

K954163 U

JUL 11 1995

510(K) SUMMARY
Retrospective II-Elite

CEC Medical Systems, Inc.
2063 South 116th Street
Milwaukee, WI 53227
Voice: (414) 545-6777
FAX: (414) 545-4126

Date of Summary: August 25, 1995

Contact for this submission: John Ellenz, Director of Engineering

Device Trade Name: Retrospective II-Elite
Device Common Name: ECG Memory Loop Recorder
Device Classification: Transmitters and Receivers, Electrocardiographic,
Telephone.
Classification Number: 74DXH

Claimed Predicate Device: Retrospective ECG Memory Loop Recorder
Manufacturer: CEC Medical Systems
510(K) Document #: K831406

Description of Device

The Retrospective II is a portable ECG memory loop recorder. It is a non-critical Type II device. The device, as well as its predicate, continuously record ECG and store several minutes of the most recent data. When the patient experiences a symptom he/she presses a button which saves this stored data. The patient then calls a receiving service and transmits the data over the telephone. The service is then able to interpret or forward the data to the patient's physician. Both the Retrospective and the Retrospective II-Elite have this same operational sequence

Both devices obtained ECG data via 3 or 5 disposable surface electrodes. The ECG signals are amplified and then digitized. A microprocessor controls the sampling of the data and then stores the data in RAM. When the symptom button is pressed the most recent stored data is then saved. When the send button is pressed the saved data is recalled by the microprocessor. The data is then frequency modulated and used to drive a speaker. This audio data is transmitted over a voice grade telephone line to the receiving hardware. Both devices accomplish this entire process using solid-state

techniques, that is no magnetic media or moving parts are employed. Both devices are powered by alkaline batteries and have no AC power connection.

Intended Use of Device

The sole intended use for the device or its predicate is for the long term monitoring of ECG in occasionally symptomatic patients. The purpose of both devices is to record occasional short-lived arrhythmia. Their usage is usually confined to otherwise healthy individuals on an out-patient basis. These recorders are not meant for use in life support or ICU situations. Their normal function is to record all ECG data and save a particular episode only when activated by the patient. The stored episode contains data before and after the activation so that the actual arrhythmia will be captured. The data is then saved for transmission to a qualified technician for interpretation. The recorders take no action and advises none to the patient other than to call the receiving station. They are totally passive devices and offers no diagnosis or perform any signal analysis.

Summary of Comparison to Predicate Device

The Retrospective II-Elite is an evolution of the original Retrospective. Both were designed with the same intended use. Improvements in technology over the past decade allow the Retrospective II-Elite to be smaller, lighter, and have longer battery life than the original device. However the underlying principal of operation is identical for both devices. Both amplify and digitize ECG data, store that data digitally in static RAM, and transmit the data via acoustic FM.

Additional features of the Elite model include the simultaneous transmission of two channels of ECG data, automatic baseline centering, multiple events, and digital time/date stamps. These features do not alter the intended use of the device, rather they allow the device to be competitive with others on the market. The quality of transmitted ECG data is not compromised by the additional features. In fact the Elite is designed to conform with ECG quality specifications suggested by The Association for the Advancement of Medical Instrumentation (AAMI) which are more rigorous than those used in the original Retrospective.

Both devices are powered by alkaline (or other standard consumer types such as carbon zinc) batteries. There is no provision for the connection of either device to any external supply. No AC risk currents exist. Data is transmitted to a receiving station over normal telephone lines. No electrical connection is made with the telephone system, as the coupling method is acoustic. Therefore the Retrospective II-Elite presents no additional electrical risks to the patient.

Test Results

The Retrospective II-Elite was designed to meet the specifications suggested by the Association for the Advancement of Medical Instrumentation (AAMI) for Ambulatory ECG Monitors. Verification testing on a sample device has shown that the Retrospective II-Elite complies with applicable AAMI performance requirements.