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Appendix 25
510(k) Summary of Safety and Effectiveness

Heartstream, Inc. ForeRunner External Defibrillator and Accessories

General Information

Classification	Class II
Trade Name	ForeRunner External Defibrillator and Accessories
Submitter	Heartstream, Inc. 2401 Fourth Avenue Suite 300 Seattle, Washington, USA 98121
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Substantially Equivalent and Preamendment Devices

<u>Manufacturer</u>	<u>Product</u>
Zoll Medical Corporation	Semi-Automatic External Defibrillator
SurVivaLink Corporation	VivaLink Semi-Automatic External Defibrillator
Laerdal Medical Corporation	Heartstart Semi-automatic External Defibrillator
Hewlett Packard Corporation	Codemaster XL Defibrillator/Monitor
PhysioControl Corporation	LifePak 100 External Defibrillator
W. Kouwenhoven, M.D. (Johns Hopkins Hospital)	Biphasic External Defibrillator
Mine Safety Appliance Company	Biphasic External Defibrillator
Katecho, Inc.	External Pacing and Defibrillation electrodes
Zoll Medical Corporation	Multi-function electrodes
SurVivaLink Corporation	Defibrillation electrodes

Intended use

The ForeRunner external defibrillator, is indicated for use on victims of sudden cardiac arrest on whom an apparent lack of circulation is indicated by unconsciousness, absence of breathing and absence of detectable pulse.

Device Description

The ForeRunner external defibrillator is a semi-automatic external defibrillator incorporating voice prompts to advise the operator of the need to deliver a defibrillating shock. The device is designed to be used by emergency responders in the treatment of cardiac arrest. The device is portable, weighing approximately 4 pounds and measuring approximately 2.5"(H) x 8"(W) x 8.8"(D). The ForeRunner product line consists of the defibrillator, a disposable battery, a pack of disposable single use electrodes, carrying cases and other optional accessories, such as event recording data cards and event review software.

Testing

Extensive environmental and performance tests are conducted on the ForeRunner external defibrillator. These tests included performance tests in accordance to established industry standards. The electrocardiogram (ECG) recognition algorithm is evaluated using recordings of actual cardiac signals in accordance to established industry standards. Further, the software for the product is validated per recognized validation techniques.

Biocompatibility testing is performed on patient contact materials of defibrillation electrodes in accordance to international standards.

All testing of the products yielded acceptable results prior to commercial distribution.

Summary of Substantial Equivalence

The ForeRunner external defibrillator is intended for emergency treatment of cardiac arrest. The ForeRunner external defibrillator is a portable, battery powered semi-automatic low energy DC defibrillator.

Portable low power DC defibrillators are commonly used by emergency personnel to defibrillate unconscious patients. The ForeRunner functions in the same manner as the predicate devices in that it is a portable, low power, battery operated defibrillator. The ForeRunner external defibrillator is semi-automatic and has visual and voice prompts for ease of operations.

The design features and materials used in the manufacture of the ForeRunner external defibrillator are substantially equivalent to the predicate products. Additionally, the ForeRunner external defibrillator is of similar shape and functionality to predicate devices. The defibrillation waveform has been shown to be substantially equivalent to predicate product waveform with respect to defibrillation effectiveness and safety in an extensive clinical trial.

Therefore, due to the similarity of design features, materials, test results, clinical results and the similarity of the indicated use to other predicate devices, Heartstream, Inc. believes this product does not raise any new safety or effectiveness issues.