Section 13: Device Description / Description of Changes

1. Device Introduction

1.1. The CG-6108 ACT-1L Continuous ECG Monitor and Arrhythmia Detector (ACT-1L) is designed for self-testing by patients at home and for analysis by medical professionals at a remote Monitoring Center.

1.2. The ECG chest-worn sensor is used for the acquisition and transmission of the ECG signal. The sensor is equipped with three electrode leads (electrodes contacts) on a harness intended to connect with FDA cleared ECG electrodes. The sensor works in conjunction with a hand held cellular device which contains the arrhythmia detection software application. Pictures of the sensor and handheld computing device are shown in Figures 1 and 2 below.

1.3. The sensor houses a 3.6V AA lithium-thionyl chloride battery, an ECG channel circuit, an impedance measurement circuit, a pacemaker detection circuit, a 2-hour flash buffer memory, a Bluetooth transceiver and a buzzer. The ECG signals are received, filtered and amplified in the input circuit, stored in the flash memory buffer and transmitted via Bluetooth to the hand held device (cellular smart phone). The hand held device runs a proprietary application that is configured to process and transmit the ECG recordings (via cellular network) that are also stored along with the detected physiological events on a micro-SD memory card. When a physiological event is detected, the handheld device transmits the recorded ECG automatically, via cellular link, to a Monitoring Center for professional analysis. If the patient is out of the cellular network coverage area, the hand-held device will send all events that were stored when the cellular link is re-established. The hand held device can also transmit ECG alarms via landline telephone through an optional landline Bluetooth modem.

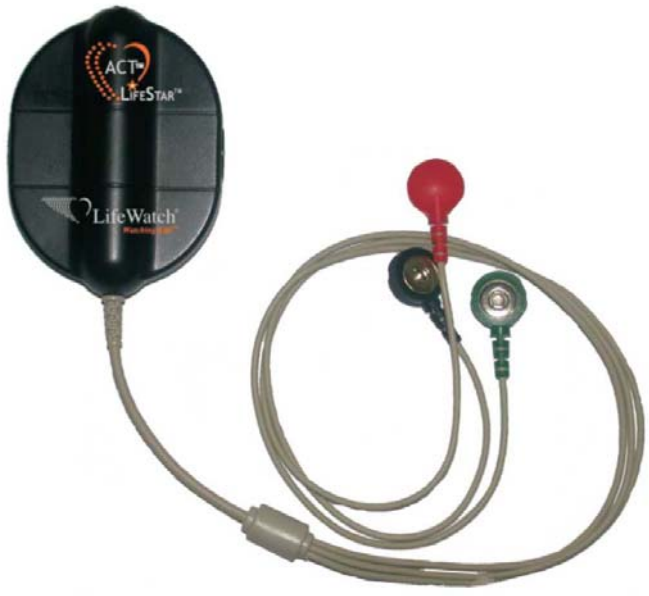

Figure 1: ACT 1L Sensor and ECG Leads

HTC 5800

Samsung i617 Blackjack

Figure 2: Available Handheld Cellular Computing Devices

2. Indications For Use:

2.1. The CG-6108 Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors a one lead ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm or generates an alarm manually triggered by the patient, and transmits the recorded data transtelephonically to a Monitoring Center. The Monitoring Center provides the ECG data to the medical practitioner for evaluation.

3. Classifying Regulation and Product Code

3.1. Regulation Number: 21 CFR 870.1025, 21 CFR 870.2920

3.2. Product Code: DSI, DXH