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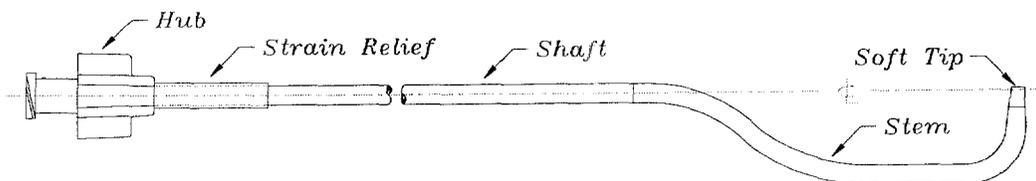
Summary of Safety and Effectiveness
for
ASC Maxi-Torque Plus Softtip Angiographic Catheters
submitted by
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Identification of a Legally Marketed Predicate Device

The ASC French Maxi-Torque Plus Softtip Angiographic Catheters (ASCMPsACs) are substantially equivalent to catheters that are manufactured and marketed by the Cordis Corporation under the Infiniti™ and TorquePlus™ trademarks.

Device Description

The ASCMPsACs are classified as Class II in 21 CFR §870.1200. The ASCMPsACs are sterile, single use, disposable devices, that are delivered non-toxic and non-pyrogenic. The ASCMPsACs consist of five components: catheter hub with luer connector, catheter shaft, catheter stem, soft distal tip, and catheter shaft braid wire. The catheter is shown below.



The catheter shaft has three sub-components: extrusion base coat, reinforcement braid wire, and extrusion top coat. The braiding is intended to provide torque control and strength.

All versions of the catheter are designed to accommodate a maximum guidewire diameter of 0.038 inches. The strain relief is imprinted with three descriptive dimensions: the French size of the catheter, minimum inside diameter, and the catheter working length.

Intended for Use

ASC Maxi-Torque Plus Softip Angiographic Catheters are designed to deliver contrast medium to selected sites in the vascular system.

Summary of Technological Characteristics

The table below compares the technological characteristics of the catheter to the predicate device.

Feature	ASCMPsAC	Predicate Device
Manufacturer	Adam Spence Corporation	Cordis Super Torque (Infiniti™)
Sterile packaging	On a card, inserted into a pouch made of Mylar® and Tyvek®	On a card, inserted into a pouch made of Mylar® and Tyvek®
Sterilization method	Ethylene Oxide Gas	Ethylene Oxide Gas
Pyrogenicity	Non-pyrogenic	Non-pyrogenic
Shelf Life	3 years	3 years
Intended use	ASCMPsACs are designed to deliver contrast medium to selected sites in the vascular system.	Cordis catheters are designed to deliver radiopaque contrast media to selected sites in the vascular system.
Hub with female luer taper	Yes	Yes
Radiopacifier, shaft	Barium Sulfate	Barium Sulfate
Radiopacifier, stem	Bismuth Oxychloride	Barium Sulfate
Radiopacifier, soft tip	Bismuth Subcarbonate	Bismuth Subcarbonate
Catheter, available sizes (French)	5, 6, and 7	5, 6, and 7
Catheter, available lengths (cm)	65, 80, 100, 110, and 125	65, 80, 100, 110, and 125
Maximum Guide Wire O.D. (inches)	0.038	0.038
Hub material	Nylon	Nylon
Reinforcement braid material	300 Series Stainless Steel	300 Series Stainless Steel
Shaft material	2 layer coaxial nylon extrusion	2 layer coaxial nylon extrusion
Stem material	Nylon	Nylon
Soft tip material	Nylon	Nylon

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Feature	ASCMP SAC	Predicate Device
Stem to soft tip attachment method	Heat fuse	Heat fuse
Stem to shaft attachment method	Heat fuse	Heat fuse
Specifications printed on hub or strain relief	Catheter length, outside diameter, and inside diameter	Catheter length, diameter, and maximum guide wire size
Maximum pressure	1200 PSI	1200 PSI
Strain relief	Yes	Yes

Summary of Performance Data

The ASCMP SACs comply with the following standards, practices, and guidances:

- Sterile, single-use intravascular catheters: International Standards Organization Reference Number 10555-1:1995(E) (1995)
- Ethylene Oxide, Ethylene Chlorhydrin, and Ethylene Glycol, Proposed Maximum Residue Limits and Maximum Levels of Exposure, 21 CFR, § 821.100, Proposed Rule, June 23, 1978
- Biological Evaluation of Medical Devices—Part 7: Ethylene oxide sterilization residuals, American National Standard, ANSI/AAMI/ISO 10993-7:1995
- Biological Evaluation of Medical Devices, ISO-10993-1

The ASCMP SACs are substantially equivalent to catheters which are legally marketed by the Cordis Corporation under the Infiniti™ and TorquePlus™ trademarks. This has been demonstrated by extensive bench testing of both devices. Testing includes jacket tensile strength, stem tensile strength, flow rate, dynamic burst strength and static burst strength. Furthermore, the devices have the same technological characteristics as the Cordis Infiniti™ and TorquePlus™ Angiographic Catheters.

All direct and indirect blood contact materials used to fabricate the ASCMP SACs pass the testing required by ISO-10993. These materials are currently used in many disposable medical devices.

The ASCMP SACs will be manufactured per specifications using good manufacturing practices that ensure the device is safe and effective for its intended use.

Since the ASCMPsAC meets the requirements of the stated standards and embody technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The ASCMPsACs will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.