K982264

JAN 25 1999

510(k) Summary

L-1. ADMINSTRATIVE INFORMATION

L-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

Date Prepared: June 24, 1998

L-1.2 Device Name

Common or Usual Name: Semi-Automatic External Defibrillator (AED)
Device Name: FirstSave™ STAR Biphasic™ AED

L-1.3 Classification

Classification Name: a) DC defibrillator
21CFR§870.5300; Class II
b) Cardiac Monitor (Cardiotachometer and Rate Alarm)
21CFR§870.2300; Class II

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

L-1.4 Applicant

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

L-2. PREDICATE DEVICE

FirstSave™ AED manufactured by SurVivaLink Corporation models 9100/9110 (K970481) and Forerunner AED manufactured by HeartStream models S, E and EM (K955628).

L-3. INDICATION FOR USE

The SurVivaLink's FirstSave STAR Biphasic AED is designed for emergency treatment of cardiac arrest by trained personnel to terminate potentially fatal arrhythmias for patients older than eight years old. The user assesses the patient's condition and confirms that the patient is unconscious, pulseless and is not breathing prior to use of the device.

L-4 DEVICE DESCRIPTION

The FirstSave STAR Biphasic AED is a portable battery operated semi-automatic low power DC defibrillator. The device's diagnostic algorithm analyzes the patient's cardiac rhythm to determine shockable versus non-shockable EKG rhythm. The operator then pushes the button to deliver the defibrillation shock. The FirstSave STAR Biphasic AED feature includes:

- Biphasic defibrillation waveform
- Lithium battery and battery fuel gauge
- Single user button
- LED diagnostic panel
- Non-volatile status indicator
- Voice prompts

The device weighs 7.4 lbs including battery, and electrodes with dimensions of 3.3in x 10.6in x 12.4in.

L-5. PERFORMANCE DATA

The performance test data is provided in the 510(k) submission. The performance data demonstrate that the device complies with the applicable sections of AAMI DF39-1993 and AAMI DF2-1996. The device was developed under design control and the hardware and software tested in accordance with established industry standards.

Tests results include rhythm detection, EMC, charge time, pulse shape, battery capacity, defibrillation recovery, design verification and validation data for hardware and software incorporated into the FirstSave STAR Biphasic AED. Environmental tests were performed on the finished device.

Clinical studies was performed to test the efficacy of the biphasic waveform in the FirstSave STAR Biphasic AED device and was found to be equivalent to the monophasic truncated exponential waveform in the FirstSave.

Test data demonstrate that the safety and effectiveness of the FirstSave STAR Biphasic AED are substantially equivalent to the HeartStream's Forerunner and the SurVivaLink's FirstSave AEDs.

L-6 SUBSTANTIAL EQUIVALENCE

The FirstSave STAR Biphasic AED is a portable, battery powered, semi-automatic, low energy DC external defibrillator. The materials, accessories and user interfaces are identical to the FirstSave AED (K970481).

The Company's FirstSave STAR Biphasic AED covered by this submission is substantially equivalent to other legally marketed semi-automatic low power DC

defibrillators. Specifically, the FirstSave STAR Biphasic AED is substantially equivalent to the SurVivaLink's FirstSave and the HeartStream Forerunner AED. The FirstSave STAR Biphasic AED has the same general indication for use, similar principles of operation, and similar technological characteristics as the previously cleared Forerunner and FirstSave devices. Although there are minor differences in the characteristics of the FirstSave STAR Biphasic AED and its predicate devices, those differences do not raise new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 1999

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

Re: K982264
FirstSave STAR Biphasic
Regulatory Class: III (three)
Product Code: 74 MKJ
Dated: November 13, 1998
Received: November 16, 1998

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. 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 submission does not affect any obligation you might have under section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

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 not 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 Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number : K982264

Device Name: FirstSave STAR Biphasic AED

Indication For Use

The FirstSave STAR Biphasic AED is intended for use by or on the order of a Physician or persons licensed by State law. It is designed for emergency treatment of cardiac arrest patients by trained personnel. The user assesses the patient's condition and confirms that the patient is unconscious, pulseless and is not breathing prior to use of the device. The FirstSave STAR Biphasic AED is intended to be used on patients older than eight years[1].

Marie Kramer

PRESCRIPTION USE ✓

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

510(k) Number _____

[1] American Heart Association (1994): "Advanced Cardiac Life Support" Ed by R.O. Cummins. pp 4-11.