510(k) Number: K190369

Applicant Information:

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Device Information:

Device Trade Name: M-Y Sheath

Common Name: Catheter Introducer

Classification Name(s): Catheter Introducer

Product Code/ Regulation: DYB / 870.1340

Classification: Class II

Predicate Device:

Cook, Flexor® Check-Flo Introducer Sheath, RAABE Modification (K142829)

Reference Device:

Abbott Vascular, Hi-Torque Whisper MS Guidewire (0.014”) (K101116)

Device Description:

The M-Y Sheath is a contralateral access guiding sheath with a proximal hemostatic valve and an integrated fixed wire at its distal end. The fixed wire is attached to the sidewall of the sheath and extends beyond the distal tip of the sheath and is used to provide sheath support during use. The wire distal end is first introduced through the ipsilateral in-dwelling femoral sheath introducer, then snared and externalized through an in-dwelling contralateral sheath introducer, thereby allowing the sheath to be positioned over the bifurcation by gentle simultaneous pushing and pulling the device using a "flossing" technique. Once the M-Y sheath tip is positioned at the desired location in the contralateral vasculature, the wire can be externally secured (e.g. using a pin vise), thereby providing stability and support when advancing interventional tools (e.g. angioplasty balloons, stents, etc.). The M-Y Sheath is compatible to fit through a standard 7 French femoral sheath introducer placed in the ipsilateral leg. The M-Y Sheath luminal diameter is sized to be compatible with 5 French therapeutic and diagnostic devices.

Indications for Use:

The M-Y Sheath is intended to enable delivery of interventional and diagnostic devices into the human vasculature, excluding coronary and neuro vasculature.

Comparison to Predicate Device:

The M-Y Sheath has the same intended use and similar indication, mechanism of action, and procedural outcomes as the Cook Flexor® Check-Flo Introducer Sheath, RAABE Modification (the predicate device). The M-Y Sheath and predicate device are intended to be used as introducer sheaths, allowing the introduction of subsequent devices into the vascular system. The M-Y Sheath functions in a substantially equivalent manner to the predicate device. The technological differences between the M-Y Sheath and its predicate do not raise new questions of safety or effectiveness. Performance data demonstrate substantial equivalence in terms of safety and performance to the predicate device.

Performance Testing

Biocompatibility testing per applicable requirements of ISO 10993 was completed.

Item #	Test	Standard Reference	Results
1	Cytotoxicity (MEM Elution)	ISO 10993-5:2009	Pass
2	Sensitization	ISO 10993-10: 2010	Pass
3	Intracutaneous Reactivity	ISO 10993-10: 2010	Pass
4	Material Mediated Pyrogenicity	ISO 10993-11:2017	Pass
5	Systemic Toxicity	ISO 10993-11:2017	Pass
6	Hemocompatibility	ISO 10993-4:2017	Pass

Bench testing to evaluate conformance with required device attributes and performance was completed. This testing included the following evaluations:

Attribute Tested	Pass/Fail

Device Dimensional Specifications	Passed
Device Visual Requirements	Passed
Device Preparation and Delivery, Deployment, and Retraction	Passed
Simulated Use Testing	Passed
Radiopacity Testing	Passed
Corrosion Resistance	Passed
Freedom from Sheath Introducer Leakage	Passed
Freedom from Hemostasis Valve Leakage	Passed
Hub/Luer Fitting conformance with ISO 594-2	Passed
Device Junctions Tensile Strength	Passed
Fracture Test for Fixed Wire	Passed
Flexing Test for Fixed Wire	Passed
Air Leakage During Aspiration	Passed

Transportation, sterilization, and shelf-life testing was completed to evaluate conformance with required attributes and performance. Sterilization validation was performed in conformance with all applicable requirements of ISO 11135-1: Sterilization of Health Care Products – Ethylene Oxide. Results demonstrate achievement of a sterility assurance level (SAL) of 10^{-6}.

Transportation and packaging validation included the following:

Attribute Tested	Pass/Fail
Transit Testing	Passed
Sterile Barrier Integrity (Bubble Test)	Passed
Packaging & Product Visual Inspection	Passed
Pouch Seal Testing	Passed

The validation of the functional performance of the M-Y Sheath in a clinical simulation bench model was successfully completed and passed all specified criteria.

Additionally, the M-Y Sheath was evaluated in an *in-vitro* 3-D anatomy simulation model. This evaluation was conducted with both the M-Y Sheath and predicate device to enable side-by-side comparative performance. The two devices were evaluated in an *in-vitro* 3-D anatomy simulation model by performing a clinical use simulation of a diagnostic/interventional procedure in the peripheral anatomy (e.g. below the knee).

In addition, the performance of the M-Y Sheath and predicate device were challenged by conducting a procedure in a worst case anatomical condition. A simulated total occlusion at the

target treatment site was included to test the ability of the sheath to provide support when the interventional device is delivered and advanced to cross the occlusion.

The test results satisfied all specified acceptance criteria and substantiated that the M-Y Sheath performs in a manner substantially equivalent to the cited predicate.

Summary:

Based upon the device description and test data provided in this pre-market notification the M-Y Sheath is substantially equivalent to the cited predicate device.