K964784

AUG 13 1997

510(k) SUMMARY

Submitter's Name:	Quinton Instrument Company
Submitter's Address:	3303 Monte Villa Parkway Bothell, Washington 98021-8906
Submitter's Phone Number:	(US) 206-402-2000
Submitter's Fax Number:	(US) 206-402-2017
Contact Person:	Matt Hedlund
Date Summary Prepared:	May 14, 1997

A. Device Trade Name:
Quinton Synergy Cardiology Information System (CIS)

B. Device Common Name:
Electrocardiograph (Accessory)

C. Device Classification Names

870.2340	Electrocardiograph
870.2450	Medical Cathode-Ray Tube Display
870.1425	Programmable Diagnostic Computer
870.2800	Medical Magnetic Tape Recorder

D. Predicate Device
The legally marketed device to which we claim equivalence is the Model Q710 Exercise and Resting Electrocardiograph. The 510(k) number for this device is K945626.

C. Device Description

The CIS is a cardiology data management system that encompasses and integrates proprietary software and third party software on a single workstation or networked workstations. The workstation may include ancillary devices as a server, bar cod system, and printer.

The CIS provides a means to establish, maintain, access, review, and edit cardiology patient records that are typically generated from ECG procedures.

D. Intended Use of Device

The intended use of the Quinton Synergy Cardiology Information System (CIS) is the acquisition, storage, and display of electrical signals of biological origin, as ECG data, that are obtained from other devices connected directly to the patient. This display on the CIS would only occur at the cessation of data acquisition by the patient connected equipment. Additionally, the CIS may acquire, store, and display data, as patient demographic information.

Acquired information may be reviewed, edited, abridged, or re-formatted and printed out.

E. Summary of Technological Characteristics Compared with the Predicate Device

Both the Synergy Cardiology Information System and the Quinton Model Q710 record and display 12 lead ECG waveforms and ECG data. Both devices display and allow editing and print-out of patient reports which may include ECG information, demographic information, and interpretive reports. All information contained within the CIS patient reports come only from the ECG device, as the Q710, unless editing occurs. The hardware platform for the CIS is a computer, keyboard, monitor, and peripherals as a laser printer. The Q710, while computer based, is ergonomically designed as a ECG device containing inputs for ECG and a built-in keyboard and printer mounted on a cart.

F. Performance Testing and Conclusions

1) Performance Testing

Performance testing was based on transmitting via serial ports randomized ECG waveforms and textual data from the Q710 and the HP PageWriter XLi to the CIS. Pre-transmitted information was compared with information received and stored at the CIS. In one set of tests the comparison was done using software to determine the integrity of the digital transfer. In another test the ECG and textual data was printed out before being transmitted from the Q710 and then printed out again after being received and stored at the CIS. Additionally, data from the HP PageWriter was printed out, transferred to the CIS by floppy disk, and then printed out again. A cardiologist compared the pre- and post transmissions for significant differences in both cases.

2) Conclusions

No differences were found in the digital comparison between pre and post transmitted data from the Q710 to the CIS. Only expected differences were found during the digital comparison of pre and post transmitted data from the HP PageWriter XLi to the CIS. These differences are due to the HP communication protocol not transmitting certain fields. Finally, no signifcant differences were found by the cardiologist when comparing the pre-transmission print-outs from the Q710 with the post-transmission print-outs at the CIS. Additionally, no significant differences were found in the PageWriter transfer test using a floppy disk.

Taken together the tests demonstrate that the CIS is substantially equivalent to the Q710 in certain limited areas of recording, displaying, and printing out ECG waveforms and textual information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Matt Hedlund
Quinton Instrument Company
3303 Monte Villa Parkway
Bothell, Washington 98021-8906

AUG 13 1997

Re: K964784
Synergy Cardiology Information System (CIS)
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: May 15, 1997
Received: May 16, 1997

Dear Mr. Hedlund:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Number (if known): K964784

ice Name: Synergy Cardiology Information System (CIS)

ications For Use:

The intended use of the Quinton Synergy Cardiology Information System (CIS) is the acquisition, storage, and display of electrical signals of biological origin, as ECG data, that are obtained from other devices connected directly to the patient. This display on the CIS would only occur at the cessation of data acquisition by the patient connected equipment. (Hence, the CIS would only operate as non-real time system.) Additionally, the CIS may acquire, store, and display administrative data, as patient demographic information.

Acquired information may be reviewed, edited, abridged, or re-formatted and distributed electronically or printed.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

scription Use X OR Over-The-Counter Use
r 21 CFR 801.109)