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510(k) SUMMARY

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A. Device Name and Classification

1) Device Trade Name
Quinton Model Q710 Exercise and Resting Electrocardiograph

2) Device Common Name
Electrocardiograph and ECG Analysis System

3) Device Classification Names

870.2340	Electrocardiograph
870.1425	Programmable Diagnostic Computer
870.2300	Cardiac Monitor
870.2370	ECG Surface Electrode System
870.2600	Signal Isolation System
870.2810	Paper Chart Recorder
870.1025	Arrhythmia Detector and Alarm (Resting Interpretation Option)

B. Predicate Device

The legally marketed device to which we claim equivalence is the Hewlett Packard Pagewriter XLi M1700A.

C. Device Description

The Q710 Exercise and Resting Electrocardiograph records resting ECG data and provides a variety of user-selectable patient reports. When equipped with the optional exercise monitor, the system can be used for exercise stress testing.

A resting interpretation option is also available that provides measurement and interpretive statements.

The device is made up of the Q710 electrocardiograph, optional CRT monitor, and cart option with a storage basket. The Q710 electrocardiograph includes an integral chart recorder, liquid crystal display (LCD), keyboard, and patient module which attaches to the patient cable. The electrocardiograph is a self-contained unit, approximately 15 x 41 x 60cm in size, and housed within a polymeric enclosure.

D. Intended Use of Device

The intended uses of the Quinton Model Q710 Exercise and Resting Electrocardiograph are acquisition, digitization, display, and recording of conventional diagnostic 12 simultaneous lead ECG waveforms and ECG data.

As an option, the Model Q710 has a resting ECG analysis program which makes measurements and provides interpretation of the ECG waveform for both adult and pediatric populations. This analysis program is offered to the physician on an advisory basis only and the physician is asked to overread and validate (or change) the ECG interpretation.

E. Summary of Technological Characteristics Compared with the Predicate Device

Both the Quinton Model Q710 and the Hewlett Packard Pagewriter XLi acquire, digitize, display, and record conventional diagnostic 12 simultaneous lead resting ECG waveforms and ECG data. As an option both devices have a resting ECG analysis and interpretation program covering adult and pediatric populations. The physical characteristics for both devices are approximately the same as each electrocardiograph has a built-in chart recorder, keyboard, and display panel contained within a unifed polymeric enclosure. Each device has rechargeable batteries for use when line power is not available. Optional carts are available for transporting the electrocardiographs.

E. Summary of Technological Characteristics Compared with the Predicate Device (Continued)

Differences between the devices include Pagewriter XLi's optional feature of displaying and/or recording signal averaging ECG (SAECG) waveforms and data. Additionally, the Pagewriter XLi has a modem feature that the Q710 does not. The Q710 has a stress test option not available on the Pagewriter XLi that allows one to control exercise devices and employ specific exercise protocols from the Q710 while simultaneously recording 12 lead ECG data and displaying such data in a variety of reports. A CRT monitor is included in this option.

F. Performance Testing and Conclusions

1) Performance Testing

Performance testing was made up of two parts, an equivalence study, and a system study. Both parts involved side-by-side comparisons of the Q710 and the Pagewriter XLi. In the equivalence study, a randomly selected number of ECG cases having sufficient statistical significance were stored on a floppy disk and ported to the Q710 and to the Pagewriter XLi. Measurements and diagnostic (interpretive) statements were generated for each case by each electrocardiograph. These results were then ported via a floppy disk to a PC and stored on the PC. A PC based program compared the measurements and interpretive statements generated by each device for each case and noted any differences. In the system study paired comparisons of outputs from the Q710 and the Pagewriter XLi were made in three areas to demonstrate that as a system both systems perform equivalently with the resting interpretation option. One area compared the ECG acquisition capability of each device. Another area assessed whether identical data inputed by the operator and identical ECG data resulted in the same printed reports at each device. Finally a certain number of ECG cases were acquired via ECG leads by both devices and the data was processed resulting in measurements and interpretive statements that were printed as reports and compared and analyzed by an overreading physician.

F. Performance Testing and Conclusions (Continued)

2) *Conclusions*

All but one case out of 1047 tests cases in the equivalence study were shown to produce exact agreement between the Q710 and the Pagewriter XLi for ECG data presented to the software digitally. These results exceed the criteria that was established for statistical equivalence in the equivalence study protocol.

Two minor defects in Q710 system software were found during the system study testing. Neither defect was associated with the Q710 resting interpretation option software. After correction of these two defects certain tests were repeated resulting in all system study acceptance criteria being met.

Taken together, the results of the equivalence study and the system study demonstrate that the Quinton Q710 with the resting interpretation option is substantially equivalent to the Hewlett Packard Pagewriter XLi.