MAR - 6 2000

K992908

510(k) SUMMARY

January 19, 2000

SUBMITTER'S NAME: Quinton Instrument Company
SUBMITTER'S ADDRESS: 3303 Monte Villa Parkway
Bothell, WA 98021
USA
SUBMITTER'S PHONE NUMBER: 425-402-2255
SUBMITTER'S FAX NUMBER: 425-402-2017
CONTACT PERSON: Karen Browne

1. **NAME OF DEVICE:** Q-Tel® Telemetry System v. 6.0 (ST)

2. **DEVICE COMMON NAME:** Cardiac Telemetry Monitor System

3. **CLASSIFICATION NAMES:** 870.1025 Arrhythmia Detector and Alarm (74DSI)
870.2910 Radiofrequency Physiological Signal Transmitter and Receiver (74DRG)

4. **PREDICATE DEVICE:** The legally marketed device for which Quinton is claiming equivalence to is:

   - K942147 PCI Model 1100

5. **DEVICE DESCRIPTION**

   The Q-Tel® Telemetry System v. 6.0 (ST) consists of a central receiver, transmitter, viewing monitor, keyboard, and accessories. ECG data is received via the transmitter to the central receiver and is displayed, stored, and analyzed, with alarms for heart rate, arrhythmia, and ST change.

6. **INTENDED USE**

   The intended use of the Q-Tel® Telemetry System v. 6.0 (ST) is the acquisition and transmission of ECG data by means of a radio-frequency transmitter worn by individual patients in a hospital or clinical setting to a central monitor where it is received, displayed, stored, and analyzed, with alarms for heart rate, arrhythmia, and ST change. The intended populations are ambulatory adults where cardiac monitoring is prescribed while undergoing exercise rehabilitation. Multiple central receivers may be used and connected to a local area network.

7. **TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO PREDICATE DEVICE**

   The Q-Tel® Telemetry System v. 6.0 (ST) and PCI Model 1100 are central monitoring stations which acquire data via radio frequency transmitters worn by individuals in a clinical setting. Data is received, viewed, stored and analyzed, with alarms for heart rate, arrhythmia, and ST change. Both central stations may be used and connected to a local area network.

8. **PERFORMANCE TESTING AND CONCLUSIONS**

   Bench testing was performed for the Q-Tel® Telemetry System v. 6.0 (ST) arrhythmia detection and ST algorithm function. Testing for arrhythmia detection was performed in accordance with AAMI recommended practice, Testing and Reporting Performance Results of Ventricular Arrhythmia Detection Algorithms. Beat-by-beat and run-by-run comparison as well as ventricular flutter and fibrillation comparisons are performed. Results are compiled in Document #900312, Arrhythmia Detection Performance Results. ST Algorithm testing was done using a test protocol from the European ST-T Database sponsored by the European Society of Cardiology. Both Episodic and ST Level comparisons are performed. Results are compiled in Document # 900419, ST Algorithm Performance Results. Conclusion shows tape-by-tape results that indicate the algorithm's ability to detect events of clinical importance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2000

Matthew J. Hedlund
Quinton Instrument Co.
3303 Monte Villa Parkway
Bothell, WA 98021-8906

Re: K992908/S1
Trade Name: Q-TEL Telemetry system V.6.0 (ST)
Cardiac Telemetry Monitor System
Regulatory Class: III
Product Code: 74 DSI
Dated: January 21, 2000
Received: January 27, 2000

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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. An 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, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA.

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) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 at (301) 443-6597.

Sincerely yours,

for Magnuson

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K992908/S1

Device Name: Q-Tel® Telemetry System v. 6.0 (ST)

Indications for Use:

The intended use of the Q-Tel® Telemetry System v. 6.0 (ST) is the acquisition and transmission of ECG data by means of a radio-frequency transmitter worn by individual patients in a hospital or clinical setting to a central monitor where it is received, displayed, stored, and analyzed, with alarms for heart rate, arrhythmia, and ST change. The intended population are ambulatory adults where cardiac monitoring is prescribed while undergoing exercise rehabilitation.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Moynahan 3/3/00

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992908/S1

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)