K971570

DEC 29 1997

510(k) SUMMARY

Submitter's Name:	Quinton Electrophysiology Corporation
Submitter's Address:	200 West Beaver Creek Road Richmond Hill, Ontario Canada L4B 1B4
Submitter's Phone Number:	(Canada) 905-709-1726
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Contact Person:	Dr. Harold Wodlinger
Date Summary Prepared:	July 16, 1997

A. Device Name and Classification

1) Device Trade Name:
EPXpress System (Timberwolf Revision)

2) Device Common Name:
Physiological Monitoring System

3) Device Classification Names

870.2340	Electrocardiograph
870.2050	Biopotential Amplifier and Signal Conditioner
870.1425	Programmable Diagnostic Computer
870.1110	Blood Pressure Computer
870.2450	Medical Cathode Ray Tube Display
870.2810	Paper Chart Recorder

B. Predicate Device

The legally marketed device to which we claim equivalence is the PE Electrophysiology Lab System and CardioLab Amplifier Module both manufactured by Prucka Engineering, Inc. . The 510(k) numbers for these devices are K902716 and K910307, respectively. Additionally, we claim equivalence to the Quinton Q-Cath System manufactured by Quinton Instrument Company. The 510(k) number for this device is K862740.

C. Device Description

The EPXpress System (Timberwolf Revision) is an integrated catheter switching amplification and display system that can be installed at the patient table in the electrophysiology lab or moved to other locations where particular procedures may require its use. The system is made up of the EPAmp, Real-Time Controller, and monitor that are usually mounted on a cart. The EPAmp unit amplifies and conditions electrical signals from intracardiac catheters and displays these signals on a real-time monitor and/or prints these results to a chart recorder. The Timberwolf Revision added the capability of numerically displaying diastolic, systolic and mean blood pressures, as well as heart rate, cycle length, and certain measurement data received from other instruments.

D. Intended Use of Device

The intended use of the Quinton Electrophysiology Corporation's EPXpress System (Timberwolf Revision) is the acquisition, amplification, display, recording, and transmission of electrical signals of biological origin obtained during physiological studies and related procedures. Such signals include ECG, intracardiac ECG, and blood pressure. Physiological parameters as diastolic, systolic, and mean blood pressure, heart rate, and cycle length may be derived from these signals and displayed numerically, recorded, and/or transmitted. Additionally, the EPXpress System may acquire, transpose, amplify, display, record and transmit measurement data received from other medical devices typically used during these procedures, such as oximeters, RF generators, or electrical thermometers.

E. Summary of Technological Characteristics Compared with the Predicate Device

The EPXpress System (Timberwolf Revision) and the predicate devices described above have amplifiers which condition incoming physiological signals. The physiological signals acquired by the EPXpress and the predicate devices include ECG, intracardiac ECG, and blood pressure. Both the EPXpress and the predicate devices may display this physiological data on a monitor or the data may be printed out on chart recorder. All systems use a mobile cart for transport and have similar power and environmental requirements. The predicate devices have hardware and software which allow for the analysis of the physiological signals. The EPXpress System does not have this capability other than the ability to transform certain waveform data into numerial displays (Timberwolf Revision). (The analysis function is supplied by the EPLab System working in conjunction with the EPXpress System)

F. Performance Testing and Conclusions

1) Performance Testing

Performance testing was an equivalence study comparing blood pressure measurements taken and numerically displayed by the EPXpress System (Timberwolf Revision) with blood pressure measurements obtained and displayed in a similar fashion by a predicate device, the Quinton Q-Cath Monitoring and Analysis System. The study was a prospective paired comparison of measurements done using a controlled, repeatable simulated input. Measurement values were selected from the range of available, pre-set values provided by a simulator. The measurement values covered the specified range for the EPXpress System (i.e. 0-300 mmHg systolic and mean, -30 to 300 mmHg diastolic) using dynamic IVBP waveforms - left ventricular, aortic, left arterial, pulmonary capillary wedge, and pulmonary arterial waveforms. This range of waveforms provided low, medium, and high values for systolic, diastolic, and mean pressures.

It was formulated that the EPXpress System (Timberwolf Revision) would be considered subtantially equivalent to its predicate device with respect to IVBP measurements if it could be shown at the 0.05 confidence level that the mean difference between each pair of diastolic, systolic, and mean measurements is less than +/- 2 mmHg.

2) Conclusions

The study results met the above criteria for substantial equivalence. Using a +/- 5% equivalence region, the study results showed that the Timberwolf can be regarded as equivalent to Q-Cath at the 95% confidence level (i.e., 0.05 significance level) for phasic IVBP systolic, diastolic, and mean pressure measurements in the range of 0-300 mmHg.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Quinton Electrophysiology Corporation
c/o Mr. Matt Hedlund
Regulatory Coordinator
Quinton Instrument Company
3303 Monte Villa Parkway
Bothell, Washington 98021-8906

DEC 29 1997

Re: K971570
The EPXpress System (Timberwolf Revision)
Regulatory Class: II (two)
Product Code: 74 DRR
Dated: September 26, 1997
Received: October 2, 1997

Dear Mr. Hedlund:

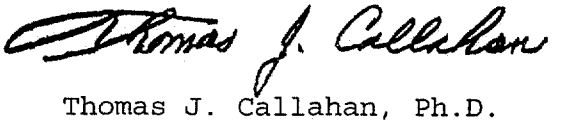
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

510(k) Number (if known): K971570

Device Name: EPXpress System (Timberwolf Revision)

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971570

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)