

K972121

510(k) Summary

NOV - 7 1997

In compliance with section 21 CFR 807.92, this document comprises a 510(k) Summary for K972121.

Submitter: Protocol Systems, Inc.
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Contact Persons: James P. Welch, Vice President, Quality Systems (Primary)

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Date Prepared: June 4, 1997

Predicate Device: "Cardiac Central Station Monitor with ST Segment Analysis" (PCI Model 2041-PC/ST, Pacific Communications, Inc. (PCI, now VitalCom), 510(k) Number K925411/A)

Device Name: Acuity Central Station

Classification Name: System, ECG Analysis (ST), Class III under section 513 of the Federal Food, Drug and Cosmetic (FD&C) Act, Panel 74 Cardiovascular, Product Code 74LOS, Federal Regulation Number 870.2340

Trade/Proprietary Name: Acuity Central Station

Common/Usual Name: Cardiac ECG ST Analysis Central Station Monitor



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 1997

Mr. James P. Welch
Protocol Systems, Inc.
8500 S.W. Creekside Place
Beaverton, Oregon 97008-7107

Re: K972121
Acuity Central Station Monitor
Regulatory Class: III (three)
Product Code: 74 MLD
Dated: September 5, 1997
Received: September 8, 1997

Dear Mr. Welch:

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.

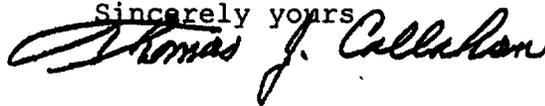
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. James P. Welch

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): K972121

Device Name: Acuity Central Station, Cardiac ECG ST Analysis Central Station Monitor

Indications For Use:

The Acuity ST Analysis option is being incorporated into the Acuity central station (licensed with Arrhythmia and Full Disclosure) as part of a network system within the hospital environment or clinical setting. The ST Analysis option is intended to be used to provide real-time monitoring and alarms for ST segment deviations (from a reference beat) for patients with suspected heart disease or anomalies.

It is recommended for use with Adult and Pediatric patients one year or older. ST Analysis is automatically disabled when the corresponding Propaq Encore is in the Neonatal patient mode.

It is intended for use by healthcare practitioners who know how to acquire and interpret patients' vital signs and are trained in the use of the Acuity System and its components. The clinician is responsible for determining the clinical significance of each alarm generated by Acuity. As with all computerized ST Analysis systems, Acuity cannot replace skilled care and proper surveillance by a clinician. A clinician should review all data obtained from Acuity before implementing therapy based on this data.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy Foreman for AAC

Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K972121



Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____