intended to be used in conjunction with semi-automatic external defibrillators (AED) to monitor and deliver defibrillation energy to the patient. The electrodes are intended to be used with AEDs that specify the use of

disposable electrodes that meet AAMI DF-39 standards. These AEDs must have compatible electrode connectors. The VivaLink AED and the V2 are examples of such AEDs.

The electrodes are intended for short term use and must be used before the expiration date listed on the packaging.

The AEDs are used for emergency treatment of cardiac arrest patients who weigh more than 90 pounds. The user assesses the patient's condition and confirms that the patient is unconscious, pulseless and is not breathing prior to applying the electrodes to the skin.

#### **H-4 DEVICE DESCRIPTION**

The SVL-9130 electrodes consists of a pair of 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-9130 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-9010 electrodes (K940455) and Katecho's D-Defib/Pace electrodes (K 914955).

#### **H-6. PERFORMANCE DATA**

The SVL-9130 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-9130 electrodes functioned as intended.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Sew-Wah Tay, Ph.D.  
SurVivaLink Corporation  
5420 Feltl Road  
Minneapolis, Minnesota 55343

Re: K971149  
SurVivaLink 9130 Defibrillation Electrode  
Regulatory Class: III (three)  
Product Code: 74 MKJ  
Dated: March 27, 1997  
Received: March 28, 1997

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 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) 594-4646. 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/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

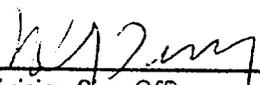
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*Prescription use* ←

  
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(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

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