August 8, 2018

Imperative Care Inc.
Jake Wolenberg
Quality Assurance and Regulatory Affairs Manager
1221 Innsbruck Drive
Sunnyvale, California 94089

Re: K180169
Trade/Device Name: EagleRay Long Sheath, EagleRay Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 3, 2018
Received: July 9, 2018

Dear Jake Wolenberg:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Xiaolin Zheng -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180169

Device Name
EagleRay Long Sheath, EagleRay Access Catheter

Indications for Use *(Describe)*

The EagleRay Long Sheath and EagleRay Access Catheter are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

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
EagleRay Long Sheath and EagleRay Access Catheter

A. Submitter Information

Submitter's Name:	Imperative Care Inc.
Address:	1359 Dell Avenue Campbell, CA 95008
Telephone:	248-496-0198
Email:	JWolenberg@ImperativeCare.com
Contact Person:	Jake Wolenberg
Date of Preparation:	July 3, 2018

B. Subject Device

Proprietary Name:	EagleRay Long Sheath, EagleRay Access Catheter
510(k) #:	K180169
Common/Usual Name:	Guide Sheath & Guide Catheter
Classification Name:	Catheter, Percutaneous
Product Code:	DQY per 21 C.F.R. 870.1250

C. Primary Predicate Device

Primary

Proprietary Name:	Neuron Max System
Manufacturer:	Penumbra Inc.
510(k) #'s:	K111380
Common/Usual Name:	Guide Sheath
Classification Name:	Catheter, Percutaneous
Product Code:	DQY per 21 C.F.R. 870.1250

D. Additional Predicate Devices

Proprietary Name:	Arc & Arc Mini Intracranial Support Catheter
Manufacturer:	Micro Therapeutics, Inc. Dba Ev3 Neurovascular
510(k) #:	K150107
Common/Usual Name:	Guide Catheter
Classification Name:	Catheter, Percutaneous
Product Code:	DQY per 21 C.F.R 870.1250

Proprietary Name:	Navien Intracranial Support Catheter
Manufacturer:	Micro Therapeutics, Inc. Dba Ev3 Neurovascular
510(k) #:	K161152
Common/Usual Name:	Guide Catheter
Classification Name:	Catheter, Percutaneous
Product Code:	DQY per 21 C.F.R 870.1250

E. Device Description:

The EagleRay Long Sheath and EagleRay Access Catheter, hereinafter referred to as EagleRay Catheters, are 0.014”-0.038” guidewire compatible single lumen catheters that provide access to peripheral, coronary and neuro vasculature which allows insertion of other interventional devices.

The catheters are comprised of a hollow cylindrical tube which is bonded to a standard luer fitting. The wall of the tube is constructed using a combination of metal coils/braids and medical grade polymers. The distal section of each catheter has a hydrophilic coating to enhance tracking through tortuous vasculature. Additionally, an angled distal tip facilitates smoother tracking past vessel branches. The distal tip also has a radiopaque marker to provide the user with clear visual confirmation of the distal tip location under fluoroscopy.

The EagleRay Catheters will be offered with various working lengths and nominal inner diameters (ID) and outer diameters (OD) as shown in **Table 1** below.

Table 1: EagleRay Catheter Device Sizes

Commercial Name	Model Number	Distal Diameter		Proximal Diameter		Nominal Usable Catheter Length
		Inner	Outer	Inner	Outer	
EagleRay Long Sheath	ICLS088080	0.088”	0.106”	0.088”	0.108”	80cm
	ICLS088090					90cm
	ICLS088100					100 cm
	ICLS088110					110 cm
EagleRay Access Catheter	ICAC071137	0.071”	0.083”	0.071”	0.083”	137cm
	ICAC055137	0.055”	0.069”	0.067”	0.080”	137cm
	ICAC045144	0.045”	0.060”	0.064”		144cm
	ICAC035158	0.035”	0.051”	0.047”	0.060”	158cm

All EagleRay Catheters are packaged with an accessory Rotating Hemostasis Valve (RHV). The RHV is designed to be attached to the proximal luer of the catheter and helps the user maintain hemostasis.

The 0.088” ID EagleRay Long Sheath is packaged with an additional accessory, a short, retractable Catheter Introducer. This accessory is intended to prevent damage to the EagleRay Long Sheath when advancing it through the hemostasis valve on the access site introducer sheath.

In addition to the supplied accessories discussed above, the adjunctive devices and supplies listed below are intended to be used with the EagleRay Catheters. All of these accessories are also commonly used with the predicate devices.

- Guidewires
- Support/Diagnostic Catheters
- Introducer Sheaths

F. Indications for Use:

The EagleRay Long Sheath and EagleRay Access Catheter are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

G. Predicate Comparison:

The primary predicate device for the EagleRay Catheters is the Neuron Max System (Penumbra, Inc) cleared under K111380. The Neuron Max System was selected as the primary predicate for the EagleRay Catheters as the Neuron Max System has similar dimensions to the largest device sizes for the EagleRay Catheters and has the same intended use.

In addition to the primary predicate device, the devices in the Micro Therapeutics Intracranial Support Catheter product line, which include the Arc and Arc Mini catheters cleared under K150107 and the Navien catheters cleared under K161152, were used as predicate devices for the smaller EagleRay Catheter device sizes as they have similar dimensions and the same intended use.

Table 2 presented below provides a comparison of the similarities and differences between the proposed EagleRay Catheters, the predicate Neuron Max System, and the predicate Micro Therapeutics Intracranial Support Catheter product line. Bench and lab testing was conducted as appropriate to evaluate any differences that were identified.

The comparison between the subject and predicate devices found that the EagleRay Catheters are substantially equivalent to the predicate Neuron Max System and Micro Therapeutics Intracranial Support Catheters, and that there are no new safety or efficacy concerns. This conclusion is based on all devices sharing the same intended use, basic technology characteristics, and performance characteristics, as demonstrated through well-designed bench and lab testing.

Table 2: EagleRay Catheters, Neuron Max System, and Micro Therapeutics Intracranial Support Catheter Comparison

Device Attribute	EagleRay Catheters (subject device)	Penumbra Neuron Max System	Micro Therapeutics Intracranial Support Catheters
FDA Product Classification	Class II, DQY, 21 CFR 870.1250	Same	Same
Intended Use	Intended for use in supporting the introduction of interventional devices into the vasculature.	Same	Same
Condition Supplied	Sterile and Single Use	Same	Same
Sterilization Method	Ethylene Oxide (EtO), SAL 10^{-6}	Same	Same

Device Attribute	EagleRay Catheters (subject device)	Penumbra Neuron Max System	Micro Therapeutics Intracranial Support Catheters
Inner Diameter (Distal)	0.035" – 0.088"	0.088"	0.035" – 0.072"
Outer Diameter (Distal)	0.051" – 0.106"	0.105"	0.044" – 0.084"
Inner Diameter (Proximal)	0.047" – 0.088"	0.088"	0.044" – 0.072"
Outer Diameter (Proximal)	0.060" – 0.110"	0.110"	0.060" – 0.084"
Effective Length	80 - 158cm	80 - 90cm	90 - 163cm
Tip Design	Beveled edge, soft, flexible, and atraumatic	Square edge, soft, flexible, and atraumatic	Square edge, soft, flexible, and atraumatic
Coating	Surmodics Hydrophilic coating	Surmodics Hydrophilic coating	Hydrophilic coating
Materials	Commonly used medical grade plastics & metals with hydrophilic coating.	Commonly used medical grade plastics & metals with hydrophilic coating.	PTFE lined polymeric catheter shaft with hydrophilic coating, nitinol support wire, and platinum marker bands.
Packaged Accessories	Catheter Introducer Rotating Hemostasis Valve (RHV)	Dilator Rotating Hemostasis Valve (RHV) Hemostasis Valve	Catheter Introducer
Packaging Configuration	The catheters are placed in a protective polyethylene tube and then mounted, along with the accessories, onto a polyethylene packaging card. The packaging card is inserted into a Tyvek® pouch which is then sealed. The sealed pouch and IFU are placed in a shelf carton.	Same	Same

H. Performance Data Supporting Substantial Equivalence:

Bench and Lab (in-vitro) testing were conducted in order to evaluate the similarities and differences between the largest diameter EagleRay Catheters and the predicate Neuron Max System. Comparative testing was also performed to evaluate the similarities and differences between the smallest EagleRay Catheters and the predicate Micro Therapeutics Intracranial Support Catheters.

The test results were reviewed and found to demonstrate that any differences between the proposed and predicate devices do not significantly impact any catheter performance parameters that would affect the safety or efficacy of the subject EagleRay Catheters.

A summary of the tests and performance specifications that were evaluated is presented in **Table 3**. These tests were performed per company approved protocols and test methods based primarily on catheter performance standard ISO 10555-1.

Table 3: Tests and Performance Specifications

Test Attribute	Specification
Delivery, Compatibility, and Retraction (Trackability)	The catheter shall be able to be delivered, deployed, and retracted per the IFU within a simulated neurological model without incurring any damage to the catheter.
Flexibility and Kink Resistance	There shall be no kinking of shaft (permanent deformation) after simulated use.
Compatibility with other devices (external)	The catheters shall be able to be delivered through the minimum introducer sheath or guide catheter size indicated in the product labeling.
Guidewire compatibility	The catheters shall be able to be delivered over the maximum size guidewire indicated in the product labeling.
Interventional device compatibility (internal)	The catheters shall be able to accommodate other interventional devices (e.g., support catheter, diagnostic catheter) up to the maximum size indicated in the product labeling.
Luer compatibility	Devices and accessories shall be compatible with standard syringe luer fittings per ISO 80369-7.
Accessory compatibility	Devices shall be compatible with catheter introducer and RHV.
Catheter Bond Strength	The catheter shall have sufficient bond strengths to remain intact throughout a procedure.

Test Attribute	Specification
Flowrate – positive (forward) pressure	The catheter lumen shall allow for a minimum flowrate comparable to competitive products.
Freedom from Leakage – positive pressure	No liquid leakage from the hub or catheter shaft at 46psi for 30 seconds.
Freedom from Leakage – negative pressure	No air leakage into a 20cc syringe when vacuum pulled for 15 seconds.
Burst Pressure	Catheter does not burst under pressures that could be seen when performing contrast injections with a standard 10cc syringe.
Catheter Torque Strength	No separation of any portion of the catheter when rotated at least two (2) full rotations (360 degrees).
Kink Resistance	There shall be no kinking of the catheter shaft (permanent deformation) after wrapping around anatomically relevant bend radii.
Flexibility	The flexibility of the catheter tip shall be comparable to competitive products and allow for easily tracking the device to the desired target anatomy.
Pushability	The proximal shaft of the catheters shall have sufficient stiffness that the user can easily push the catheter to the target anatomy without buckling.
Coating - Particulate	The amount of particulate matter that comes off the hydrophilic-coated shaft during simulated use testing shall be determined and compared to competitive products and techniques.
Coating - lubricity	Coating must be lubricious and maintain a minimum lubricity over 15 test cycles.
Corrosion Resistance	No visible corrosion present on devices after saline immersion followed by 30 minutes in boiling water followed by 48 hours in 37°C water bath.
Radiopacity	The radiopaque marker on the catheter can be seen under fluoroscopy during use.

I. Biocompatibility Testing:

Biocompatibility testing was performed on all direct and indirect patient contacting components of the EagleRay Catheters. This testing was conducted to ensure that the components and raw materials used in the proposed EagleRay Catheters, as well as the manufacturing processes and sterilization processes result in a biocompatible product. All biocompatibility tests were conducted pursuant to 21 CFR Part 58, Good Laboratory Practices, ISO 10993-1, and per the recommendations in FDA guidance document titled: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

As the EagleRay Catheters are in direct contact with circulating blood and the average length of an endovascular procedure is typically less than 2 hours, the devices were evaluated for the tests recommended for the patient contact category: External communicating device, blood path direct, limited contact duration.

A summary of the selected biocompatibility tests performed for the EagleRay Catheters is presented for reference below and on the following pages in **Table 4**. All test results passed, indicating that the EagleRay Catheters are biocompatible for their intended use.

Table 4: Biocompatibility Test Summary

Test	Test Method	Extraction Methods/Conditions	Acceptance Criteria	Results
Cytotoxicity: ISO MEM* Elution	ISO 10993-5	Test device extracted in MEM with 5% serum at 37 ± 1°C for 24 ± 2 hours	Sample extracts must yield cell lysis grade 2 or lower.	**Pass, Non-cytotoxic**
Cytotoxicity: ISO MTT* Assay	ISO 10993-5	Test device extracted in MTT* Assay Media at 37 ± 1°C for 24 ± 2 hours	The percentage of cells exhibiting lysis should be similar for all test devices.	**Pass, No Significant Differences**
Sensitization: Magnusson-Kligman Method, 2 extracts	ISO 10993-10	Guinea pigs exposed to test device extracts. Challenged sites observed for skin sensitization 24 ± 2 and 48 ± 2 hours after removal of extracts. Extracts were prepared at 50 ± 2°C for 72 ± 2 hours.	Test Group shall yield Grade < 1 score on Magnusson and Kligman scale (provided control Grade < 1).	**Pass, Non-Sensitizing**

Test	Test Method	Extraction Methods/Conditions	Acceptance Criteria	Results
Irritation: ISO Intracutaneous Irritation Test	ISO 10993-10	Rabbits are injected with extracts of test device. Injection sites examined/scored at 24 ± 2, 48 ± 2 and 72 ± 2 hours after injections. Extracts were prepared at 50 ± 2°C for 72 ± 2 hours.	The difference in the mean test article and mean control score must be grade 1.0 or lower.	**Pass, Non-Irritant**
Systemic Toxicity: ISO Materials Mediated Rabbit Pyrogen	ISO 10993-11:2006	Test device extracted in 0.9% NS* and injected in the marginal ear vein. Rectal temperatures recorded prior to injection and every 30 min until 1-3 hours post injection. Extracts were prepared at 50 ± 2°C for 72 ± 2 hours	Sample Extracts must not cause a total rise in body temperature of ≥0.5°C.	**Pass, Non-pyrogenic**
Systemic Toxicity: ISO Acute Systemic Injection Test	ISO 10993-11	Mice are injected with extracts of test device. Animals are observed for signs of toxicity immediately after injection, 4 ± 0.75, 24 ± 2, 48 ± 2 and 72 ± 2 hours after injections. Body weights are measured prior to injection and on all 3 days. Extracts were prepared in 0.9% NS* and Sesame Oil at 50 ± 2°C for 72 ± 2 hours.	Sample extracts must not cause the following: • > 10% weight loss in 3 or more test animals • Mortality of 2 or more test animals • Toxic signs such as convulsions and prostration in 2 or more test animals	**Pass, Non-Toxic**
Hemocompatibility: Complement Activation	ISO 10993-4 ASTM F756	Preformed in vitro using a prepared Enzyme Immunoassay (EIA) kit. This kit will detect the presence of specific complement enzymes. Test device incubated in serum at 37± 2°C and tested for C3a and SC5b at 0.5, 1, and 1.5 hours.	The concentrations of C3a and SC5b-9 in the test devices are statistically similar to the predicate device (Penumbra Neuron Max 6F Catheter) and statistically lower than the positive control for all exposure times.	**Pass, No Significant Differences** The test device had statistically similar or lower concentrations than the predicate and negative controls.

Test	Test Method	Extraction Methods/Conditions	Acceptance Criteria	Results
Hemocompatibility: Hemolysis (Direct Contact Method)	ASTM F 756 ISO 10993-4	Test device extracted in PBS* and diluted blood at 37 ± 2°C for 3 ± 5 minutes. Test device exposed to blood cell suspension. % hemolysis is measured.	Sample extracts must be nonhemolytic (≤ 2% hemolytic index).	**Pass, Non-hemolytic**
Hemocompatibility: Hemolysis (Extract Method)	ASTM F 756 ISO 10993-4	Test device extracted in PBS at 50 ± 2°C for 72 ± 2 hours. Extract exposed to blood cell suspension. % hemolysis is measured.	Sample extracts must be nonhemolytic (≤ 2% hemolytic index).	**Pass, Non-hemolytic**
Standard In vivo Thrombogenicity, Ovine Jugular NAVI (ISO)	ISO 10993-4:2002	Performed in duplicate. Test and control device are placed in alternate sides of the juggler vein. The devices are implanted and remains in place for 4 ± 0.5 hours.	The device must have similar or lesser thrombogenic potential after 4 hours in vivo when compared to a control device (Penumbra Neuron Max 6F Catheter).	**Pass, Minimal Thrombogenic Potential** The test device had less thrombogenic potential than the control device.

*MEM=Minimal Essential Media,
MTT Assay = (3-(4,5-Dimethylthiazol-2-yl)-2,5-Diphenyltetrazolium Bromide)
NS = Normal Saline
PBS=Phosphate Buffered Saline

J. Sterilization:

The EagleRay Catheters are sterilized using a validated EtO process with a sterility assurance level of $1x10^{-6}$. The sterilization process was validated per the overkill method described recognized consensus standard ISO 11135, "Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices." A summary of the completed testing is presented below in **Table 5**.

Table 5: Sterilization Validation Summary

Requirement/Acceptance Criteria	Results	Summary
Positive BI controls must be positive in fractional, half and full cycles.	**PASS**	All positive controls in each cycle read positive.
Fractional cycle requirements: 1) IPCDs must be equal or less difficult to sterilize than the EPCDs 2) The IPCDs and EPCDs may show growth after 7 days with the EPCD required to be equal or more EtO resistant. 3) Product Sterility testing must show no growth in all samples. 4) Bacteriostasis/Fungistasis testing must show that the product is not inhibitory for growth.	**PASS**	1) IPCDs showed growth after 7 days. 2) EPCDs were equal or more EtO resistant than the IPCDs. 3) The devices did not show any growth when tested per the methods in ISO 11737-2. 4) Bacteriostasis/Fungistasis Testing showed product is not inhibitory to growth when tested per the methods in ISO 11737-2.
Half cycle requirements: 1) The IPCDs must show no growth after 7 days 2) EPCD are expected to show no growth after 7 days. A few positives are allowed by ISO 11135.	**PASS**	1) IPCDs showed no growth after 7 days. 2) EPCDs showed no growth after 7 days.
Full cycle requirements: 1) The IPCDs must show no growth after 7 days 2) Selected EPCD must show no growth after 7 days. 3) Samples exposed to 2X sterilization cycle must pass EtO residual testing.	**PASS**	1) IPCDs showed no growth after 7 days. 2) EPCDs showed no growth after 7 days. 3) Samples passed EtO residual testing at 0 hour aeration time point.

K. Shelf Life and Packaging:

Accelerated aging testing based on ASTM F1980 was conducted to verify device, accessory, and packaging performance. A real time aging equivalent of 13 months was used for this testing and will allow for labeling of product with a 1-year shelf life.

Device and accessory performance was verified by repeating the functional tests previously presented in Section H of this 510(k) summary.

Packaging and sterile barrier integrity through transportation has been verified for both the packaging configurations used for the EagleRay Catheters, a straight packaging configuration and a circular packaging configuration. Aging testing has also been performed that supports the sterile barrier integrity following 13 months of accelerated aging. A summary of the completed packaging test is presented below in **Table 6**.

Table 6: Packaging Validation Summary

Test	Test Method	Straight Packaging Results (Pass/Fail)	Circular Packaging Results (Pass/Fail)
Packaging Visual Inspection	ASTM F1886 Imperative Care TM00071	Pass	Pass
Pouch Integrity Test – Gross Leak Detection	ASTM F2096	Pass	Pass
Pouch Seal Strength – Peel Strength	ASTM F88	Pass	Pass
Label Integrity	Imperative Care TM00071	Pass	Pass

L. Animal Studies

A series of subacute and chronic animal studies were conducted to evaluate the safe use of the EagleRay Catheter design in a porcine model. 510(k) cleared neurovascular catheters, including the predicate Penumbra Neuron Max System, were used as control devices. The studies concluded that:

- There was no angiographic evidence of vessel injury in any of the treated vessel segments (test or control).
- No significant histological findings were found in relation to use of the test or control devices.
- Use of the test devices resulted in no significant vascular response during these studies and was found to be comparable to the control devices by the study pathologist and the study director.

M. Conclusions:

Where differences were identified between the subject EagleRay Catheters, the predicate Neuron Max System, and the predicate Micro Therapeutics Intracranial Support Catheters, a risk assessment was completed to determine if the difference would result in new safety or efficacy concerns regarding the use of the device. As appropriate, bench, lab, and animal testing was conducted to support this assessment.

Based on the results of the conducted risk assessments and associated bench, lab, and animal testing, it is concluded that EagleRay Catheters are substantially equivalent to the predicate Neuron Max System and predicate Micro Therapeutics Intracranial Support Catheters and that there are no new safety or efficacy concerns associated with the identified differences. This conclusion was determined based on the fact that the subject device and multiple predicate devices share the same intended use, basic technology characteristics, and performance characteristics, as confirmed through well-designed bench, lab, and animal testing.