

510(K) Summary - K172014

Trade Name: Wedge Microcatheter

Generic Name: Percutaneous Catheter

Classification: II, 21 CFR 870.1250, DQY

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Predicate Device: Headway 21 Microcatheter (K093160)
Headway 17 Microcatheter (K083343)
AXS Offset Delivery Assist Catheter (K163259)

Device Description:

The Wedge Microcatheter is a single lumen catheter designed to be introduced over a steerable guidewire to access small, tortuous vasculature. The microcatheter has a semi-rigid proximal section with an outer shaft made of Grilamid nylon. The catheter shaft transitions to progressively softer durometers and different lengths of Polyether block amide (Pebax). The distal-most length of the microcatheter, beyond the enlarged segment, consists of a softer, atraumatic polyurethane.

The enlarged segment on the distal end of the Wedge is designed to reduce the gap between the OD of the guidewire and ID of the Sofia 6F. The tapered bulb section, approximately 1 cm length and located approximately 1.5 cm from the distal tip, can be identified on fluoroscopy between the two radiopaque

proximal marker bands of the Wedge Microcatheter. The bulb OD (0.068”) is sized specifically to work with the lumen ID (0.070”) of the Sofia 6F allowing for continuous flush of saline through the Sofia.

Three radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the microcatheter is coated with a hydrophilic polymer coating to reduce friction during navigation in the vasculature. The lubricious inner liner is made from polytetrafluoroethylene (PTFE). A luer fitting on the Microcatheter hub is used for the attachment of accessories. The hub/strain relief provides for the kink resistance at the proximal end. The microcatheter has a straight tip that is designed to be steam shaped by the physicians at the time of the use. A steam shaping mandrel and introducer sheath (accessories) are packaged with the catheter.

Indications for Use:

The Wedge Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and to assist in the delivery of interventional devices, such as the SOFIA 6F Catheter, in the neurovasculature.

Technological Characteristics and Product Feature Comparison:

The subject device, Wedge Microcatheter is substantially equivalent to the predicate devices in terms of:

- Intended use
- Scientific technology
- Fundamental design
- Materials and processes for packaging and sterilization of devices

A tabular comparison of the technological characteristics between the predicate devices and subject device is provided below.

Product Feature Comparison of Subject Device with Predicate Devices (K083343, K093160, K163259)

Device Characteristics	Headway 17 Microcatheter (K083343)	Headway 21 Microcatheter (K093160)	AXS Offset Delivery Assist Catheter (K163259)	Wedge Microcatheter (Proposed)
Device Classification/ Product Code	Class II/ DQY (Percutaneous catheters)	Class II/ DQY (Percutaneous catheters)	Class II/ DQY (Percutaneous catheters)	Class II/ DQY (Percutaneous catheters)
Intended Use	The Headway Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.	Intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.	The AXS Offset Delivery Assist Catheter is intended to assist in the delivery of interventional devices, such as distal access catheters, in the neurovasculature.	The Wedge Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and to assist in the delivery of interventional devices, such as the SOFIA 6F Catheter, in the neurovasculature.
Catheter OD	.025" -.031"	.028" - .034"	.050"	.028" - .034" Equivalent to predicates
Catheter ID	.017"	.021"	.021"	.021" Equivalent to predicates
Tip	Shapeable 15 cm	Shapeable 15 cm	Straight 2 cm	Shapeable, same as predicates Headway 17 and Headway 21

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 Premarket Notification, Traditional 510(k)
 Wedge Microcatheter

Device Characteristics	Headway 17 Microcatheter (K083343)	Headway 21 Microcatheter (K093160)	AXS Offset Delivery Assist Catheter (K163259)	Wedge Microcatheter (Proposed)
Distal segment/bulb	N/A	N/A	The distal outer diameter (OD) of the AXS Offset Catheter gradually increases from 0.036in at the RO Marker to 0.050in, 2 cm proximal to the RO marker. The bulb section with a 0.050in OD is maintained for 28 cm, then gradually decreases towards the proximal section. The overall distal profile of the AXS Offset catheter acts as a smooth transition and reduces the gap between the outer diameter of a steerable guidewire and inner diameter of a DAC while allowing for continuous saline flush through the DAC.	Using the same principle as the predicate AXS Offset, the slightly enlarged segment (bulb) of the Wedge reduces the gap between the outside diameter of the guidewire and the inside lumen of the Sofia allowing for continuous flush of saline through the Sofia.
Effective Length	150 cm ± 2	150 cm ± 2	150 cm	158-160 cm Equivalent to predicates
Coating	Hydrophilic Coating	Hydrophilic Coating	Hydrophilic Coating	Hydrophilic coating of the same composition as predicates Headway 17 and Headway 21 to reduce friction during use.
Hydrophilic Coating Length	100-105 cm	100-105 cm	80 cm	110-115 cm Equivalent to predicates

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Device Characteristics	Headway 17 Microcatheter (K083343)		Headway 21 Microcatheter (K093160)	AXS Offset Delivery Assist Catheter (K163259)	Wedge Microcatheter (Proposed)
Packaging	Material	Dispenser hoop: Polyethylene Mounting card: Polyethylene Pouch: Tyvek Carton Box: Bleached Sulfate	Same as Headway 17	Catheter is placed in a dispenser coil, then inserted into a pouch and placed inside a carton box.	Same as predicates Headway 17 and Headway 21; equivalent to AXS Offset.
	Package Config.	Microcatheter is placed in a dispenser hoop and accessories on a mounting card that is then inserted into the pouch. The pouch is then placed inside a carton box.			
Method of Supplying	Sterile and single use		Sterile and single use	Sterile and single use	Same
Method of Sterilization	Ethylene oxide		Ethylene oxide	Ethylene oxide	Same

Verification Test Summary:

The results of verification and validation testing conducted on the subject device demonstrate that it performs as intended and are summarized as follows:

Test Description	Result
Surface Contamination	Pass
Physical Attributes	Pass
Force at Break (Catheter Distal Section)	Pass
Force at Break (Catheter Hub Junction)	Pass
Freedom from Leakage (Low Pressure, Long Duration)	Pass
Freedom from Leakage (High Pressure, Short duration)	Pass
Freedom from Leakage - Air	Pass
Static Burst Pressure	Pass
Dynamic Burst Pressure	Pass
Coating Durability/Lubricity	Pass
Tip Shape and Tip Retention	Pass
Simulated Use	Pass
Flow Rate	Pass
Kink Resistance	Reference Only
Catheter Stiffness	Pass
Catheter Flexural Fatigue	Pass
Catheter Particle Testing	Pass
Dead Space	Reference Only
Torque Strength	Pass
Corrosion Resistance*	Pass
Gauging Test*	Pass
Separation Force*	Pass
Unscrewing Torque*	Pass
Resistance to Overriding*	Pass

Test Description	Result
Stress Cracking*	Pass
Radiopacity* (Visibility under fluoroscopy)	Pass
Pyrogenicity*	Pass
Ship Testing*	Pass
Shelf Life Testing	Pass

* Testing was previously conducted on test article that was equivalent to the Wedge Microcatheter in all aspects relevant to the testing performed, therefore it was deemed unnecessary to repeat the testing for the Wedge Microcatheter.

Animal Testing Summary:

The acute performance/efficacy and safety parameters analyzed (insertion of introducer sheath into RHV, peel away introducer sheath from catheter, track test with guidewire, track test with guidewire/SOFIA 6F and overall performance) were comparable between the Wedge Microcatheter and predicate Headway 21 with no dissection, perforation, luminal narrowing, thrombus formation or distal emboli were noted for both test articles.

Histopathology Results: Morphometric measurements showed no neointimal growth or stenosis in both, the Wedge Microcatheter and predicate Headway 21, with largely identical endothelial loss and no incidence of vessel wall thinning or aneurysmal dilatation. There were no disruptions of the internal elastic lamina or medial layers in any vessel regardless of treatment device. Injury was limited to minimal to occasionally marked endothelial cell denudation without remarkable thrombus deposition in any treated vessel segment. Overall, the results of the study demonstrated substantial equivalence of the Wedge Microcatheter to the predicate.

Biocompatibility Evaluation:

The in vitro and in vivo biocompatibility safety studies performed on the Wedge Microcatheter have demonstrated the biocompatibility of the Wedge Microcatheter and support compliance with the ISO 10993-1:2009 and FDA guidelines. The device was determined to be non-cytotoxic, non-sensitizing, intracutaneously non-irritating, systemically non-toxic, non-pyrogenic (material-mediated), non-hemolytic, have no effect on clotting, non-complement activating, and non-thrombogenic. The results of biocompatibility evaluation are summarized as follows:

Test	Test Summary	Conclusions
Cytotoxicity - Medium Eluate Method	The test article extract exhibited between no cell lysis (grade 0) to slight reactivity (grade 1).	Non-cytotoxic
Sensitization: Maximization Test in Guinea Pigs	No irritation was present on any of the test or negative control (0% sensitized) guinea pigs.	Non-sensitizer
Intracutaneous Reactivity	No evidence of irritation (score 0.0).	Non-irritating
Systemic Injection Test in Mice	No weight loss, mortality, or evidence of systemic toxicity from the extract exposure to the mice was observed.	Systemically non-toxic
Rabbit Pyrogen Test	The rise of rabbit temperatures during the three hours of observation did not exceed 0.5°C.	Nonpyrogenic
ASTM Blood Compatibility - Direct and Indirect Contact Hemolysis	The test article demonstrated 0.59% hemolysis in direct contact and 1.25% hemolysis in indirect contact.	Non-hemolytic
Unactivated Partial Thromboplastin Time Test	An average clotting time of the test article showed no significant difference from the control.	No effect on clotting
Complement Activation	The plasma exposed to the test article for 90 minutes was found to exhibit no statistically significant increase in C3a.	Non-activated
Thrombogenicity	Both animals exhibited no signs of toxicity during the study (score 0)	Non-thrombogenic

Summary of Substantial Equivalence:

The information presented in this 510(k) demonstrates the substantial equivalence between the predicates Headway 21 Microcatheter (K093160), Headway 17 (K083343), AXS Offset (K163259), and the Wedge Microcatheter in regard to the design, construction materials, operating principle, and intended use.