K182512
510(k) Summary

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Device Name:	Route 92 Medical Delivery Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter (Product Code DQY, 21 CFR 870.1250)
Legally Marketed Predicate Device:	Route 92 Medical Delivery Catheter

Device Description

The Delivery Catheter is a single-lumen, variable stiffness catheter with a flexible, tapered tip delineated by two radiopaque markers. The distal shaft of the Delivery Catheter has a hydrophilic coating. On the proximal end is a hypotube attached to a luer hub for guidewire introduction. This proximal hypotube includes a fluoro-saver marker indicating when the tip of the catheter is about to exit a long femoral sheath/guide. The devices are provided sterile and non-pyrogenic and are intended for single use only. During use, a standard neurovascular guidewire may be inserted through the Delivery Catheter. The Delivery Catheter is inserted through a compatible access catheter. The Delivery Catheter and access catheter are advanced to the targeted location under fluoroscopy using standard endovascular techniques.

Indications for Use

The Route 92 Medical Delivery Catheter is indicated for use with compatible catheters in facilitating the insertion and guidance of catheters into a selected blood vessel in the neurovascular system.

Comparison to Predicate Device

The method of action, design, and materials of the Route 92 Medical Delivery Catheter are identical to the Delivery Catheter component of the Route 92 Medical Access System as shown in the following table.

Attribute	Predicate Delivery Catheter Provided as Part of the Route 92 Medical Access System (K180201)	Subject Route 92 Medical Delivery Catheter
Indications for Use	The Route 92 Medical Access System is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the neurovascular systems.	The Route 92 Medical Delivery Catheter is indicated for use with compatible catheters in facilitating the insertion and guidance of catheters into a selected blood vessel in the neurovascular system.
Device Description	The Delivery Catheter is a sterile, single-use, single-lumen, hydrophilically coated, variable stiffness catheter with a flexible, tapered tip.	Same as predicate device
User	Physicians trained in neurovascular interventional techniques	Same as predicate device
Anatomical Sites	Neurovasculature only	Same as predicate device
Materials	Biocompatible polymers and metals commonly used in the manufacture of medical devices Distal shaft: varying durometers of Pebax Proximal shaft: PTFE coated stainless steel Luer: polycarbonate	Same as predicate device
Inner Diameter	0.019”	Same as predicate device
Outer Diameter	Distal: 0.062” Proximal: 0.028”	Same as predicate device
Device Working Length	143 cm	Same as predicate device
Hydrophilic Coating	Present on polymer section of the Delivery Catheter	Same as predicate device
Accessories Included	No accessory included	Same as predicate device
Packaging	Nylon/Tyvek pouch inside of an SBS shelf carton	Same as predicate device
Sterilization Method	Ethylene Oxide	Same as predicate device
Shelf Life	8 months	Same as predicate device
Sterility	Validated to achieve Sterility Assurance Level (SAL) of 10^{-6}	Same as predicate device
Endotoxin Testing	Meets requirement for less or equal to 2.15 endotoxin units per device	Same as predicate device

Attribute	Predicate Delivery Catheter Provided as Part of the Route 92 Medical Access System (K180201)	Subject Route 92 Medical Delivery Catheter
Principle of Operation	During use, a standard neurovascular guidewire may be inserted through the Delivery Catheter. The Delivery Catheter is inserted through a compatible access catheter. The Delivery Catheter and access catheter are advanced to the targeted location under fluoroscopy using standard endovascular techniques.	Same as predicate device

Non-Clinical Testing

Biocompatibility Testing

The Route 92 Medical Delivery Catheter is constructed using materials that are commonly used in the medical device industry. All patient contacting components have been evaluated for biocompatibility in accordance with ISO 10993-1 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. The Route 92 Medical Access System is classified per ISO 10993-1 as externally communicating with limited circulating blood contact (≤ 24 hours). The following biocompatibility testing was performed for the predicate Route 92 Medical Access System (K180201) and leveraged from the predicate device submission to support the biocompatibility profile of the subject device because the subject Route 92 Medical Delivery Catheter contains the same materials of construction, design, and manufacturing processes as the predicate device.

Test	Results	Conclusions
Cytotoxicity – ISO MEM Elution	Grade 0 at 24, 48, 72 ± 4 hrs	The test article is non-cytotoxic.
Sensitization – ISO Guinea Pig Maximization Sensitization Test (Normal Saline and Sesame Oil)	Clinical Observations: none of the animals showed abnormal clinical signs during the test period. Main Test Results: Negative Control, grade =0 Normal Saline, grade = 0 Sesame Oil, grade = 0	Test article did not elicit a sensitization response.
Irritation – ISO Intracutaneous Reactivity (Normal Saline and Sesame Oil)	Dermal observations: Comparative Results Mean Test-Mean Control (Normal Saline) = 0 Mean Test-Mean Control (Sesame Oil) = 0.1 Differences between mean test and control scores were less than 1.0	Requirements of the ISO intracutaneous reactivity test have been met for the test article.
Acute Systemic Toxicity – ISO Acute Systemic Injection (Normal Saline and Sesame Oil)	None of the test article extract treated animals were observed with clinical signs consistent with toxicity. Body weight changes were within acceptable parameters.	Requirements of the ISO acute systemic injection test have been met for the test article.

Pyrogen – Material Mediated Pyrogen (Normal Saline)	During the 3-hr observation period, none of the rabbits administered with the text article extract had a temperature rise ≥ 0.5°C at the required observation time points. The response did not exceed the USP limits and meets the requirements for this test.	The test article is non-pyrogenic.
Test	**Results**	**Conclusions**
Hemocompatibility – Complement Activation (C3a & SC5b-9)	When compared to a legally US-marketed device, the minimal increase in complement activation noted in the test article would not be expected to result in adverse effects in vivo.	The test article would not be expected to result in adverse effects in vivo.
Hemocompatibility – Partial Thromboplastin Time (PTT)	The PTT of the test article was 100% of the negative control.	The test article is considered to be a non-activator of the intrinsic coagulation pathway and passes the test.
Hemocompatibility – ASTM Hemolysis	Blank corrected hemolytic index above the negative control: Direct Method: 0.0% Extract Method: 0.3%	The test article is considered non-hemolytic.
Hemocompatibility – Thromboresistance	All test animals survived the general anesthesia and study observation interval without test article related complications. The combined data of blood test reports, pre- and post-implant weight differences, and the patency and thrombus scores were not subjectively different between the test and control articles.	The test devices appear to have similar thromboresistance characteristics as the control devices.
Genotoxicity – ISO Bacterial Mutagenicity Test – Ames Assay (Normal Saline and Polyethylene Glycol)	The test article did not induce substantial increases in reversion rates of the type that are associated with mutagenesis and no substantial test article toxicity was noted that may have interfered with the ability of the test system to detect mutagens.	The test article is considered non-mutagenic.
Genotoxicity – ISO In Vitro Mouse Lymphoma (Normal Saline and Polyethylene Glycol)	The test article did not cause notable changes in the typical growth pattern of the L5178Y cells in suspension culture during the growth and expression period. The cloning efficiencies of these preparations were within normal limits.	The test article is considered to be non-mutagenic and non-clastogenic.

Performance Testing – Bench

The successful completion of the performance testing listed in the following table demonstrates that the Route 92 Medical Delivery Catheter is suitable for its intended use. The following performance (bench) tests, except the dimensional verification, were all leveraged from the predicate Route 92 Medical Access System (K180201) because the subject Route 92 Medical Delivery Catheter is identical in design to the same catheter component in the predicate device.

Test	Test Method	Results
Dimensional Verification	Device dimensions were measured to confirm conformance to the specifications	**PASS** All samples met the pre-determined acceptance criteria
Luer Integrity	Tested per ISO 80369-7:2016	**PASS** All samples met the pre-determined acceptance criteria
RHV Sealing	RHV sealing were tested	**PASS** All samples met the pre-determined acceptance criteria
Tensile Strength	The tensile strength of the catheter sections and bonds was tested	**PASS** All samples met the pre-determined acceptance criteria
Kink Resistance	Test specimen segments were formed into a defined bend diameter to evaluate kink resistance	**PASS** All samples met the pre-determined acceptance criteria
Torsion Resistance	The test specimens were rotated to evaluate integrity after rotation	**PASS** All samples met the pre-determined acceptance criteria
Tip Flexibility	Test specimens were tested for tip flexibility	**PASS** All samples met the pre-determined acceptance criteria
Air Leakage	Tested per ISO 10555-1:2013 Annex D.	**PASS** All samples met the pre-determined acceptance criteria
Liquid Leakage	Tested per ISO 10555-1:2013 Annex C.	**PASS** All samples met the pre-determined acceptance criteria
Hydrophilic Coating Integrity	The integrity of the hydrophilic coating was evaluated after multiple insertion and withdrawal cycles.	**PASS** All samples met the pre-determined acceptance criteria
Particulate Recovery	After multiple insertion and withdrawal cycles, the effluent water rinsed and flushed from the devices and model was tested per USP <788>.	**PASS** All samples met the pre-determined acceptance criteria
Corrosion Resistance	Tested per ISO 10555-1:2013 Annex A.	**PASS** All samples met the pre-determined acceptance criteria
Catheter Burst Pressure (Static & Dynamic)	Tested per ISO 10555-1:2013 Annex F.	**PASS** All samples met the pre-determined acceptance criteria

Catheter Flow Rate	Tested per ISO 10555-1:2013 Annex E.	**PASS** All samples met the pre-determined acceptance criteria
Test	**Test Method**	**Results**
Simulated Use Testing	Deliverability and compatibility with accessory devices was evaluated in a neurovascular model	**PASS** All samples met the pre-determined acceptance criteria
Packaging Integrity	ISO 11607-1 Part 1 ISO 11607-2 Part 2	**PASS** All samples met the pre-determined acceptance criteria
Radiopacity	Radiopacity of the device was evaluated in an animal model under fluoroscopy	**PASS** All samples met the pre-determined acceptance criteria

Substantial Equivalence

The Route 92 Medical Delivery Catheter has the same intended use, the same technological characteristics and same method of action as the predicate Route 92 Medical Access System. Therefore, based on the identical design and materials of construction between the subject and predicate devices and the completed non-clinical testing, the subject Route 92 Medical Delivery Catheter is substantially equivalent to the predicate Route 92 Medical Access System (K180201).