

VII: 510(K) SUMMARY

Manufacturer: NAMIC USA Corporation
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Trade Name: Selector Angiographic Catheter

Common Name: Angiographic Catheter

Classification Name: Catheter, Angiographic
Catheter, Cardiovascular
Catheter, Intravascular, Diagnostic

Predicate Device: Selector Angiographic Catheter (K922552)

Intended Use:

The Selector Angiographic Catheter is intended to deliver contrast medium during angiography as well as to provide a conduit for various diagnostic and therapeutic procedures. Selector Angiographic Catheters are intended for single-patient use only.

Product Description:

The Selector Angiographic Catheter consists of a radiopaque shaft with an attached molded female luer lock hub. The shaft of the catheter includes a flexible section and an optional soft distal tip. The Selector Angiographic catheter may vary with respect to length, diameter, curve style, and the number of side holes present.

Selector Angiographic Catheters can be introduced into the selected blood vessel by either cutdown or percutaneous entry techniques.

VII. 510(K) Summary (Continued).

Comparison to Predicate Device:

The Selector Angiographic Catheter is equivalent to the currently marketed Selector Angiographic Catheter. The proposed new Selector Angiographic Catheter will be offered in a larger French size (diameter) than the currently marketed device.

The Selector Angiographic Catheter is manufactured in the same manner as the predicate device. Packaging and sterilization for the Selector Angiographic Catheter are the same as for other NAMIC devices.

Performance Testing:

The new Selector Angiographic Catheter has been subjected to non-clinical performance testing to provide data supporting the safety and effectiveness of the device. The test protocol included verification of tensile, dynamic pressure testing, flow rate, diameters, and radiopacity. The resultant data demonstrates that the device meets the required performance criteria.

Biocompatibility:

Biocompatibility testing has been performed on the currently marketed Selector Angiographic Catheter (K922552). The material composition of the new Selector Angiographic Catheter is the same as currently marketed NAMIC products.