

K961883

Ideas for Medicine, Inc.  
Versa-Cath Arterial Catheter  
510(k) Notification  
K961883

JAN 13 1997

**SAFETY and EFFECTIVENESS SUMMARY**

**PROPRIETARY NAME:**

Versa-Cath Arterial Catheter

**COMMON USUAL NAME:**

Embolectomy Catheter

**CLASSIFICATION:**

Class II

**CLASSIFICATION NUMBER:**

74 DXE

**DEVICE DESCRIPTION:**

**DESCRIPTION:**

The Versa-Cath Arterial Catheter is a dual lumen nylon tube with a natural latex balloon attached to a distal end. There are two stopcocks affixed to the proximal end, one for balloon inflation and the other for fluid irrigation and/or aspiration. It will be packaged with a syringe and a stylet. The syringe is a pre-amendment device and the stylet is marketed under 510(k) K832023. The catheter will be available in 5 sizes and 3 lengths.

The catheters are primarily intended for use in the removal of arterial emboli and thrombi during embolectomy and thrombectomy.

The catheter with the balloon deflated is advanced into the vessel and advanced beyond the obstruction. The balloon is inflated with sterile solution. The catheter is withdrawn pulling the embolism with it, thus removing it from the artery. The dual lumen design allows for a more versatile catheter. It can be used for injection of contrast media or heparinized saline, and/or irrigation and aspiration. The balloon when inflated can be used for vessel occlusion. Finally, it can be used for catheter placement over a guidewire.

The materials used on the Versa-Cath Arterial Catheters have been used for years on other models of Ideas for Medicine, Inc. catheters except the suture, which has been certified to USP grade. Other catheter materials have been certified to meet the requirements of USP Class VI tests. Every lot is supplied sterile and non-pyrogenic.

**SUBSTANTIAL EQUIVALENCE:**

The intended use of these devices is to remove arterial emboli and thrombi, vessel irrigation, aspiration and occlusion, perfusion and catheter placement using a guidewire. Both the Fogarty Thru-Lumen and Robicsek Angiography catheters have the same intended use.