

## Section II. Safety and Effectiveness Summary (SMDA Requirement)

### A. Safety and Effectiveness Summary

#### 1. Determination of Substantial Equivalence

The CCO/SvO<sub>2</sub>/VIP™/REF Catheter is substantially equivalent to the CCO/SvO<sub>2</sub>/VIP™ Catheter (K934742) and the REF Catheter (K896466) in that the CCO/SvO<sub>2</sub>/VIP™/REF Catheter combines the intended uses of the two predicate devices. Furthermore, substantial equivalence is based upon the fact that the CCO/SvO<sub>2</sub>/VIP™/REF Catheter is equivalent to the CCO/SvO<sub>2</sub>/VIP™ Catheter in construction, materials, components, and functional specifications, in addition to meeting the minimum thermistor response time specification required of thermodilution catheters that are indicated for REF measurement. The CCO/SvO<sub>2</sub>/VIP™/REF Catheter is also substantially equivalent to the Oximetry PACEPORT Catheter (K905458) in its use of tantalum markers to assist in catheter positioning with the use of fluoroscope. Because all aspects of the intended use, manufacture, and functional specifications of the CCO/SvO<sub>2</sub>/VIP™/REF Catheter can be deemed equivalent to that of the predicate devices, the safety and efficacy of the CCO/SvO<sub>2</sub>/VIP™/REF Catheter are similarly equivalent.

#### 2. Device Name

Swan-Ganz® Continuous Cardiac Output/Oximetry/Venous Infusion Port/REF Thermodilution Catheter (CCO/SvO<sub>2</sub>/VIP™/REF Catheter)

#### 3. Predicate Device(s)

The following devices are those upon which the claim of substantial equivalence is based:

- Swan-Ganz® Continuous Cardiac Output/Oximetry/Venous Infusion Port (CCO/SvO<sub>2</sub>/VIP™) Thermodilution Catheter, 510(k) No. K934742 [subsequently referred to as the CCO/SvO<sub>2</sub>/VIP™ Catheter] - substantial equivalence is based upon materials, performance specifications, design, and intended use.
- Swan-Ganz® Thermodilution Ejection Fraction/Volumetric Catheter, 510(k) No. K896466 [subsequently referred to as the REF Catheter] - substantial equivalence is based upon the indication for use in REF measurement.
- Swan-Ganz® Oximetry PACEPORT Catheter, 510(k) No. K905458 [subsequently referred to as the Oximetry PACEPORT Catheter] - substantial equivalence is based upon the use of tantalum markers to assist in catheter positioning under fluoroscope.

#### 4. Device Description

Like the predicate devices, the CCO/SvO<sub>2</sub>/VIP™/REF Catheter is a single-use, flow-directed pulmonary artery thermodilution catheter with a useable length of 110 cm. Like the CCO/SvO<sub>2</sub>/VIP™ Catheter, the CCO/SvO<sub>2</sub>/VIP™/REF Catheter is constructed from an 8 French, seven-lumen, radiopaque, plasticized polyvinyl chloride (PVC) extrusion, and is packaged in a barrier tray which is placed into a pouch, and the entire package is sterilized with 100% ethylene oxide gas.

#### 5. Intended Use of Device

The CCO/SvO<sub>2</sub>/VIP™/REF Catheter is used for continuous cardiac output (CCO) measurement when used with a Vigilance Monitor, mixed venous oxygen saturation (SvO<sub>2</sub>) monitoring when used with an Explorer, SAT-2 or Vigilance Monitor, right ventricular ejection fraction (REF) determinations when used with an Explorer or REF-1 Monitor, thermodilution cardiac output measurement when used with a Vigilance, Explorer, COM-2, REF-1, SAT-2, or 9520A monitor, hemodynamic pressure monitoring, blood sampling, and infusion of saline and dextrose solutions.

#### 6. Intended Use of Predicate Device(s)

The CCO/SvO<sub>2</sub>/VIP™ Catheter is used for continuous cardiac output (CCO) measurement when used with a Vigilance Monitor, mixed venous oxygen saturation (SvO<sub>2</sub>) monitoring when used with an Explorer, SAT-2 or Vigilance Monitor, thermodilution cardiac output measurement when used with a Vigilance, Explorer, COM-2, REF-1, SAT-2, or 9520A monitor, hemodynamic pressure monitoring, blood sampling, and infusion of saline and dextrose solutions.

The REF Catheter is used for right ventricular ejection fraction (REF) determinations when used with an Explorer or REF-1 Monitor, thermodilution cardiac output measurement when used with a Vigilance, Explorer, COM-2, REF-1, SAT-2, or 9520A monitor, hemodynamic pressure monitoring, blood sampling, and infusion of saline and dextrose solutions.

The Oximetry Paceport Catheter is used for mixed venous oxygen saturation (SvO<sub>2</sub>) monitoring when used with an Explorer, SAT-2 or Vigilance Monitor, thermodilution cardiac output measurement when used with a Vigilance, Explorer, COM-2, REF-1, SAT-2, or 9520A monitor, temporary transvenous pacing, hemodynamic pressure monitoring, blood sampling, and infusion of saline and dextrose solutions. However, substantial equivalence of the CCO/SvO<sub>2</sub>/VIP™/REF Catheter to the Oximetry Paceport Catheter is based on the use of tantalum markers to assist in catheter positioning with the use of fluoroscope.

#### 7. Technological Comparison of the CCO/SvO<sub>2</sub>/VIP™/REF Catheter and the Predicate Devices

The CCO/SvO<sub>2</sub>/VIP™/REF Catheter is equivalent to the CCO/SvO<sub>2</sub>/VIP™ Catheter in components, materials, construction, and performance specifications. Furthermore, the CCO/SvO<sub>2</sub>/VIP™/REF Catheter thermistor meets the minimum thermistor response time specification for REF measurement. Additionally, the CCO/SvO<sub>2</sub>/VIP™/REF Catheter incorporates tantalum markers like those used in the Oximetry Paceport Catheter to assist in catheter positioning with the use of fluoroscope. All components and materials have been deemed *biocompatible* and chemically acceptable and are, thus, safe and effective for the catheter's intended use.

#### 8. Discussion of Non-Clinical Tests and Conclusions

The following non-clinical testing information for the CCO/SvO<sub>2</sub>/VIP™/REF Catheter is included in this submission:

- . biocompatibility/chemical acceptability testing,
- . performance/packaging testing, and
- sterilization testing

Because the CCO/SvO<sub>2</sub>/VIP™/REF Catheter is equivalent to the predicate devices in construction, materials, performance, packaging, and sterilization, the testing listed above was not repeated as the predicate device testing is applicable to the equivalent device. All acceptance criteria for the testing was met. The biocompatibility/chemical acceptability test methods and results are contained in Appendix 1. The performance and packaging test protocol and results are contained in Appendix II. The sterilization test methods and results are contained in Appendix III. Further discussion of this testing appears in Section V, subpart E of this submission.

Because the injectate port on the CCO/SvO<sub>2</sub>/VIP™/REF Catheter is a single-hole configuration located at 26 cm as compared to the multi-hole configuration located at 21 cm on previously marketed REF Catheters, additional non-clinical testing was performed to analyze the impact of injectate port location on the reliability of REF measurements. As was anticipated from the findings of Dr. Francis Spinale, the injectate port location on the catheter relative to the tip or thermistor did not impact REF measurement with any statistical significance. As the following summary of Dr. Spinale's study demonstrates, properly positioning the injectate port in the right atrium is more critical to obtaining reliable REF measurements than the distance from the injectate port to the thermistor:

Dr. Spinale performed porcine model testing to demonstrate the impact of injectate port-to-tricuspid valve distance and thermistor-to-pulmonic valve distance on REF measurement. In his evaluation, Dr. Spinale determined that "in large hearts [a large animal model with an RV geometry similar to humans], the rapid-response thermistor mounted on the RV thermodilution catheter can be positioned over a wide range of pulmonic valve to thermistor distances without significantly affecting RVEF [REF] measurements. 1. Dr. Spinale goes on to say that, "optimal catheter positioning occurs when the injectate port is located within the main body of the right atrium."

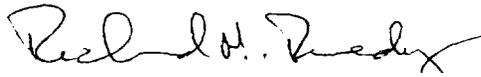
Dr. Spinale's study shows that, given two catheters with thermistors mounted at the same position relative to the catheter distal tip, one catheter with the injectate port located at 26 cm would provide statistically similar REF measurements to another catheter with the injectate port located 21 cm provided that the injectate ports are properly positioned in the right atrium. Hence, the increased distance from the injectate port to the catheter distal tip (i.e. from 21 cm to 26 cm) and, consequently, from the injectate port to the thermistor, does not compromise the catheter's ability to measure REF given the flexibility of thermistor placement in the PA that is illustrated in Dr. Spinale's study. Rather, it is proper positioning of the injectate port in the right atrium that is more critical. The package insert for the CCO/SvO<sub>2</sub>/VIP™/REF Catheter and the predicate devices instructs the clinician to position the injectate port in the right atrium as Dr. Spinale's study suggests. Refer to Appendix IV for a copy of Dr. Spinale's article.

An in vitro qualification of the CCO/SvO<sub>2</sub>/VIP™/REF Catheter was also performed on a pulsatile flow bench to evaluate REF measurement accuracy when using a catheter configured with the single-hole, 26 cm injectate port. Four catheters (two REF

prototypes and two CCO/SvO<sub>2</sub>/VIP™/REF Catheters) were randomly assigned to four REF-compatible monitors. The response time of each catheter was measured prior to testing to ensure that the thermistors met the minimum response time specification. The **pulsatile** flow bench simulated a pre-determined range of **hemodynamic** parameters which allowed a comparison of the standard REF **injectate** port (24 cm, multi-hole) with the **injectate** port on a CCO/SvO<sub>2</sub>/VIP™/REF Catheter (26 cm, **single**-hole) in effectively equivalent **hemodynamic** states. The testing established that there was no statistical difference between the port configurations. The bench test protocol and results are in Appendix V.

#### 9. Summary of Safety and Efficacy

The battery of non-clinical tests discussed above demonstrates that, like the predicate devices, the CCO/SvO<sub>2</sub>/VIP™/REF Catheter is safe and effective for its intended use.



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