510(k) Summary

Device Trade Name: AXS Offset Delivery Assist Catheter

Common Name: Percutaneous Catheter

Classification Name: Percutaneous Catheter, 21CFR 870.1250 Class II

Product Code: DQY

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Date Prepared: July 27, 2017

Predicate Device:

Primary Predicate Device	
K113778 (clearance granted April 20, 2012)	Excelsior XT-27 Microcatheter
Reference Predicate Device	
K122576 (clearance granted January 11, 2013)	Transform Occlusion Balloon Catheter

Device Description

The AXS Offset Delivery Assist Catheter ("AXS Offset") is a sterile, single lumen, variable stiffness catheter designed for use in facilitating the insertion and delivery of appropriately sized interventional devices, such as distal access catheters (DAC), into a selected blood vessel in the neurovascular system.

The AXS Offset catheter, when used in conjunction with an appropriately sized steerable guidewire and DAC, provides a smooth interventional device system profile. 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.

The catheter shaft has a hydrophilic coating to reduce friction during use. The catheter includes a radiopaque marker on the distal end for angiographic visualization and a luer hub on the proximal end allowing attachments for flushing.

Accessories

No accessories are provided with the AXS Offset.

Indications for Use

The Indications for Use are similar to the predicate devices and are as follows:
The AXS Offset Delivery Assist Catheter is intended to assist in the delivery of interventional devices, such as distal access catheters, in the neurovasculature.

Technological Characteristics and Product Feature Comparison

The subject device, AXS Offset Delivery Assist Catheter is substantially equivalent to the predicate devices in terms of:

- indications for use
- fundamental scientific technology
- fundamental design
- materials and processes for packaging and sterilization of devices

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

Product Feature Comparison of Subject Device with Predicate Devices (K113778, K122576)

Characteristics	Subject Device	Primary Predicate Device	Reference Predicate Device
Device Name	**AXS Offset Delivery Assist Catheter**	**Excelsior® XT-27 Microcatheter**	**Transform Occlusion Balloon Catheter**
510(k)	**Current Notification**	**K113778**	**K122576**
Device Classification/ Product Code	Class II/ DQY (Percutaneous catheters)	Class II/ DQY (Percutaneous catheters)	Class II/MJN (Temporary Intravascular Occluding Catheter)
Intended Use	The AXS Offset Delivery Assist Catheter is intended to assist in the delivery of interventional devices, such as distal access catheters, in the neurovasculature.	Stryker Neurovascular Excelsior XT-27 Microcatheter is intended to assist in the delivery of diagnostic agents (such as contrast media), therapeutic agents, and non-liquid interventional devices (such as stents) that are indicated for use in the neurovasculature and with a catheter of 0.027 inches in inner diameter.	The Stryker Neurovascular TransForm Occlusion Balloon Catheters are indicated for use in the neuro and peripheral vasculature to temporarily stop or control blood flow and for balloon assisted embolization of intracranial aneurysms.

Characteristics	Subject Device	Primary Predicate Device	Reference Predicate Device
Device Name	**AXS Offset Delivery Assist Catheter**	**Excelsior® XT-27 Microcatheter**	**Transform Occlusion Balloon Catheter**
510(k)	**Current Notification**	**K113778**	**K122576**
Principle of Operations	Delivery Assist Catheters are used to access and navigate the vasculature as well as to deliver Distal Access Catheters (DAC). The AXS Offset Delivery Assist Catheter is inserted through a DAC and guided through the vasculature with the aid of a guidewire (over-the-wire catheter).	Microcatheters are used to access and navigate the vasculature as well as to deliver diagnostic therapeutic agents, and/or interventional devices. Typically these vascular microcatheters are inserted with a guide catheter and guided through the vasculature with the aid of a guidewire (over-the-wire microcatheters).	The device is advanced into the vasculature using an 0.014 inch OD guidewire and inside a 5F or larger guide catheter placed in the femoral artery. The radiopaque markers are observed under fluoroscopy as a guide to positioning the balloon at the intended treatment site. Once at the treatment site, the guidewire is used to seal the distal end of the catheter allowing inflation of the balloon. A mixture of saline and contrast is injected into the catheter lumen to inflate the balloon to its nominal volume; fluoroscopy is used to ensure proper positioning. Once beyond the distal tip of the catheter, the guidewire can be moved distally or proximally while maintaining balloon inflation.

Characteristics	Subject Device	Primary Predicate Device	Reference Predicate Device
Device Name	**AXS Offset Delivery Assist Catheter**	**Excelsior® XT-27 Microcatheter**	**Transform Occlusion Balloon Catheter**
510(k)	**Current Notification**	**K113778**	**K122576**
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

Design Comparison of Subject Device with Predicate Devices (K113778, K122576)

Feature	Proposed Device	Predicate Device	Predicate Device	Rationale for difference (if applicable)
	AXS Offset Delivery Assist Catheter	**Excelsior® XT-27 Microcatheter**	**Transform Occlusion Balloon Catheter**	
	Current Notification	**K113778**	**K122576**	
Proximal OD	3.0F (1.0mm)	2.9F (0.97mm)	2.8F (0.95mm)	No significant difference
Distal OD	2.7F (0.91mm)	2.7F (0.91mm)	2.7F (0.95mm)	N/A - Same as primary predicate

Feature	Proposed Device	Predicate Device	Predicate Device	Rationale for difference (if applicable)
	AXS Offset Delivery Assist Catheter	Excelsior® XT-27 Microcatheter	Transform Occlusion Balloon Catheter	
	Current Notification	K113778	K122576	
Maximum Catheter Diameter (distal section)	3.8F (1.27mm) *reference figure	2.7F (0.91mm) *reference figure	3.8F(1.27mm) *reference figure	The AXS Offset outside diameter is similar to the predicate devices. AXS Offset has the same materials as the predicate as seen in table 13-7. Thrombogenicity testing demonstrated no risk of thrombosis for the AXS Offset Catheter like the predicate device. Biocompatibility testing was also completed to show no increased risk compared to the predicate devices. The bench testing was performed in a neurovascular tortuosity model to confirm the continuous flush solution will be adequately maintained between the AXS Offset and DAC during use.
ID	0.53mm (.021in)	0.69mm (0.027in)	0.31mm (.0124in)	AXS Offset ID of .021” is within the ranges of both predicate devices. .021” ID is a common size for a catheter of this length and OD.

Feature	Proposed Device	Predicate Device	Predicate Device	Rationale for difference (if applicable)
	AXS Offset Delivery Assist Catheter	Excelsior® XT-27 Microcatheter	Transform Occlusion Balloon Catheter	
	Current Notification	K113778	K122576	
Hydrophilic Coating Length	80cm	80cm	80cm - 83cm	N/A - Same as primary predicate
Effective Length	150cm	135 cm 150 cm	150 cm - 153cm	N/A - Same as primary predicate
Tip Length	2cm	6 cm 18 cm	1cm – 3cm	AXS Offset tip length of 2cm is similar to the predicate devices. The tip length is used to describe the section distal of the bulb feature of the AXS Offset but the tip length does not significantly affect the product performance. The materials of the tip are more impactful to product performance. Both AXS Offset and Excelsior XT-27 have the same distal tip materials and distal OD and thus have similar performance.
Tip Shape	Straight	Straight Preshaped	Straight	N/A - Same as primary predicate

Risk Assessment
Risk assessment of the AXS Offset Delivery Assist Catheter has been conducted in accordance with EN ISO 14971 and Stryker Neurovascular's risk management procedures. Stryker Neurovascular has determined that the AXS Offset Delivery Assist Catheter raises no new safety or effectiveness issues.

Results of verification and validation testing have demonstrated the subject device is substantially equivalent to the predicate devices.

Testing Summary
The results of verification and validation testing conducted on the subject device demonstrate that it performs as designed, and is suitable for its intended use. Specifically, the following tests were performed on the subject device:

Test	Test Method	Results
Dimensional Verification	Verified dimensions using specified measurement tool	Dimensional verification meets acceptance criteria for catheter effective length, uncoated length, distal tip outer diameter, and inner diameter Substantial Equivalence: XT-27 and AXS Offset meet the same dimensional effective length, uncoated length, and distal tip outer diameter acceptance criteria For inner diameter, XT-27 and AXS Offset meet their respective dimensional inner diameter acceptance criteria. The inner lumens of both devices are compatible with standard neurovascular guide wires.
Dimensional: Maximum Outer Diameter	Verified dimensions using specified measurement tool	Dimensional verification meets acceptance criteria for maximum outer diameter Substantial Equivalence: XT-27 and AXS Offset meet their respective dimensional (maximum outer diameter) acceptance criteria. The differences in the max OD between the XT27 and AXS Offset are related to the differences in the indications for use of both devices.
Friction Force	Measured friction force to determine the lubricity and durability of the coating on a catheter shaft using a friction tester	Friction force meets acceptance criteria Substantial Equivalence: XT-27 and AXS Offset meet the same friction force acceptance criteria.
Catheter Distal Tip Buckling	Measured force required to buckle distal shaft using tip buckling tester	Distal tip buckling meets acceptance criteria Substantial Equivalence: XT-27 and AXS Offset meet the same distal tip buckling acceptance criteria.
Catheter Tensile Strength	Measured catheter shaft peak tensile strength using Instron tensile tester per test guideline, ISO10555-1 Peak Tensile Force	Catheter tensile strength meets acceptance criteria Substantial Equivalence: XT-27 and AXS Offset meet the same catheter tensile strength acceptance criteria.
Catheter Hub Tensile Strength	Measured catheter shaft to hub tensile junction strength using Instron tensile tester per test guideline, ISO10555-1 Peak Tensile Force	Catheter hub tensile strength meets acceptance criteria Substantial Equivalence: XT-27, Transform, and AXS Offset meet the same catheter hub tensile strength acceptance criteria.
Liquid-Leakage	Determined whether liquid leaks from the catheter under pressure per EN ISO 10555-1:2013 and EN 1707:1996.	Liquid-leakage meets acceptance criteria Substantial Equivalence: XT-27, Transform, and AXS Offset meet the same liquid-leakage acceptance criteria.

Air Aspiration Leakage	Determined whether air leaks into the hub assembly during aspiration per EN ISO 10555-1:2013 and EN 1707:1996.	Air aspiration leakage meets acceptance criteria Substantial Equivalence: XT-27, Transform, and AXS Offset meet the same air aspiration leakage acceptance criteria.
Particle Analysis for Catheters	Performed simulated use procedures for *in vitro* acute phase particulate characterization using a particle counter	Particle analysis characterization testing completed and is for reference only. Particulate count results for the AXS Offset in all particulate size ranges are similar or lower than the predicate device XT-27
Coating Integrity	Checked visual condition of catheter and noted observations of the catheter coatings before and after simulated use	Neither the Baseline test articles nor the Post-tracking test articles exhibited any delamination at coating edges (either proximal or distal). The Baseline test articles did not exhibit any coating defects (voids or scratches). The post tracking devices exhibited no anomolies along the 80cm coating length. When considered in conjunction with coating lubricity and durability results and the particulate generation results, the coating functions as intended and has exhibited appropriate integrity (via visual assessment) post simulated use.
Track and Advance Force	Measured the advance and retraction force in simulated use conditions from the petrous segment of the internal carotid artery to the M1 of the middle cerebral artery.	AXS Offset catheter advance and retraction force in simulated use testing has been demonstrated to be equivalent or lower than the predicate XT-27.
Flow Rate	Measured flow rate for saline infusion through a Distal Access Catheter (DAC) when the AXS Offset catheter was positioned within the lumen of the DAC.	Testing has demonstrated a continuous positive displacement of saline fluid through the lumen of the DAC with the AXS Offset catheter positioned in the DAC lumen. Testing was conducted in a simulated neurovascular tortuosity model.
Catheter Kink Radius	Measured the kink radius of catheter using a fixture	Catheter kink radius meets acceptance criteria Substantial Equivalence: XT-27 and AXS Offset meet the same kink radius acceptance criteria.
Catheter Torsional Resistance	Measured the strength of catheter shaft while it rotates in a clinically relevant vascular path to determine how many turns (360-degree rotations) are required to break the catheter	Catheter torsional resistance meets acceptance criteria Substantial Equivalence: XT-27 and AXS Offset meet the same torsional resistance acceptance criteria.

Visual Standards	Visually checked catheter length for extraneous matter and process defects. Additionally, checked for smooth and rounded distal tip using specified measurement tools	Visual standards meet acceptance criteria for catheter length being free from extraneous matter and process defects and for catheter distal tip being smooth and rounded. Substantial Equivalence: XT-27 and AXS Offset meet the same visual standards acceptance criteria.
Visual and Dimensional Integrity – Chemical Compatibility	Performed visual, dimensional, and mandrel passage examinations to determine visual and dimensional integrity of the hub, inner lumen, and outer distal region of catheter after exposure to saline, non-ionic contrast, and ionic contrast.	Visual and Dimensional Integrity – Chemical Compatibility meets acceptance criteria Substantial Equivalence: XT-27 and AXS Offset meet the same visual and dimensional integrity – chemical compatibility acceptance criteria.
Device Trackability	The device was advanced to the M1 using standard access methods similar to XT-27. In order to meet acceptance criteria, the evaluating physician/s must state that the test articles can advance to the M1 in conjunction with the intermediate catheter in the bench model.	Device Trackability meets acceptance criteria Substantial equivalence: XT-27 and AXS Offset meet the same device trackability acceptance criteria. After advancing the Test article with the intermediate catheters in the model, the physicians confirmed that all of the test articles were able to advance to the M1 using standard access methods similar to XT-27.
Device – Durability and Integrity	The integrity of the device was assessed throughout the duration of the procedure using the bench model. In order to meet acceptance criteria, the evaluating physician/s must state that all test articles maintain their integrity throughout procedure.	Device Durability and Integrity meets acceptance criteria The evaluating physicians confirmed that the all test articles maintained their integrity throughout procedure. Substantial Equivalence: XT-27 and AXS Offset meet the device-durability and integrity acceptance criteria.
Guidewire Compatibility	Guidewires up to 0.018in OD were allowed to advance and withdraw from the AXS Offset device during the procedure using the bench model. In	Guidewire Compatibility meets acceptance criteria The evaluating physicians confirmed that all test articles allowed smooth advancement and withdrawal of standard guidewires up to 0.018in OD.

	order to meet acceptance criteria, the evaluating physician/s must state that all test articles allow smooth advancement and withdrawal of standard guidewires up to 0.018in OD.	Substantial Equivalence: XT-27 and AXS Offset meet the same guidewire compatibility acceptance criteria.
Labelling requirements	The physician read the DFU and labeling. In order to meet acceptance criteria, the evaluating physician/s must state that DFU and labeling of all test articles clearly identify the product and provide information adequate to ensure the safe use of the device.	Labelling Requirements meet acceptance criteria The evaluating physicians confirmed that the DFU and labeling of all test articles clearly identify the product and provide information adequate to ensure the safe use of the device. Substantial Equivalence: XT-27 and AXS Offset meet the labeling requirements acceptance criteria.
Intended Use Environment	During the procedure using the bench model, the device was assessed whether it withstood the simulated use conditions. In order to meet acceptance criteria, the evaluating physician/s must state that all test articles can withstand conditions that can typically be seen during use environment of the product.	Intended Use Environment meets acceptance criteria The evaluating physicians confirmed that all Test articles withstand conditions that can typically be seen during use environment of the product. Substantial Equivalence: XT-27 and AXS Offset meet the same intended use environment acceptance criteria.

Visibility	The visibility of the tip of the AXS Offset (marker) was assessed using fluoroscopy during delivery to and withdrawal from the intended location in the bench model. In order to meet acceptance criteria, the evaluating physician/s must state that all test articles are visible under fluoroscopy during delivery to and withdrawal from the intended location.	Visibility meets acceptance criteria The evaluating physicians confirmed that all test articles are visible under fluoroscopy during delivery to and withdrawal from the intended location. Substantial Equivalence: XT-27 and AXS Offset meet the same visibility acceptance criteria.
Packaging	Performed packaging visual, dimensional, and performance testing on carton, labels, DFU, and pouch	Packaging visual, dimensional, and performance testing meets the acceptance criteria for all packaging components (carton, labels, DFU, and pouch). Substantial Equivalence: XT-27 and AXS Offset meet the same packaging visual, dimensional, and performance acceptance criteria.

Biocompatibility

The AXS Offset Delivery Assist Catheter was assessed for impact to biocompatibility. All proposed materials to be used in the AXS Offset Delivery Assist Catheter as per this assessment have a history of safe clinical use throughout the medical device industry and/or within Stryker Neurovascular and have supporting biocompatibility data. The materials used and the manufacturing process used in the AXS Offset Delivery Assist Catheter are the same or very similar to materials used in the cleared reference predicate Transform Occlusion Balloon Catheter (K122576).

The history of safe use and supporting biological test data leveraged from ~~for~~ the reference predicate device~~s~~ noted above, indicates potential exposure to these existing materials at the amounts present under the proposed clinical conditions of use for the AXS Offset Delivery Assist Catheter will be toxicologically insignificant.

The minor material and manufacturing differences between the AXS Offset Delivery Assist Catheter and the cleared reference predicate device are considered low risk in terms of impact to the biocompatibility of the AXS Offset Delivery Assist Catheter. Therefore, the supporting Transform Occlusion Balloon Catheter (K122576) biocompatibility test data presented in Transform Occlusion Balloon Catheter Biocompatibility Results Summary Table are applicable to the AXS Offset Delivery Assist Catheter.

Although these differences are considered low risk for the biocompatibility of the AXS

Offset Delivery Assist Catheter, screening tests were conducted to further provide supporting evidence that these differences do not adversely impact the product. The AXS Offset Delivery Assist Catheter Biocompatibility Results Summary table summarizes the biocompatibility tests that were conducted using the AXS Offset Delivery Assist Catheter. EN ISO 10993 parts are referenced where applicable.

AXS Offset Delivery Assist Catheter Biocompatibility Results Summary

Test	Test Summary	Conclusion
MEM Elution Cytotoxicity/Part 5	The test article extract showed no evidence of causing cell lysis or toxicity, with a grade of 0 (no reactivity).	Pass. No cytotoxicity or cell lysis. The test article is considered non-cytotoxic.
Hemolysis Extract/Direct Contact Method/Part 4	The hemolytic index for the test article in direct contact with blood and for the extractwas <5%.	Pass. Results are considered pass if the hemolytic index of the test article is 5% or less.
USP Physicochemical <661>/Part 18	The results for the test article were: Non-volatile residue: 7 mg Residue on ignition: < 1 mg Heavy metal: < 1 ppm Buffering capacity: < 1.0 ml	Pass. The test results indicate there are no gross residuals or volatiles.
FTIR / Part 18	FTIR scan done to establish baseline for reference only	The baseline identified polyamide type materials which are constituents of the device.
Natural Rubber Latex ELISA Inhibition Assay for Antigenic Protein ASTM D6499-12	The test article extract showed no detectable latex.	Pass. Latex below level of detection.
In-vitro Blood Loop Assay with Comparison Article	The test article (AXS DAC) received a worst case score of '1.' And the comparison article (Transform) received a worst case score of '1' where for a score of 0, 1 or 2 the test article is deemed thromboresistant.	Pass. Both the test article (AXS Offset DAC) and comparison article (Transform) considered thromboresistant.

The following tests were leveraged from biocompatibility testing conducted with the Transform Occlusion Balloon Catheter:

Transform Occlusion Balloon Catheter Biocompatibility Results Summary

Test	Test Summary	Conclusion
MEM Elution Cytotoxicity/ Part 5	The test article extract showed no evidence of causing cell lysis or toxicity, with a grade of 0 (no reactivity).	Pass. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).
Guinea Pig Maximization Sensitization/Part 10	The test article showed no evidence of causing delayed dermal contact sensitization.	Pass. The test article is not considered a sensitizer.
Intracutaneous Reactivity/Part 10	The difference between test extract mean score and the control mean score was 0.0.	Pass. The test article met the requirements of the test.
Acute Systemic Injection/Part 11	There was no mortality or evidence of systemic toxicity.	Pass. The test article met the requirements of the test.
Materials Mediated Rabbit Pyrogen/Part 11	The total rise of rabbit temperatures during the three hour observation was within acceptable USP limits.	Pass. The test article was judged as nonpyrogenic.
Ames Mutagenicity/Part 3	The test article extracts were considered to be nonmutagenic to *Salmonella typhimurium* test strains and to *Escherichia coli* test strains.	Pass. The test article was considered nonmutagenic
Genotoxicity – Mouse Lymphoma Assay/Part 3	The test article extracts did not cause a twofold or greater increase in the mean mutant frequency of the L5178Y/TK$^{+/-}$ cell line in either the absence or presence of metabolic activation.	Pass. The test article was considered nonmutagenic
Hemolysis Direct Contact and Extract Method/Part 4	The hemolytic index for the test article in direct contact with blood was 0.0%, and the hemolytic index for the test article extract was 0.1%.	Pass. The test article met the criteria of <5%.
Partial Thromboplastin Time /Part 4	Clotting time of the test article was 67% of the negative control.	Pass. The test article met the acceptance criteria of ≥50%.
In Vitro Hemocompatibility Assay/Part 4	All counts for the test article were not significantly different from the reference material.	Pass. Results for the test article comparable to the reference material.
Complement Activation (SC5b-9)/Part 4	Concentration of SC5b-9 for the test article was not statistically higher than the negative control.	Pass. The test article was not considered to be a potential activator of the complement system.

Test	Test Summary	Conclusion
Complement Activation (C3a)/Part 4	Concentration of C3a for the test article was not statistically higher than the negative control.	Pass. The test article was not considered to be a potential activator of the complement system.
USP Physicochemical <661> / Part 18	The results for the test article were: Non-volatile residue: 1 mg Residue on ignition: < 1 mg Heavy metal: < 1 ppm Buffering capacity: < 1.0	Pass. The test results indicated there are no gross residuals or volatiles.
Natural Rubber Latex ELISA Inhibition Assay for Antigenic Protein ASTM D6499-07	The results for the test article were <0.2 ug/g and >0.1ug/dm2	Pass. The results for the test article were considered passing.
In-Vivo Thromboresistance	For both the test article and control, platelet counts and APTT time were within normal ranges. The test article and control article scored the same for thrombosis and vessel patency.	Pass. The test article demonstrated comparable thromboresistance to the control article.

Biocompatibility testing previously conducted for Transform Occlusion Balloon Catheter product is representative of the AXS Offset Delivery Assist Catheter product due to similarity of materials, manufacturing processes and design. There are no new manufacturing processes, processing aids or chemicals (fillers, additives, cleaning agents etc.) for the manufacture of the AXS Offset device. Screening tests were conducted on AXS Offset Delivery Assist Catheter devices to further provide supporting evidence that the minor differences do not adversely impact the product.

Following completion of testing and review of materials, the AXS Offset Delivery Assist Catheter is considered to have no residual risk of biological hazards. It meets requirements as outlined in EN ISO 10993-1 *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process* for an externally communicating, circulating blood and limited contact (≤24 hrs) duration device.

Sterilization and Shelf life

The AXS Catalyst Distal Access Catheter and all system components are sterilized with100% Ethylene Oxide. The AXS Catalyst Distal Access Catheter is provided sterile to a sterility assurance level (SAL) of 10-6, and is for single use only.

The test results for this device are within the ANSI/AAMI ST72:2011 Endotoxin Limit of 20 Endotoxin Units per device (EU/device). Bacterial endotoxin (pyrogen) testing of the AXS Offset Delivery Assist Catheter will be monitored to ensure product release meets specifications.

Ethylene oxide (EO) residuals on a sample representative of the AXS Catalyst DistalAccess Catheter are less than the maximum allowed for EO residuals per EN ISO 10993-7 for a limited contact delivery system –externally communicating.

The labeled shelf life for the AXS Offset is 3 years. Bench testing was conducted on accelerated aged AXS Offset Delivery Assist Catheters to confirm the shelf-life of the device is maintained over the duration of the labeled shelf-life.

Summary of Substantial Equivalence

The subject device is substantially equivalent to the predicate devices based on similar intended use / indications for use, same or similar materials, same fundamental design, and the same fundamental operating principles. Minor differences between the subject and predicate devices do not introduce different questions of safety and effectiveness. The conclusions drawn from risk assessments and the bench testing conducted using the subject device demonstrate that the device performs as designed, is suitable for its intended use, and that the benefits of the device outweigh any residual risks when used in accordance with device Instructions for Use.

Comparison Summary Table for Design

Feature	Proposed Device	Predicate Device	Predicate Device	Rationale for difference (if applicable)
	AXS Offset Delivery Assist Catheter	**Excelsior® XT-27 Microcatheter**	**Transform Occlusion Balloon Catheter**	
	Current Notification	**K113778**	**K122576**	
Proximal Outer Diameter	3.0F (1.0mm)	2.9F (0.97mm)	2.8F (0.95mm)	No significant difference
Distal Tip Outer Diameter	2.7F (0.91mm)	2.7F (0.91mm)	2.7F (0.95mm)	N/A - Same as primary predicate
Maximum Catheter Diameter (distal section)	3.8F (1.27mm)	2.7F (0.91mm)	3.8F(1.27mm)	The AXS Offset outside diameter is the same as the Transform and similar to the XT-27 predicate devices. The differences between XT27 and AXS Offset are related to the differences in the indications for use.
Inner Diameter	0.53mm (.021in)	0.69mm (0.027in)	0.31mm (.0124in)	AXS Offset ID of .021" is within the ranges of both predicate devices. .021" ID is a common size for a catheter of this length and OD.
Hydrophilic Coating Length	80cm	80cm	80cm - 83cm	N/A - Same as primary predicate

Feature	Proposed Device AXS Offset Delivery Assist Catheter Current Notification	Predicate Device Excelsior® XT-27 Microcatheter K113778	Predicate Device Transform Occlusion Balloon Catheter K122576	Rationale for difference (if applicable)
Effective Length	150cm	135 cm 150 cm	150 cm - 153cm	N/A - Same as primary predicate
Tip Length	2cm	6 cm 18 cm	1cm – 3cm	AXS Offset tip length of 2cm is in the range of the predicate Transform, but much shorter than the XT-27 predicate. Tip materials impact product performance more than tip length. Both AXS Offset and Excelsior XT-27 have the same distal tip materials and distal OD and thus have similar performance.
Tip Shape	Straight	Straight Pre-shaped	Straight	N/A - Same as primary predicate