Appendix I

510(k) Summary

A. Determination of Substantial Equivalence

The Intramed® Side Branch Occlusion (SBO) System is substantially equivalent to the CRI Vessel Occlusion System/CRI Occlusion Coil, which was cleared for marketing under premarket notification K914523. The angioscope in the Introducer Catheter is substantially equivalent to the Intramed® .7 mm Passive Angioscope, which was cleared for marketing under K894459.

B. Device Name

Intramed® Side Branch Occlusion System, Models 700095 and 700098

C. Predicate Device

The claim of substantial equivalence is based on the following devices:

- CRI Vessel Occlusion System/CRI Occlusion Coil, 510(k) No. K914523
- Intramed® .7 mm Passive Angioscope, 510(k) No. K894459

D. Device Description

The Intramed® SBO System, like the CRI Occlusion System, was developed for the intravascular delivery and placement of occlusion coils into tributaries during *in situ* saphenous vein bypass graft procedures. The system includes (1) a Coil Delivery Catheter, which is preloaded with an occlusion coil, and (2) an Introducer Catheter, which is used to visualize the side branches and mechanically direct the Coil Delivery Catheter into the side branch for occlusion.

The Coil Delivery Catheter consists of a flexible catheter shaft with an occlusion coil positioned in the distal portion of the catheter lumen. A guide wire is contained within the inner shaft immediately proximal to the occlusion coil. At the proximal end of the catheter, this guide wire connects to a plunger mechanism. When the plunger is depressed, the guide wire pushes the coil out of the catheter and into the side branch for occlusion.

The occlusion coil provided with the Intramed® SBO System is purchased from Cook Incorporated. This product is a preamendment device that has been commercially distributed for vessel occlusion/embolization applications. The use of this coil in the Intramed® SBO System is within the intended use of the occlusion coils as marketed by Cook Incorporated.

The Introducer Catheter has a composite shaft with two lumens. One lumen contains a miniature diameter angioscope with self-contained optics for visualization during the procedure. The other lumen is used to pass the Coil Delivery Catheter to the site of the side branch to be occluded. The catheter has an actuator handle to advance or retract the angioscope by a small amount to provide visualization of the vessel when the angioscope is in the extended position and visualization of the tributary when in the retracted position. The proximal end of the catheter consists of a coil catheter receiver as well as an eyepiece and light source connector for the angioscope.

E. Intended Use of Device

The Intramed® SBO System is intended for the intravascular delivery and placement of occlusion coils into tributaries during *in situ* saphenous vein bypass graft procedures. The angioscope within the Introducer Catheter is intended to be used for vessel visualization, specifically to visualize the lumen of the saphenous vein during the *in situ* procedures.

F. Intended Use of Predicate Device

The CRI Vessel Occlusion System is intended for the intravascular delivery and placement of occlusion coils into tributaries during *in situ* saphenous vein bypass graft procedures. The Intramed® .7 mm Passive Angioscope is intended to be used for visualization of peripheral vasculature.

G. Technological Comparison of the Intramed® SBO System and the Predicate Device

The Intramed® SBO System is similar to the CRI System in the type of system components and mode of operation. Both systems include (1) a coil, (2) a delivery catheter through which the coil is inserted into the tributary and (3) a catheter through which the coil delivery catheter and coil are directed/steered into the tributary. The systems are both used intraoperatively and the use of both systems entails locating the tributary, directing the coil delivery catheter into the tributary and injecting the coil into the tributary. The coils in both systems are intended to cause a thrombus to form in the tributary, thereby occluding the tributary and preventing formation of an arteriovenous fistula in the grafted vessel. Overall, the mode of operation is the same for the two products.

The Intramed® SBO and CRI systems have some differences in materials and mechanics. The coils used with both systems are made of metal but the SBO coil also contains attached synthetic fibers. Both coils have been demonstrated to adequately occlude vessels in the clinical environment. The mechanisms by which the catheter systems direct the delivery catheters and, therefore, the coils, into the tributary are also somewhat different. The Intramed® SBO System mechanically directs the coil; that is, the tip of the Introducer Catheter is angioscopically aimed at the tributary so that the path of the Coil Delivery Catheter is directed into the tributary. The CRI system utilizes a steerable catheter whose tip is manipulated via

a control system, thereby aiming or steering the delivery catheter into the tributary. In addition, the CRI coils are ejected hydraulically, while the Intramed® SBO System catheter injects the coil mechanically via a guide wire/plunger. Finally, as indicated previously, the Intramed® SBO System contains an integral angioscope that aids in both locating the side branch and in directing the delivery catheter and coil into the side branch. The CRI system requires the use of an external angioscopic device or fluoroscopy in locating the side branches and aiming the delivery catheter. These differences in design of the systems do not affect the intended use or indication for use of the product, nor do they affect the similarities in the general operation of the systems. As indicated previously, both systems function similarly; the introducer catheter passes down the saphenous vein, directs the coil delivery catheter into the side branches of the vein and occlusion coils are deployed through the delivery catheters into the side branches.

The angioscope used in the Intramed® SBO System and the Intramed® .7 mm Passive Angioscope both consist of light and image transmitting borosilicate fiber bundles contained within the angioscope body. The image is transmitted through the fibers to an eyepiece or focusing coupler and a camera system. The technology of the two products is equivalent as are the materials, device characteristics and intended use.

H. Discussion of Non-Clinical Tests and Conclusions

The following non-clinical testing was performed on the Intramed® SBO System:

- biocompatibility testing
- functional/bench testing, and
- cadaver testing.

Biocompatibility testing was performed on the catheter samples in accordance with the requirements specified in ISO 10993 standard for Transient Contact Duration, Blood Path Direct, Externally Communicating Devices. The catheters and their materials were found to be biocompatible and nontoxic and acceptable for their intended use.

Functional testing was performed on the Intramed® SBO System to evaluate the integrity and performance of the device. The testing demonstrated that the product meets its performance requirements.

Evaluation of the product in cadavers was conducted to verify the product's performance in saphenous veins. The studies demonstrated that the Intramed® SBO System visualizes and identifies side branches and can place coils in appropriate side branches

I. Summary of Clinical Testing

Clinical evaluation of the Intramed® SBO System showed that it is as safe and effective as the CRI system for the delivery of occlusion coils during *in situ* saphenous vein bypass surgery.

J. Summary of Safety and Effectiveness

The above testing demonstrates that the Intramed® Side Branch Occlusion System is safe and effective for its intended use.

Irene Ponzoa Parker

Irene Ponzoa Parker, R.N., M.B.A.
Manager, Regulatory Affairs and Clinical Programs
Edwards Critical-Care and Vascular Systems Divisions