OCT 2 8 1999

K993245

Attachment 4

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Submitted by:

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Contact: Ted Vander Wiede
Managing Director, Alba Critical Care Ltd.

Date of summary: 27th September 1999

Device Information:

Trade Name: Continuous Cardiac Output Pulmonary Artery Catheter and Continuous Cardiac Output Monitor

Common Name: Pulmonary Artery Catheter and Cardiac Output Monitor

Classification Name: Flow-directed catheter and Single-function, pre-programmed diagnostic computer per 21 CFR 870.1240 and 870.1435 respectively

Predicate Device: The modified device is substantially equivalent to the previously cleared Ami-MED Continuous Cardiac Output Pulmonary Artery Catheter and Continuous Cardiac Output Monitor, 510(k) number K925444

Device Description: The Continuous Cardiac Output Pulmonary Artery Catheter, (catalogue # TruCATH), is a six-lumen, heparin-coated, polyvinyl chloride (PVC) flow-directed Pulmonary Artery Catheter. Once placed, the proximal

extensions of the catheter are attached to the second part of the system, the Monitor.

The Continuous Cardiac Output Monitor, (catalogue # TruCCOM), is a microprocessor-based computer which, when interfaced with the TruCATH, continuously calculates and displays cardiac output. The Monitor calculates cardiac output based on the thermodynamic principle of heat transfer using thermal power produced by the thermal coil area on the Catheter. Alternatively, the monitor can also be used by the clinician to measure cardiac output intermittently through using the injectate capabilities of the catheter.

Intended Use:

The Continuous Cardiac Output Pulmonary Artery Catheter and Continuous Cardiac Output Monitor system's intended use is for the assessment of a patient's haemodynamic condition through direct intracardiac (right heart) and pulmonary artery pressure monitoring, cardiac output determination and for infusing solutions. The distal port on the catheter also allows for sampling of venous blood.

Comparison to Predicate Device:

The modifications in comparison with the previously cleared device are as follows (these modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device):

a) Catheter

i. Re-position the heat transfer device (HTD) to assist the user in correctly positioning the HTD.

ii. Change to a more flexible material for the extension tubes.

iii. Change the solvent used to bond the luer locks to provide a better bond.

b) Monitor

i. Change in mechanical display

ii. Changes in user interface software

These changes improved the elecromagnetic compatibility (EMC) performance of the monitor.

Summary of non-Clinical Tests:

The following outlines the testing performed, as a result of the risk analysis, to demonstrate substantial equivalence to the predicate device:

a) Catheter

i. Functional Bench Testing
ii. Functional and visual testing
iii. Pull test

b) Monitor

i. Electromagnetic compatibility testing
ii. Software validation

Conclusion:

The above test results confirmed that the modified device met the same specifications as the predicate device, and is therefore substantially equivalent with respect to safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 1999

Mr. Ted Vander Wiede
Managing Director
Alba Critical Care Limited
Phoenix Crescent
Strathclyde Business Park
Bellshill
SCOTLAND ML4 3NJ

Re: K993245
Continuous Cardiac Output Pulmonary Artery Catheter and Continous Cardiac Output Monitor
Regulatory Class: II (Two)
Product Code: 74 DYG, 74 KFN
Dated: September 27, 1999
Received: September 28, 1999

Dear Mr. Vander Wiede

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 legally marketed predicate 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known): K993245 ~~K925444~~

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Device Name:_____

INDICATIONS FOR USE STATEMENT

510(k) number (original): ~~K925444~~ K993245

Device Name: Continuous Cardiac Output Pulmonary Artery Catheter and Continuous Cardiac Output Monitor

Indications For Use:

The Continuous Cardiac Output Pulmonary Artery Catheter and Continuous Cardiac Output Monitor system's intended use is for the assessment of a patient's haemodynamic condition through direct intracardiac (right heart) and pulmonary artery pressure monitoring, cardiac output determination and for infusing solutions. The distal port on the catheter also allows for sampling of venous blood.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas Skelton Acting

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number ~~K925444~~ K993245

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)