October 13, 2023

Wallaby Medical
Joseph Tang
Design Quality Engineer
22901 Mill Creek Drive
Laguna Hills, California 92653

Re: K232437
Trade/Device Name: Paragon 8F Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, QJP
Dated: August 11, 2023
Received: August 14, 2023

Dear Joseph Tang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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and Neurodiagnostic Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232437

Device Name

Paragon 8F Balloon Guide Catheter

Indications for Use *(Describe)*

The Paragon 8F Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Paragon 8F Balloon Guide Catheter is also indicated for use as a conduit for retrieval devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary (K232437)

As required by 21 CFR 807.92:

Applicant:	Wallaby Medical 22901 Mill Creek Drive Laguna Hills, CA 92653
Contact:	• Primary contact: Joseph Tang E-mail: joseph.tang@wallabyphenox.com Phone: +1 714 904 6097 • Secondary contact: Rachel McDaid E-mail: rachel.mcdaid@wallabyphenox.com Phone: +353 91 740 100
Date Prepared:	October 10th, 2023
Device Trade Name:	Paragon 8F Balloon Guide Catheter
Device Common Name:	Balloon Guide Catheter
Classification Name:	Percutaneous Catheter
Regulation Number:	21 CFR 870.1250
Product Code:	DQY, QJP
Predicate Device:	8F FlowGate Balloon Guide Catheter (K153729)
Reference Device 1:	087 Balloon Guide Catheter System (K192525)
Reference Device 2:	Neuron™ MAX System (K111380)

Device Description

The Paragon™ 8F Balloon Guide Catheter (BGC) is a multi-lumen, braid-reinforced, variable stiffness catheter with a radiopaque marker on the distal end and a bifurcated luer hub on the proximal end. A compliant balloon is mounted on the distal end. Balloon inflation and deflation can be facilitated through the side port of the bifurcated luer hub. The 10 mm long balloon can be inflated up to a maximum volume of 0.6 mL. At this volume, the balloon diameter is 10 mm. The through-lumen extends from the center port of the bifurcated luer hub to the distal tip. The external distal segment of the catheter shaft has hydrophilic coating to reduce friction during use. The coating starts from the proximal balloon bond and extends proximally for 19 cm in length. There are two Paragon 8F BGC configurations which have working lengths of 85 cm and 95 cm. The difference in device length resides in the proximal shaft segment only. The 16 cm distal flexible segment and the balloon are identical for both configurations.

The Paragon 8F Balloon Guide Catheter is compatible with minimum 0.110 inch inner diameter (ID) introducer sheaths, guidewires up to 0.038 inch outer diameter (OD), and 6F catheters up to 0.085 inch OD. The Paragon 8F Balloon Guide Catheter is sterile, non-pyrogenic, and intended for single use only.

Indications for Use

The Paragon 8F Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Paragon 8F Balloon Guide Catheter is also indicated for use as a conduit for retrieval devices.

Comparison to Predicate and Reference Devices

The table below provides the comparison of technological characteristics and indications for use of the subject device with the predicate and reference devices.

Table 1: Comparison to Predicate and Reference Devices

Device Name	**Subject Device: Paragon™ 8F Balloon Guide Catheter**	**Predicate Device: 8F FlowGate Balloon Guide Catheter**	**Reference Device: 087 Balloon Guide Catheter System**	**Rationale for Difference (if applicable)**
510(k) No.	**K232437**	**K153729**	**K192525**	
Classification	Class II, DQY, QJP	Class II, DQY	Class II, DQY	Same
Indication for Use	The Paragon 8F Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Paragon 8F Balloon Guide Catheter is also indicated for use as a conduit for retrieval devices.	FlowGate Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for retrieval devices.	The 087 Balloon Guide Catheter System is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neurovasculature. The balloon provides temporary vascular occlusion during such procedures. The 087 Balloon Guide Catheter System is also indicated for use as a conduit for retrieval devices.	Same
Anatomical Locations	Peripheral and neuro vasculature	Peripheral and neuro vasculature	Peripheral and neuro vasculature	Same
Catheter Shaft				
Material	Outer layer: Pebax, Polyamide, Polyurethane Inner layer: PTFE	Outer layer: Pebax, Pebax with Barium Sulfate, Polyamide with Barium Sulfate Inner layer: PTFE	Outer layer: Pebax, Polyamide, Polyurethane Inner layer: PTFE	The differences in the outer layer materials do not raise new questions of safety and effectiveness. The subject device has been evaluated via bench and biocompatibility testing.
Shaft Reinforcement	Stainless steel braid	Stainless steel braid	Stainless steel coil	Same
Shaft Construction	Single-wall lamination shaft with four equally spaced 0.5 mm wide inflation lumens embedded in the shaft's wall forming a multi-lumen shaft.	Dual-wall lamination shaft with an inner and outer shaft forming a coaxial lumen shaft.	Single-wall lamination shaft with three inflation lumens embedded in the shaft's wall forming a multi-lumen shaft.	The subject device has small inflation channels embedded in the shaft's wall. These differences in shaft construction do not raise new questions regarding safety and effectiveness.

Device Name	Subject Device: Paragon™ 8F Balloon Guide Catheter	Predicate Device: 8F FlowGate Balloon Guide Catheter	Reference Device: 087 Balloon Guide Catheter System	Rationale for Difference (if applicable)
				The subject device has been evaluated via bench and biocompatibility testing.
Radiopacity	Distal tip has one radiopaque Pt-Ir marker band and stainless-steel reinforcement in the catheter shaft, rendering the shaft visible under fluoroscopy.	Distal tip has one radiopaque Pt-Ir marker band and stainless-steel reinforcement in the catheter shaft, rendering the shaft visible under fluoroscopy.	Distal tip has two radiopaque Pt-Ir marker bands and stainless steel reinforcement in the catheter shaft rendering the shaft visible under fluoroscopy.	Same
Coating	Hydrophilic Coating	None	Hydrophilic Coating	Since the predicate device does not have a hydrophilic coating, a reference device is utilized for coating related benchtop testing to demonstrate substantial equivalence.
Compliant Balloon Material	Low durometer (52A) polyurethane	Silicone elastomer	Low durometer urethane	The material differences do not raise new questions of safety and effectiveness. The subject device has been evaluated via bench and biocompatibility testing.
Hub	Polyamide	Polyurethane	Similar	The material differences do not raise new questions of safety and effectiveness. The subject device has been evaluated via bench and biocompatibility testing.
Strain Relief	Pebax	Pebax, Polyolefin	Polyolefin	The material differences do not raise new questions of safety and effectiveness. The subject device has been evaluated via bench and biocompatibility testing.
Accessories				
Accessories Provided	RHV (1), Peel-Away Sheaths (2), Three-Way Stopcocks (2), 1 mL Syringe (1), Extension Tubing (1)	RHV (1), Peel-Away Sheaths (2), Luer-Activated Valve (1), Dilator (1), Tuohy Borst Valve with Sideport (1), Extension Tubing (1)	Three-Way Stopcock (1), Peel-Away Sheath (1), Hub Extension (1), 1 mL Syringe (1)	Similar. The differences do not raise new questions of safety and effectiveness.
Dimensions				
Balloon Catheter Labeled Outer Diameter	8F (0.109 in)	8F (0.106 in)	8.4F (0.110 in)	Similar
Balloon Catheter Labeled Inner Diameter	0.087 in	0.084 in	0.087 in	Similar
Working Lengths	85 cm, 95 cm	85 cm, 95 cm	90 cm, 95 cm, 100 cm	Same as the predicate device.
Radiopaque Marker Band Location	0.04 in from the distal tip edge	0.08 in from the distal tip edge	0.06 in from the distal tip edge (distal of the balloon) and 0.66 in from the distal tip edge (proximal of the balloon)	Similar
Maximum Balloon Volume	0.6mL	0.6mL	0.6mL	Same

Device Name	Subject Device: Paragon™ 8F Balloon Guide Catheter	Predicate Device: 8F FlowGate Balloon Guide Catheter	Reference Device: 087 Balloon Guide Catheter System	Rationale for Difference (if applicable)
Tip Shapes	Straight	Straight	Straight	Same
Packaging				
Pouch	Polyamide/Tyvek pouch	Tyvek and LLDPE/Nylon Film Pouch, Chipboard carton	Similar	Similar - packaging materials are similar and common for medical devices and maintain sterility of the device throughout the shelf life.
Tubing	Polyethylene tubes	Polyethylene tubes	Polyethylene tubes	Same
Packaging Card	HDPE	HDPE	HDPE	Same
Sterilization Method	EtO	EtO	EtO	Same
How Supplied	Sterile, single use	Sterile, single use	Sterile, single use	Same
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	Same
Shelf Life	12 months	36 months	36 months	A 12-month shelf life was validated for the subject device.

To establish substantial equivalence of the subject device and ensure the device meets the design specification and requirements, non-clinical bench and biological compatibility testing were conducted per the risk analysis. The testing performed and results are summarized below.

Design Verification Testing – Bench

Performance testing was conducted to support the Paragon™ 8F Balloon Guide Catheter submission. The results of the design verification and validation testing (Table 2) confirm that the subject device conforms to the pre-defined specifications and test acceptance criteria are met.

Table 2: Paragon™ 8F Balloon Guide Catheter Bench Testing Summary

Performance Bench Testing Summary		
Test	**Description**	**Results**
Visual Inspection	To verify the visual surface requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Dimensional Inspection	To verify the dimensional specifications are met.	Pass – all samples met the pre-determined acceptance criteria
Simulated Use	To evaluate the performance of the device and accessories in simulated anatomy model.	Pass – all samples met the pre-determined acceptance criteria
Kink Resistance	To evaluate the device around bends of clinically relevant radii and verify kink resistance requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Coating Lubricity	To evaluate frictional forces and verify coating lubricity requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Radiopacity	To evaluate marker band visibility under fluoroscopy.	Pass – all samples met the pre-determined acceptance criteria

Performance Bench Testing Summary		
Test	**Description**	**Results**
Delivery/Retrieval	To evaluate the device in an anatomical model and verify frictional force requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Balloon Inflation Time	To verify balloon inflation time requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Balloon Deflation Time	To verify balloon deflation time requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Distal Tip Stiffness	To evaluate distal tip deflection force and verify distal tip stiffness requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Coating Integrity	To evaluate device pre- and post-insertion and retrieval through a simulated vascular model and verify coating integrity requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Torque Strength	To evaluate device integrity after applied hub rotations with distal end held stationary and verify torque strength requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Shaft & Hub Tensile	To verify tensile strength requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Liquid Leak	To verify liquid leak requirements per ISO 10555-1 are met.	Pass – all samples met the pre-determined acceptance criteria
Air Leak	To verify air leak requirements per ISO 10555-1 are met.	Pass – all samples met the pre-determined acceptance criteria
Hub Compatibility	To verify BGC bifurcated luer hub requirements per ISO 80369-7 are met.	Pass – all samples met the pre-determined acceptance criteria
RHV Luer	To verify RHV luer requirements per ISO 80369-7 are met.	Pass – all samples met the pre-determined acceptance criteria
Static Burst	To verify static burst requirements per ISO 10555-1 are met.	Pass – all samples met the pre-determined acceptance criteria
Dynamic Burst	To verify dynamic burst requirements per ISO 10555-1 are met.	Pass – all samples met the pre-determined acceptance criteria
Resistance to Lumen Collapse	To demonstrate that the main lumen does not collapse under aspiration.	Pass – all samples met the pre-determined acceptance criteria
Corrosion Resistance	To verify corrosion resistance requirements per ISO 10555-1 are met.	Pass – all samples met the pre-determined acceptance criteria
Extension Tubing Tensile	To verify tensile strength requirements per ISO 10555- 1 are met.	Pass – all samples met the pre-determined acceptance criteria
Particulate	To evaluate the device within a simulated anatomy model and verify particulate count is similar to the comparator device.	Pass – all samples met the pre-determined acceptance criteria
Balloon Fatigue	To evaluate repetitive balloon inflation and deflation cycles and verify fatigue requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Balloon Joint Integrity	To evaluate tensile force and verify balloon joint integrity requirements are met.	Pass – all samples met the pre-determined acceptance criteria

Performance Bench Testing Summary		
Test	**Description**	**Results**
Balloon Burst Volume	To verify balloon burst volume requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Balloon Diameter to Inflation Volume (Compliance)	To characterize balloon diameter for pre-defined balloon inflation volumes.	All samples were characterized
Shelf Life	To verify device performance after accelerated aging.	Pass – all samples met the pre-determined acceptance criteria
Transit Testing	To subject the device, accessories, and packaging to environmental conditioning and shipping simulation and verify performance requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Packaging – Bubble Leak	To evaluate packaging per ASTM F2096-11 and verify requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Packaging – Pouch Seal Strength	To evaluate packaging per ASTM F88 Technique A (unsupported peel) and verify requirements are met.	Pass – all samples met the pre-determined acceptance criteria
Sterility	To subject the device, accessories, and packaging to sterilization and verify the requirements are met.	Pass – all samples met the pre-determined acceptance criteria

Animal Study

Animal study was not deemed necessary to demonstrate substantial equivalence.

Sterilization and Shelf Life

The subject device is sterilized using an Ethylene Oxide (EtO) sterilization cycle. The sterilization cycle was verified to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135:2014, *Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices*.

Shelf-life studies for the subject device have demonstrated that the subject device and packaging remain functional for the labeled use by date. Shelf-life studies for packaging integrity, seal strength, and device functionality were performed and met all acceptance criteria.

Biocompatibility

Biocompatibility evaluation for the subject device was performed in accordance with ISO 10993-1:2018, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. Biocompatibility testing completed for the device is included in Table 3.

Table 3: Biocompatibility Testing

Test	Standard	Results	Conclusion
Balloon Guide Catheter			
MEM Elution Cytotoxicity	Cytotoxicity 10993-5	Test article scored 0 at 48 hours.	Non-cytotoxic
MTT – L-929 Cytotoxicity Study	Cytotoxicity 10993-5	1XMEM test extract showed no cytotoxic potential to L-929 mouse fibroblast cells undiluted or at any dilution.	Non-cytotoxic
ISO Intracutaneous Irritation (GLP – 2 Extracts)	Irritation or Intracutaneous Reactivity 10993-10	The delta between the average scores of the extract of the test article and the vehicle control are 0.0; 0.0.	Non-irritant
ISO Guinea Pig Maximization Sensitization (GLP – 2 Extracts)	Sensitization 10993-10	Test and control animal's response not greater than "0".	Did not elicit sensitization response
ISO Acute Systemic Toxicity (GLP – 2 Extracts)	Systemic Toxicity 10993-11	None of the animals were observed with abnormal clinical signs indicative of toxicity for 72 hours. All were alive at the end of 72 hours and body weight changes were within acceptable parameters.	Non-toxic
ISO Material Mediated Rabbit Pyrogen (GLP)	Pyrogen 10993-11	No rabbit temperature rise >=0.5°C.	Non-pyrogenic
Complement Activation – SC5b-9 Assays (GLP)	Hemocompatibility 10993-4	Results were within acceptable range and not statistically different than activated NHS control or negative control.	Not a potential activator of complement system
ASTM Hemolysis – Direct Contact and Extract Method (GLP)		Blank corrected hemolytic index: 0.1.	Test device is non-hemolytic
Thromboresistance Evaluation (GLP – 4 Hour – 3 Dog)		No adverse effects or clinical signs during test period and no thrombus score >3 for either test or control device.	Thromboresistance of the test device is similar to control
In Vitro Hemocompatibility Assay with Sponsor-Supplied Comparison (GLP)		Test article results were within acceptable range.	Test article not a risk for adversely affecting concentrations of various cellular and non-cellular components in blood
Partial Thromboplastin Time (PTT) with Sponsor- Supplied Comparison Article (GLP)		Test article was found to be 99.5% of the negative control and not statistically different from the comparison article.	Not at risk for clotting
Chemical Characterization- Physiochemical Tests for Plastics (Buffering Capacity, Non-Volatile Residue (NVR) and Heavy Metals)	Chemical Characterization 10993-18	Extractable and leachable chemical characterization and the toxicological risk assessment of the BGC device suggest that the likelihood of having any adverse toxic effect is negligible during intended clinical use.	The risk is acceptable
3-Way Stopcock and Extension Tubing			
MEM Elution Cytotoxicity	Cytotoxicity 10993-5	Test article scored 0 at 24, 48, and 72 hours.	Non-cytotoxic
ISO Intracutaneous Irritation (GLP – 2	Irritation or Intracutaneous	The delta between the average scores of the extract of the test article and the vehicle	Non-irritant

Test	Standard	Results	Conclusion
Extracts)	Reactivity 10993-10	control are ≤1.	
ISO Guinea Pig Maximization Sensitization (GLP – 2 Extracts)	Sensitization 10993-10	Test and control animal's response not greater than "0".	Did not elicit sensitization response
ISO Acute Systemic Toxicity (GLP – 2 Extracts)	Systemic Toxicity 10993-11	None of the animals were observed with abnormal clinical signs indicative of toxicity for 72 hours. All were alive at the end of 72 hours and body weight changes were within acceptable parameters.	Non-toxic
ISO Material Mediated Rabbit Pyrogen (GLP)	Pyrogen 10993-11	No rabbit temperature rise >=0.5°C.	Non-pyrogenic
ASTM Hemolysis – Direct Contact and Extract Method (GLP)	Hemocompatibility 10993-4	Blank corrected hemolytic index: 0.1.	Test device is non-hemolytic
1 mL Syringe			
MEM Elution Cytotoxicity	Cytotoxicity 10993-5	Test article scored 0 at 48 hours.	Non-cytotoxic
ISO Intracutaneous Irritation (GLP – 2 Extracts)	Irritation or Intracutaneous Reactivity 10993-10	The delta between the average scores of the extract of the test article and the vehicle control are ≤1.	Non-irritant
ISO Guinea Pig Maximization Sensitization (GLP – 2 Extracts)	Sensitization 10993-10	Test and control animal's response not greater than "0".	Did not elicit sensitization response
ISO Acute Systemic Toxicity (GLP – 2 Extracts)	Systemic Toxicity 10993-11	None of the animals were observed with abnormal clinical signs indicative of toxicity for 72 hours. All were alive at the end of 72 hours and body weight changes were within acceptable parameters.	Non-toxic
ISO Material Mediated Rabbit Pyrogen (GLP)	Pyrogen 10993-11	No rabbit temperature rise >=0.5°C.	Non-pyrogenic
ASTM Hemolysis – Direct Contact and Extract Method (GLP)	Hemocompatibility 10993-4	Blank corrected hemolytic index: 0.1	Test device is non-hemolytic
Peel-Away Sheath			
MTT – L-929 Cytotoxicity Study	Cytotoxicity 10993-5	Test article scored 0 at 24, 48, and 72 hours.	Non-cytotoxic
ISO Intracutaneous Irritation (GLP – 2 Extracts)	Irritation or Intracutaneous Reactivity 10993-10	The delta between the average scores of the extract of the test article and the vehicle control are <1.	Non-irritant
ISO Guinea Pig Maximization Sensitization (GLP – 2 Extracts)	Sensitization 10993-10	Test and control animal's response not greater than "0".	Did not elicit sensitization response
ISO Acute Systemic Toxicity (GLP – 2 Extracts)	Systemic Toxicity 10993-11	None of the animals were observed with abnormal clinical signs indicative of toxicity for 72 hours. All were alive at the end of 72 hours and body weight changes were within acceptable parameters.	Non-toxic
ISO Material Mediated Rabbit	Pyrogen 10993-11	No rabbit temperature rise >=0.5°C.	Non-pyrogenic

Test	Standard	Results	Conclusion
Pyrogen (GLP)			
ASTM Hemolysis – Direct Contact and Extract Method (GLP)	Hemocompatibility 10993-4	Blank corrected hemolytic index: 0.1.	Test device is non-hemolytic
RHV			
Cytotoxicity MEM Elution	Cytotoxicity 10993-5	Percent Cell Lysis: 0% Cytotoxic Score: 0	Non-Cytotoxic
ISO Intracutaneous Irritation (GLP – 2 Extracts)	Irritation or Intracutaneous Reactivity 10993-10	The delta between the average scores of the extract of the test article and the vehicle control are 0.0; 0.0.	Negligible Irritant
ISO Guinea Pig Maximization Sensitization (GLP – 2 Extracts)	Sensitization 10993-10	Test and control animal's response not greater than "0".	Did not elicit sensitization response
ISO Acute Systemic Toxicity (GLP – 2 Extracts)	Systemic Toxicity 10993-11	None of the animals were observed with abnormal clinical signs indicative of toxicity for 72 hours. All were alive at the end of 72 hours and body weight changes were within acceptable parameters.	Non-toxic
ISO Materials Mediated Rabbit Pyrogen (GLP)	Pyrogen 10993-11	No rabbit temperature rise ≥0.5°C.	Non-pyrogenic
ASTM Hemolysis – Direct Contact and Extract Method (GLP)	Hemocompatibility 10993-4	Blank corrected hemolytic index: 0.0, 0.1.	Test device is non-hemolytic

Clinical Study

Clinical study was not deemed necessary to demonstrate substantial equivalence.

Conclusion

The Paragon™ 8F Balloon Guide Catheter is substantially equivalent to the predicate device, 8F FlowGate Balloon Guide Catheter (K153729), based on successful completion of non-clinical bench testing, biocompatibility, sterility, and comparison of the device operating principle, technological characteristics, and indications for use.