K962115

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SECTION 2.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

As required under Section 12, part (a)(i)(3A) of the Safe Medical Device Act of 1990, an adequate summary of any information regarding safety and effectiveness follows:

2.1 General Information

Name and Address of Submitter:

Cambridge Heart, Inc.
One Oak Park
Bedford, MA 01730

Contact:

Robert T. Miragliuolo
V.P. of Regulatory and Clinical Affairs

Date of Summary:

May 15, 1996

Name of Device:

Cambridge Heart Hi-Res™ ECG Electrode

Common/Usual Name of Device:

ECG Electrode

Device Classification:

Electrocardiograph Electrode

Predicate Devices:

Smart™ Bi-Lectrode (K791006)
Quinton Quik-Prep Electrode(K782079)
3M Red Dot Electrode (K821438)
HP M1176A Cardiac Monitor (K882609)

2.2 Device Description and Intended Use

The Cambridge Heart Hi-Res™ ECG Electrode is a pregelled, single use, multi-segment Ag/AgCl electrode used in measuring electrocardiogram signals. It was designed specifically for use with the Cambridge Heart, Inc. CH 2000 Stress Test System and successor systems.

The Cambridge Heart Hi-Res™ ECG Electrode is intended for short term use to measure electrocardiogram signals at rest and during ECG stress testing with the CH 2000 Stress Test System and successor systems. This device is supplied non-sterile and is intended for one time use only.

The Hi-Res™ ECG Electrode is constructed of a polyester basepad, four silver-silver chloride ink electrode segments, an adhesive coated die cut foam, a conductive gel, and a silicone coated polystyrene carrier (release liner).

The electrode comprises four closely spaced electrode segments, consisting of three equal sized segments equidistant around a center segment, each capable of receiving ECG signals. By itself, the center segment functions as a standard Ag/AgCl ECG electrode. It is non-polarizing should defibrillation be required when the electrode is in place. The ECG signal received by the center segment is the primary source of the ECG reported on the display screen and on printouts of the CH 2000 Stress Test System.

The three ring segments are used to receive additional ECG signals and are used, along with the center segment, to obtain real time measures of electrode surface-to-skin impedance and trans-thoracic (respiratory) impedance. These additional ECG signals and impedance measurements are used by the noise reduction algorithms on the CH 2000 to reduce baseline wander and movement artifact from the ECG.

The Cambridge Heart Hi-Res™ ECG Electrode can be used to measure electrocardiogram signals at rest and during stress testing with the CH 2000 Stress Test System and successor systems.

The Hi-Res™ ECG Electrode reduces baseline wander, movement artifact and muscle artifact from the ECG, when used with the CH 2000 Stress Test system or successor systems.

The center segment of the electrode is non-polarizing should defibrillation be required while the electrode is in place.

The electrode is flexible, has a low profile, is capable of adhering to the skin under the variety of conditions particular to exercise stress testing, and is pregelled as required for lowering skin-electrode impedance.

The Hi-Res™ ECG Electrode was designed to specifications, confirmed by testing, that meet or exceed the following voluntary guidelines and standards as they apply to disposable ECG electrodes used for exercise testing: ISO 10933-5 and ANSI/AAMI EC12-1991.

The Hi-Res™ ECG Electrode is used at LL, V2, V4, V5, V6, I and H. It interfaces with a high resolution patient lead cable supplied by Cambridge Heart, Inc., for use with the CH 2000 Stress Test System. This high resolution patient lead cable is similar to the standard 14 electrode patient lead cable included in the 510(k), K950018, for the CH 2000 Stress Test System with the exception that the leadwires and electrode connectors have been changed so as to be used with the Hi-Res™ ECG Electrode. Testing has confirmed that the high resolution patient cable meets the AAMI EC-53 standard.

A noise reduction algorithm has been added to the CH 2000 specifically for recognizing and processing the additional ECG and impedance signals from the Hi-Res™ ECG Electrode. This algorithm creates a weighted average of the ECG signals from the segments of the each electrode to reduce noise through adaptive cancellation of artifact in the ECG. In creating the average, the algorithm also uses the impedance signals to cancel baseline noise artifact. This noise reduction process creates an ECG signal that can then be processed by the CH 2000 like a standard ECG signal from a conventional single segment electrode.

The CH 2000 Stress Test System and the HP M1176A device, K882609, measure respiratory impedance in a similar manner. Both devices inject a low level high-frequency current through the torso, using existing electrodes, and measure the resulting voltage drop across the body.

The Hi-Res™ ECG Electrode is substantially equivalent to the Smart™ Bi-Lectrode (K791006), the Quinton Quik-Prep Electrode (K782079), and the 3M Red Dot Electrode (K821438). Refer to Exhibit 2.1 for a summary of similarities and differences.

2.3 Summary of Similarities and Differences

The table below shows the frequency and current used by the CH 2000 and the predicate device for the purpose of measuring respiratory impedance. The CH 2000 current is significantly lower than the maximum of 280 μA allowed by AAMI standard ES1, Section 3.5 for a frequency of 28 kHz.

	CH 2000	HP M1176A
Frequency	28 kHz	39 kHz
Maximum RMS current	100 μA	68 μA

Please refer to the exhibit 2.1 on the following page for a summary of the similarities and differences.

EXHIBIT 2.1

SUMMARY OF SIMILARITIES AND DIFFERENCES

Characteristics	Cambridge Heart HI-Res™ ECG Electrode	Quinton Quik-Prep Electrode	3M Red Dot Electrode	Smart™ Bi-Lectrode
Indications for Use	The Cambridge Heart Hi-Res™ ECG Electrode is intended for short term use to measure electrocardiogram signals at rest and during stress testing with the CH 2000 Stress Test System or successor systems.	The Quinton Quik Prep electrode represents an addition to Quinton's line of disposable ECG electrodes. The electrode is designed for stress or exercise test as well as longer term monitoring	Red Dot Electrodes are designed for obtaining electrocardiographic signals from subjects who are being monitored in all areas of a hospital or in a clinical setting	Intended for patient ECG monitoring
Number of Electrode Sements	Four	One	One	Two
Conductive System				
Electrode	Silver-Silver Chloride	Silver-Silver Chloride	Silver-Silver Chloride	Silver-Silver Chloride
Conductive Gel	YES	YES	YES	UnKnown
SAFETY STANDARDS				
Biological Response Evaluation	Protocol- ANSI/AAMI EC12- 1991 Cytotoxicity Kligman Sensitivity Primary Skin Irritation PASSED	Not Specified	Protocol - Unknown Cytotoxicity Human Dralze Cumulative Irritancy Protocols PASSED	Unknown

EXHIBIT 2.1 (continued)

SUMMARY OF SIMILARITIES AND DIFFERENCES

Performance Standard ANSI/AAMI EC12-1991	Cambridge Heart Hi-Res™ ECG Electrode	Quinton Quik Prep Electrode	3M Red Dot Electrodes No.2250	Smart™ Bi-Lectrode
	Shelf Life Labeling- 8 months	Shelf Life Labeling- 9 months	Shelf Life Labeling- 1 year	No Information Available
	CENTER DOT SEGMENT			
AC Impedance (10Hz) Avg <2 KΩ Max < 3 KΩ	AC Impedance (10Hz)- Average - 029 KΩ Max - <3 KΩ	Impedance (60Hz)- 1.5 KΩ	AC Impedance (10Hz)- Average - 686 KΩ Max - 3 KΩ	
DC Offset Voltage- < 100mV after 1min.	DC Offset Voltage- Average - 0.3mv Max - <100 mV	DC Offset Voltage- < 30mv	DC Offset Voltage- Average - 1.72mV Max - 100 mV	
Combined Offset Instability and Noise <150µV	DC Offset Instability and Internal Noise- Average - 0.4 µV / sec Max - <150µV	DC Offset Drift- <30 microV/sec.	DC Offset Instability and Internal Noise- 54 microV / sec	
SDR <100mV @5 sec	Defibrillator Recovery- Average 8.6 mV @5 sec Max - <100mV @5 sec	Defibrillator Recovery- <100mv @5 sec	Defibrillator Recovery- 89.4mv @5 sec	
Bias Current Tolerance <100 mV over 8 hrs	Bias Current Tolerance- Average 0.4 mV over 8 hours Max - <100mV over 8 hours	Bias Current- Not Specified	Bias Current Tolerance- 11.4 mv over eight hours	
	ANSI/AAMI EC-12-1991	(Not specified)	(Proposed AAMI Standard May 1981)	

2.4 Substantial Equivalence Decision Tree

The 510(k) "Substantial Equivalence" Decision Making Process in ODE Guidance Memo #K86-3, was used in making the determination of substantial equivalence. The answer to these questions lead to a determination of substantial equivalence.

1. Does New Device Have the Same Indication Statements?

   Yes. The Hi-Res™ ECG Electrode and the predicate electrode devices are all indicated for the same basic purpose of conducting the ECG signal from the surface of the skin to the electrocardiograph. The Hi-Res™ ECG Electrode is indicated for short time use, at rest and during stress testing; the predicate devices are intended for the same use and also for long term monitoring. The HP M1176A is a cardiac device for obtaining ECG and respiratory measurements. The CH 2000 Stress Test System is intended for the recording of ECGs and vector cardiograms by a physician, or under the direction of a physician , at rest and during ECG stress testing.

2. Does the New Device Have the Same Technology Characteristics, e.g., Design, Materials, Etc.?

   Yes. The Hi-Res™ ECG Electrode functions in the same manner as the predicate devices in that it is a transducer of the electrical signals emanating from the heart by converting an ionic signal in tissue to a metal conductive electrical signal. It has a similar conductive system consisting of silver-silver chloride elements to increase the rate of depolarization; a conductive gel to enhance skin contact and conductivity; and an adhesive on a flexible material, made from a relatively inert polymer, to hold the electrode on to the skin. The multi-segment design of the Hi-Res™ ECG is an extension of the bi-segment design of the Smart™ Bi-Lectrode.

The CH 2000 Stress Test System and the HP M1176A device, K882609, measure respiratory impedance in a similar manner. Both devices inject a low level high-frequency current through the torso, using existing electrodes, and measure the resulting voltage drop across the body.

3. Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

NO. The descriptive characteristics are not precise enough to ensure safety of effectiveness equivalence.

4. Are Performance Data Available to Assess Equivalence

The Hi-Res™ ECG Electrode was tested and met the performance requirements of ANSI/AAMI EC12-1991 and the biocompatibility requirements of ISO 10993-5. In their respective premarket applications, the Quik Prep Electrode and the 3M Red Dot Electrode were tested to demonstrate compliance with certain voluntary standards as they applied to ECG electrodes. The requirements of these standards are similar to the requirements of ANSI/AAMI EC12-1991 and ISO10933-5 for performance and biocompatibility.
The CH 2000 Stress Test System's method of measuring respiratory impedance meets the AAMI Standard For Safe Current Limits for Electromedical Apparatus ES1, Section 3.5.

5. Performance Data Demonstrates Equivalence?

Yes. The results of biocompatibility testing on the Hi-Res™ ECG Electrode and on the predicate devices were substantially equivalent. The results of the performance testing on the Hi-Res™ ECG Electrode and the predicate devices were substantially equivalent. The results of the testing demonstrate

that the manner in which CH 2000 Stress Test System measures respiratory impedance is substantially equivalent to the predicate device.

Based on the FDA's decision tree, the Hi-Res™ ECG Electrode is substantially equivalent to the Smart™ Bi-Lectrode, the Quinton Quik-Prep Electrode, and the 3M Red Dot Electrode, and the HP M1176A and CH 2000 Stress Test System are substantially equivalent.