

K964978

MAY 21 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: April 11, 1997

A. Device Name and Classification

- 1) Device Trade Name:
Vital Statistics System (Q-Cath Accessory)
- 2) Device Common Name:
Physiological Monitoring and Analysis System
- 3) Device Classification Names
870.2700 Oximeter
870.1130 Noninvasive Blood Pressure Measurement System

B. Predicate Device

The legally marketed device to which we claim equivalence is the Nellcor Puritan Bennett *N-180 Pulse Oximeter* and the Colin Medical Instrument *BP-508 Patient Monitor (PILOT model No. 9200)*. The 510(k) numbers for these devices are K913695 and K922668, respectively.

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C. Device Description

The Vital Statistics System (VSS) is an accessory to the Quinton Q-Cath catheterization analysis system. The purpose of the VSS is to acquire, calculate, and transmit physiological data as blood pressure (acquired non-invasively), blood oxygen saturation data, and heart rate to the Q-Cath during cardiac cath procedures. Additionally, the VSS has 'pass-through' input and output connections for the purposes of acquiring and transmitting low voltage signal data to the Q-Cath from external devices and from the Q-Cath Signal Conditioning System component. Set-up of the VSS modules occurs at the Q-Cath via software controls.

The VSS is made up of a 3" x 20" x 12" metal enclosure that has compartments for insertion of the non-invasive blood pressure module, SP02 module, and two pass-through modules. A power supply within the device is capable of converting line voltage to regulated low voltage needed by the modules. The VSS weighs 35 lbs when all modules are in place within the VSS.

D. Intended Use of Device

The intended use of the Quinton Vital Statistics System (Q-Cath Accessory) is the acquisition, calculation, and transmission of physiological parameters as diastolic and systolic blood pressure, blood oxygen saturation levels, and heart rate to the Quinton Q-Cath during cardiac cath procedures.

E. Summary of Technological Characteristics Compared with the Predicate Device

The NIBP and SP02 modules are manufactured by Nellcor Puritan Bennett and Colin Medical, respectively. These modules are modifications of the devices that are used as the predicate devices in this 510k notification, as referenced in Section B, supra. The SP02 module acquires, calculates, and transmits oximetry and heart rate data as the Nellcor N-180. The SP02 and heart rate measurement system in the module and in the N-180 are 'equivalent' within certain statistical parameters. [See 'Performance Test and Conclusions' in Section F, infra.] Differences between the Nellcor N-180 and the VSS SP02 module are that the N-180 is a self-contained unit having controls, alarms, and a display. For the VSS module these features are contained on the Q-Cath. The VSS NIBP module acquires, calculates, and transmits diastolic and systolic blood pressure and heart rate data, as the Colin BP-508. The blood pressure and heart rate measurement system in the module and in the BP-508 are 'equivalent' within certain statistical parameters. [See 'Performance Test and Conclusions' in Section F, infra.] Differences between the Colin BP-508 and

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

the VSS NIBP module are that the BP-508 is a self-contained unit having controls, alarms, and a display. For the VSS NIBP module these features are contained on the Q-Cath. Additionally, the BP-508 has measurement and recording capability covering ECG, invasive blood pressure, SP02, tonometry blood pressure, and C02. These features are not on the VSS NIBP module.

F. Performance Testing and Conclusions

1) Performance Testing

Performance testing was an equivalence study comparing blood pressure measurements and heart rate obtained by the VSS NIBP module with blood pressure measurements and heart rate obtained by the predicate device, the Colin BP-508 NIBP monitor, over both adult and neonate modes. Randomized simulated oscillometric NIBP and HR outputs over the specified range of both the NIBP module and the predicate device were obtained from a NIBP simulator. The test was conducted by the VSS NIBP module taking blood pressure and heart rate measurements from the simulator for a certain number of randomized samples. This was then repeated for the predicate device at the same blood pressure levels and heart rate. The number of randomized blood pressure, heart rate samples chosen were such that a meaningful statistical analysis and conclusion could be reached.

The SP02 performance testing was conducted in a similar fashion. Randomized simulated SP02 and HR outputs over the specified range of both the SP02 module and the Nellcor N-180 Pulse Oximeter were obtained from a SP02 simulator. The test was conducted by the VSS SP02 module taking SP02 data and heart rate measurements from the simulator for a certain number of randomized samples. This was then repeated for the predicate device at the same SP02 levels and heart rate. The number of randomized blood pressure, heart rate samples chosen were such that a meaningful statistical analysis and conclusion could be reached.

It was formulated that both modules would be considered substantially equivalent to their respective predicate devices if it could be shown at the 0.05 confidence level that the mean percentage difference between each pair of measurements taken by the devices being compared is less than 5%.

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F. Performance Testing and Conclusions (Continued)

2) Conclusions

Using a +/- 5% equivalence region, the study results showed the following:

- The VSS NIBP module operating in adult mode can be regarded as equivalent to the Colin BP-508 at the 95% confidence level (e.g., 0.05 significance level);**
- The VSS NIBP module operating in neonate mode can be regarded as equivalent to the Colin BP-508 at the 95% confidence level; and**
- The VSS SP02 module can be regarded as equivalent to the Nellcor N-180 pulse oximeter at the 95% confidence level.**



MAY 21 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K964978
Vital Statistics System (Q-Cath Accessory)
Regulatory Class: II (two)
Product Code: 73 DQA
Dated: April 15, 1997
Received: April 17, 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 2 - 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.

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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) 594-4646. 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): K96 4978

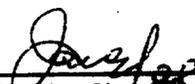
Device Name: Vital Statistics System (Q-Cath Accessory)

Indications For Use:

The intended use of the Quinton Vital Statistics System (Q-Cath Accessory) is the acquisition, calculation, and transmission of physiological parameters as diastolic and systolic blood pressure, blood oxygen saturation levels, and heart rate to the Quinton Q-Cath during cardiac cath procedures.

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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 K964978

Prescription Use X
Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

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(Optional Format 1-2-96)