510(K) Summary – K190644

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General Information	
Trade Name:	Guide Sheath
Common / Usual Name:	Catheter Introducer
Classification:	Class 2 per 21 CFR 870.1340
Product Code:	DYB – Catheter Introducer
Predicate Device:	Cook Flexor Shuttle (K142819)

Device Description

The Surmodics Guide Sheath is designed to perform as a guide sheath and/or introducer sheath. The sheath is braid reinforced with an embedded radiopaque marker band to identify the distal tip. It also has a hydrophilic coating over the working length to provide a lubricious surface to ease insertion. The device comes packaged with a dilator, which is either .018" or .035" guidewire compatible.

This highly flexible, braid reinforced sheath is designed to resist kinking and maximize strength while keeping a minimized profile. Incorporated in the sheath is a radiopaque marker band located approximately 5mm from the distal tip. The Guide Sheath has an atraumatic tip and has a hydrophilic coating over the working length.

The dilator hub is designed to snap into the Guide Sheath cross cut valve cap. Additionally, the dilator shaft design allows for simultaneous movement of the sheath and dilator assembly. The dilator features an atraumatic tip, which is designed to extend beyond the sheath tip by approximately 5 cm. The dilator shaft is radiopaque.

The Guide Sheath features a custom designed cross cut valve that is integrated into the sheath hub and includes a 3-way stopcock with sidearm extension tubing. No assembly is required.

The sheath is packaged in a dual sterile barrier configuration. The sheath and dilator will be placed individually in high density polyethylene (HDPE) coiled hoops, which are then placed in a poly-tyvek pouch within a shelf box.

Indication for Use

The Guide Sheath is intended to introduce therapeutic or diagnostic devices into the vasculature, excluding the coronary and neuro vasculature.

Comparison of Technological Characteristics

The Surmodics Guide Sheath device is substantially similar to the legally marketed predicate device in design, intended use, principles of use, materials, sizes and sterility. The Surmodics Guide Sheath and the predicate device are intended for assisting with introduction of therapeutic devices into the peripheral anatomy. Both devices have similar dimensions and similar accessory compatibility. The devices are made from similar materials and both have a lubricious coating.

Substantial Equivalence and Summary of Studies

Results of design verification testing demonstrate that the technological differences identified do not raise new questions of safety or effectiveness compared to the predicate device. The Guide Sheath is substantially equivalent to the predicate device based on intended use/indications for use and technological characteristics. The subject device has been evaluated through the following bench tests:

Sheath & Dilator

- Visual inspections
- Dimensional evaluations
- Radiopacity, F640
- Tensile strength, ISO 11070:2014
- Tip tensile strength
- Liquid Leak Test, ISO 11070:2014
- Hub/Luer Connector Compatibility, ISO 594-1:1986 and ISO 594-2:1998
- Simulated use
- Kink Radius, BS EN 13868:2002
- Tracking Forces
- Torque Strength
- Coating Length
- 3 Point Bend, ASTM F2606-8
- Coating Integrity
- Coating Coverage
- Vertical Pinch Test
- Removal Force
- Lamination
- Particulate, USP 788

Packaging Testing

The following packaging tests were performed in accordance with ISO 11607-1:2016/(R)2010:

- Visual Inspection per ASTM F1886-09
- Seal Strength per ASTM F88M-15
- Bubble Leak per ASTM F2096-11
- Environmental Monitoring per ISTA P2A (2011)
- Distribution Simulation per ASTM D4169-16
- Shelf Life

Biocompatibility

The following biocompatibility tests were performed in accordance with ISO 10993-1:2009:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous reactivity
- Acute Systemic toxicity
- Hemolysis
- Pyrogencity
- Thrombogenicity
- Unactivated Partial Thromboplastin Time (UPTT)
- Complement Activation

All test results met documented acceptance criteria and did not raise new questions of safety or effectiveness. The Surmodics Guide Sheath is substantially equivalent to the predicate device.

Sterilization

The results of the sterilization product testing demonstrate that the Ethylene Oxide (EtO) sterilization method for the Guide Sheath meet the requirements of ISO 11135:2014, and that the sterility of the device will be maintained over the entirety of the shelf life.

Clinical Data

No clinical data is being submitted for the Surmodics Guide Sheath.

Conclusions

Based upon the device description, indications for use, technological characteristics & performance data it can be concluded that the Guide Sheath is substantially equivalent to the predicate device and is appropriate for the intended use.