K955818

FoamSeal Retrograde Cardioplegia Catheter
510(k) Summary of Safety and Effectiveness

I. Device Name:

Classification Name:	Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Common/Usual Name:	Retrograde Cardioplegia Catheter
Proprietary Name:	FoamSeal Retrograde Cardioplegia Catheter

II. Predicate Devices:

FoamSeal Retrograde Cardioplegia Catheter - # K941916
Research Medical Retrograde Cardioplegia Catheter - K880103

III. Intended Use:

The FoamSeal Retrograde Cardioplegia Catheter is intended for use in perfusing cardioplegia solutions retrograde through the coronary sinus by means of transatrial introduction.

IV. Summary of Substantial Equivalence:

The proposed modified FoamSeal Retrograde Cardioplegia Catheter is identical to the original FoamSeal Retrograde Cardioplegia Catheter (marketed under 510(k) # K941916), with the exception of a more rigid guide stylet. Research Medical, Inc., markets a retrograde cardioplegia catheter (model # RC-014) under 510(k) # K880103. A comparison of the devices is shown in figure 1 below.

Stylet guide collapse testing was performed on the stylet guide from the proposed modified FoamSeal Retrograde Cardioplegia Catheter, and was compared to collapse values from the stylet guide used in the Research Medical retrograde cardioplegia catheter (Retroplegia® Cannula Model # RC-014, marketed under 510(k) # K880103). The purpose of this test was to evaluate the force that can be generated by the stylet before buckling occurs, thereby providing a means for comparing stylet rigidity.

Test results demonstrate that the modified FoamSeal Retrograde Cardioplegia Catheter stylet is less rigid than the Research Medical stylet, thereby presenting less of a potential for damage to the coronary sinus. We believe, therefore, that the modified device does not raise new questions of safety or effectiveness, and is substantially equivalent to legally marketed devices.

	Proposed Modified FRCC	Original FRCC # K941916	Research Medical RC-014 # K880103
Intended Use	Intra-operative delivery of cardioplegia solution	Intra-operative delivery of cardioplegia solution	Intra-operative delivery of cardioplegia solution
Material	Silicone catheter body & extension tube Stainless steel stylet Polycarbonate stopcock Polypropylene clamp Polycarbonate female luer connector Silicone balloon Polyurethane foam	Silicone catheter body & extension tube Stainless steel stylet Polycarbonate stopcock Polypropylene clamp Polycarbonate female luer connector Silicone balloon Polyurethane foam	PVC catheter body & extension tube Stainless steel stylet Polycarbonate/ polyethylene stopcock Polypropylene clamp PVC female luer connector Polyurethane balloon No foam
Packaging	Tyvek/polymylar	Tyvek/polymylar	Tyvek/paper
Sterilization	100% EtO	100% EtO	EtO
Biocompatibility	Tripartite	Tripartite	Unknown
Features	Foam-filled cuff/ auto inflating 15 fr.size Pressure monitoring port Pinch clamp on delivery lumen Suture ring Malleable stylet	Foam-filled cuff/ auto inflating 15 fr. size Pressure monitoring port Pinch clamp on delivery lumen Suture ring Flexible guidewire stylet	Self-inflating cuff 14 fr. size Pressure monitoring port Pinch clamp on delivery lumen Suture ring Malleable stylet

figure 1 - Comparison Table

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Date