

K955816

Appendix I

MAY - 6 1997 510(k) Summary

Product (Trade) Name

Vigilance Continuous Cardiac Output/Oximetry (CCO/SvO₂) Monitor

Model Number: VGS

Common, Usual or Classification Name

Cardiac Output/Dual Oximeter/Ejection Fraction Computer

Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435)

Device Classification

This generic device has been classified as Class II by the Circulatory Systems Devices Panel.

Reason for Submission

Baxter intends to market a modified version of the Vigilance CCO/SvO₂ Monitor. The software algorithm in the monitor has been modified to enhance the CCO estimation process. No change has been made to other functions of the monitor system or to the hardware.

Predicate Device Identification

The Vigilance CCO/SvO₂ Monitor is substantially equivalent to the Vigilance CCO/SvO₂ Monitor which was cleared for marketing under premarket notifications K924452 and K940795.

Compliance with 513/514

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act.

General Description, Components and Specifications

The Vigilance CCO/SvO₂ Monitor is a microprocessor-based instrument which, when connected to a Baxter thermodilution catheter, measures mixed venous oxygen saturation and cardiac output both continuously (CCO) and by the intermittent bolus (injectate) method (ICO). The Vigilance monitor measures cardiac output continuously by injecting small pulses of electrical power into the blood and recording the corresponding blood temperature changes via the catheter. The software based CCO algorithm within the monitor converts these

power and blood temperature measurements into an estimate of cardiac output. The Vigilance instrument displays the cardiac output in two modes:

1. The Standard (or trend) CCO monitoring user interface is an historical trend plot (i.e., cardiac output vs. time) that allows the user to see the trend of the CCO values over a period of time.
2. The STAT mode CCO display is a numeric presentation of the last ten STAT mode cardiac output estimates.

The Vigilance CCO/SvO₂ Monitor that is the subject of this premarket notification varies from the predicate device in that it contains modifications to the CCO algorithm. These modifications enhance the CCO estimation process.

No change has been made to other functions or features of the monitor system or to the monitor's components or hardware. In addition, the specifications for the software defined in the Operator's Manual have not changed as a result of this software modification.

Comparative Information

Labeling

The labels for the Vigilance CCO/SvO₂ Monitor have not changed as a result of the algorithm modification. However, modifications have been made to the Operator's Manual.

Intended Use

The Vigilance CCO/SvO₂ Monitor is intended to measure both bolus/injectate and continuous cardiac output in addition to mixed venous oxygen saturation. The system also calculates hemodynamic and oxygenation parameters. The intended use of this monitor has not been changed with the modification to the algorithm that is the subject of this premarket notification and is the same as that of the predicate device.

Physical Characteristics

The physical characteristics/hardware of the Vigilance CCO/SvO₂ Monitor have not changed as a result of the algorithm modification. No changes have been made to the circuit components or connectors for the monitors. The CCO specifications provided in the operator's manual have not changed. The changes made to the device are only in the algorithm to enhance CCO processing.

Anatomical Sites

The Vigilance CCO/SvO₂ Monitor is connected to a thermodilution catheter which is placed in the pulmonary artery for right heart and pulmonary artery hemodynamic measurements. The site of use is the same as that for the predicate device.

Target Population

The target population for this product includes patients who require hemodynamic monitoring. The target population is the same as that for the predicate device.

Performance Testing

1. Bench Testing

Bench testing was performed to show that the software requirements were met and that the modified Vigilance CCO/SvO₂ Monitor performs comparably to the unmodified (predicate) device. The reproducibility and response time of the modified Vigilance CCO software, as well as the ability of the monitor to adapt to external noise, were evaluated in a hydro flow model system and were compared against the previous software version (predicate device).

The results of the bench testing demonstrate that the modified Baxter Vigilance CCO/SvO₂ Monitor meets the performance requirements and its performance is comparable to the predicate device.

2. Animal Testing

The performance of the modified Vigilance CCO/SvO₂ Monitor was demonstrated in the bench testing above. Evaluation of the device using two sheep was conducted to further verify the performance of the CCO algorithm in a simulated clinical environment. The results of the testing demonstrate that the STAT and trend CCO estimates perform as required.

3. Clinical Testing

The modifications in the software algorithm were evaluated on the bench and *in vivo*. These evaluations demonstrated that the modified algorithm performs as required and is substantially equivalent to the unmodified/predicate device. Clinical evaluation of the product is not considered to be necessary for this change.

Safety Characteristics

The testing presented for the modified product demonstrates that the Vigilance CCO/SvO₂ Monitor is comparable to the predicate device in safety characteristics.

Software Validation and Verification

Hazard Analysis

Hazard analysis of the software modifications was conducted to evaluate the effect of the changes on the safety of the product. The hazard analysis evaluated the potential hazardous events, their cause, level of concern and method of control/corrective action. All hazards were reviewed and, where appropriate, testing was performed to ensure that the applicable corrective action occurs.

Level of Concern

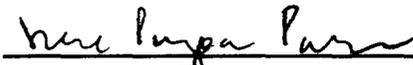
This device has been determined to have a moderate level of concern based on the intended use and potential hazards of the device. The level of concern for the modified components of the software is identified in the Hazard Analysis. The components were determined to be of moderate or minor concern.

Development Documentation

Development of software at Baxter is conducted in accordance with Baxter's procedure for software development which lists the requirements for the life cycle of software. All components of the software cycle were documented and tested appropriately. The protocol and results for testing were documented and approved by all appropriate functional departments including Quality Engineering. Design reviews were conducted as required throughout the development cycle. Prior to initiating use of the modified software in production, a Document Change Request will be generated listing the changes made to the device and a justification for the changes. These changes will require the approval of the software R&D engineer and representatives from Quality Engineering, Regulatory Affairs and Manufacturing Engineering in accordance with Baxter procedures to ensure that all requirements have been met for the change.

Summary

The physical characteristics of the modified Vigilance CCO/SvO₂ Monitor have not changed. The modifications in the software algorithm were evaluated on the bench and *in vivo*. These evaluations demonstrated that the modified algorithm performs as required and is substantially equivalent to the unmodified/predicate device.



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