510(k) Summary

A. Submitter Information

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Date of Preparation: October 31, 2018

B. Subject Device

Proprietary Name: MantaRay (071, 055, 045, 035) Reperfusion Catheters; Imperative Care Aspiration Tubing Set
Common/Usual Name: Catheter, Thrombus Retriever
Classification Name: Catheter, Percutaneous
Product Code: NRY per 21 C.F.R. 870.1250

C. Primary Predicate Device

Proprietary Name: Penumbra System
Manufacturer: Penumbra Inc.
510(k) #'s:

Predicate Device Model	Corresponding 510(k)
ACE68	K152541, K142458[1]
5MAX	K090752
4MAX	K113163
3MAX	K113163

Common/Usual Name: Catheter, Thrombus Retriever
Classification Name: Catheter, Percutaneous
Product Code: NRY per 21 C.F.R. 870.1250

[1] The Penumbra System ACE68 Reperfusion Catheter was cleared under K142458 with an Indications for Use in the internal carotid artery (ICA) only. In K152541, animal study data was submitted showing that the catheters were safe to use in a "wedged" position and Indications for Use for the same Penumbra System ACE68 Reperfusion Catheter design was expanded to include the ICA, M1, M2, vertebral, and basilar arteries.

D. Device Description:

The MantaRay Reperfusion Catheter is a single lumen, braid and coil reinforced, variable stiffness catheter that facilitates removal of thrombus/clot from the neurovasculature when connected to a vacuum source generated from the Imperative Care Aspiration Pump using the Imperative Care Aspiration Tubing. The MantaRay Reperfusion Catheter will be offered with various working lengths and nominal inner diameters (ID) and outer diameters (OD) as shown in **Table 1** below.

Table 1: MantaRay Reperfusion Catheter Sizes

Product Name (Used Throughout 510k)	Model Number	Distal Diameter		Proximal Diameter		Nominal Usable Catheter Length	Hydrophilic Coating Length
		Inner	Outer	Inner	Outer		
0.071” ID MantaRay	ICRC071137	0.071”	0.083”	0.071”	0.083”	137 cm	35cm
0.055” ID MantaRay	ICRC055137	0.055”	0.069”	0.067”	0.080”	137 cm	35cm
0.045” ID MantaRay	ICRC045144	0.045”	0.060”	0.064”	0.080”	144 cm	65cm
0.035” ID MantaRay	ICRC035158	0.035”	0.051”	0.047”	0.060”	158 cm	90cm

The MantaRay Reperfusion Catheter is 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 the MantaRay Reperfusion Catheter has a hydrophilic coating to enhance tracking through the vasculature. The beveled distal tip allows for atraumatic tracking past vessel branches during insertion. A radiopaque marker provides the user with visual confirmation of the distal tip location under fluoroscopy.

The MantaRay Reperfusion Catheter is 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.

In addition to the supplied accessories discussed above, the adjunctive devices and supplies listed below are intended to be used with the MantaRay Reperfusion Catheter. All of these accessories are also commonly used with the predicate Penumbra System.

- Guidewires
- Support/Diagnostic Catheters
- Introducer Sheaths

Imperative Care will offer an Aspiration Pump and Tubing that can be used with the MantaRay Reperfusion Catheter (referred to as Imperative Care Aspiration Pump and Imperative Care Aspiration Tubing). The Imperative Care Aspiration Pump and Tubing will be packaged and sold separately from the MantaRay Reperfusion Catheter.

The Imperative Care Aspiration Pump was cleared under K180115 and the Imperative Care Aspiration Tubing is a part of this 510(k) submission. The Imperative Care Aspiration Pump (K180115) and Aspiration Tubing are manufactured for Imperative Care by Taiwan Biomaterial Co., Ltd. (TWBM). The MantaRay Reperfusion Catheter has been tested with and verified to perform as intended when used in conjunction with the Imperative Care Aspiration Pump and Tubing.

E. Indications for Use:

The MantaRay Reperfusion Catheters, with the Imperative Care Aspiration Tubing Set and Imperative Care Aspiration Pump (or equivalent vacuum pump), are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

The Imperative Care Aspiration Tubing Set is intended to connect the Imperative Care Reperfusion Catheter to the canister of the Imperative Care Aspiration Pump and to allow the user to control the fluid flow.

F. Predicate Comparison:

The predicate device for the MantaRay Reperfusion Catheter is the Penumbra System Reperfusion Catheter (ACE68, 5MAX, 4MAX, and 3MAX). The Penumbra System Reperfusion Catheter was selected as the predicate device as it has the same intended use and similar catheter designs as the subject MantaRay Reperfusion Catheter.

There are multiple catheter sizes in the predicate device product family that were cleared over a series of 510(k) submissions, as indicated in **Table 2** below. Each of the MantaRay Reperfusion Catheter sizes was designed to correspond to one of the predicate Penumbra System Reperfusion Catheter sizes.

Table 2: Subject and Predicate Device Models

Subject Device Model	Distal Inner Diameter x Working Length	Corresponding Predicate Device Model	Distal Inner Diameter x Working Length	Predicate Device 510(k)
0.071” ID MantaRay	0.071” x 137cm	ACE68	0.068” x 132cm	K152541 K142458[2]
0.055” ID MantaRay	0.055” x 137cm	5MAX	0.054” x 132cm	K090752
0.045” ID MantaRay	0.045” x 144cm	4MAX	0.041” x 139cm	K113163
0.035” ID MantaRay	0.035” x 158cm	3MAX	0.035” x 153cm	K113163

Table 3 presented below provides a comparison of the similarities and differences between the subject MantaRay Reperfusion Catheters and the predicate Penumbra System Reperfusion Catheters. Bench and lab testing was conducted as appropriate to evaluate any differences that were identified.

[2] The Penumbra System ACE68 Reperfusion Catheter was cleared under K142458 with an Indications for Use in the internal carotid artery (ICA) only. In K152541, animal study data was submitted showing that the catheters were safe to use in a “wedged” position and Indications for Use for the same Penumbra System ACE68 Reperfusion Catheter design was expanded to include the ICA, M1, M2, vertebral, and basilar arteries.

The comparison between the subject and predicate devices found that the MantaRay Reperfusion Catheter is substantially equivalent to the predicate Penumbra System Reperfusion Catheter, and that there are no new safety or effectiveness concerns. This conclusion is based on all devices sharing the same intended use, basic technology characteristics, and performance characteristics, as demonstrated through bench, lab, and animal testing.

Table 3: Subject and Predicate Device Comparison

Device Attribute	MantaRay Reperfusion Catheter (Subject Device)	Penumbra System Reperfusion Catheter (Predicate Device)
FDA Product Classification	Class II, NRY, 21 CFR 870.1250	Same
Intended Use	Revascularization of patients with acute ischemic stroke.	Same
Condition Supplied	Sterile and Single Use	Same
Sterilization Method	Ethylene Oxide (EtO), SAL 10^{-6}	Same
Inner Diameter (Distal)	0.035” – 0.071”	0.035” – 0.068”
Outer Diameter (Distal)	0.051” – 0.083”	0.050” – 0.084”
Inner Diameter (Proximal)	0.047” – 0.071”	0.043” – 0.068”
Outer Diameter (Proximal)	0.060” – 0.083”	0.062” – 84
Effective Length	137 - 158cm	132 - 160cm
Tip Design	Beveled edge, soft, flexible, and atraumatic	Square edge, soft, flexible, and atraumatic
Coating	Surmodics Hydrophilic coating	Surmodics Hydrophilic coating
Materials	Commonly used medical grade plastics & metals with hydrophilic coating.	Commonly used medical grade plastics & metals with hydrophilic coating.
Packaged Accessories	Rotating Hemostasis Valve (RHV)	Rotating Hemostasis Valve (RHV) Peelable Catheter Introducer Steam Shaping Mandrel
Packaging Configuration	The catheter is 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 carton box.	Same

Device Attribute	MantaRay Reperfusion Catheter (Subject Device)	Penumbra System Reperfusion Catheter (Predicate Device)
Key Device Components	Imperative Care Aspiration Pump Imperative Care Aspiration Tubing Set	Penumbra Pump MAX Penumbra Hi-Flow Tubing
Critical Aspiration Pump Performance Requirements		
Aspiration Pressure	-20 inHg to max vacuum	-20 inHg to max vacuum
Flowrate (Air)	0 to 23 LPM	0 to 23 LPM
IEC 60601 Compliance	Pump is compliant with electrical safety standards.	Pump is compliant with electrical safety standards.
Critical Aspiration Tubing Requirements		
Tubing ID	0.110” Minimum	0.110” Minimum
Tubing Length	112”	112”
Flow Control Mechanism	Flow Control Switch	Flow Control Switch

G. Performance Data Supporting Substantial Equivalence:

Bench and Lab (in-vitro) testing were conducted in order to evaluate the similarities and differences between the MantaRay Reperfusion Catheter with Imperative Care Aspiration Pump and Aspiration Tubing Set and the predicate Penumbra System. The largest and smallest diameter catheter sizes were tested for both the subject and predicate devices.

The test results were reviewed and found to demonstrate that the differences between the subject and predicate devices do not significantly impact any performance parameters that would negatively affect the safety or effectiveness of the subject MantaRay Reperfusion Catheter used with the Imperative Care Aspiration Pump and Aspiration Tubing Set.

A summary of the tests and performance specifications that were evaluated is presented in **Table 4**. These tests were performed per company approved protocols and test methods based primarily on catheter performance standard ISO 10555-1.

Table 4: 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.
Clot Retrieval	The catheter will be able to be delivered in a clinically relevant model and used to effectively aspirate clots with the aspiration pump and aspiration tubing set when placed at appropriate locations based on the size of 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 guidewire size 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 the accessory RHV.

Test Attribute	Specification
Visual	Free of kinks, breaks, separation or particulate (greater than $0.25mm^2$). No exposed metal.
Dimensional	All defined catheter dimensions are within the specified tolerances.
Catheter Bond Strength	The catheter shall have sufficient bond strengths to remain intact throughout a procedure.
Flowrate – positive (forward) pressure	The catheter lumen shall allow for a minimum flowrate comparable to competitive products.
Flowrate – vacuum pressure	The flowrate under a vacuum shall be similar to or greater than competitive devices.
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 (720 degrees).
Lumen Integrity	The catheter lumen shall not collapse under vacuum.
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.
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.

Test Attribute	Specification
Corrosion Resistance	No visible corrosion present on devices after saline immersion followed by 30 minutes in boiling water followed by 48 hours in 37ºC water bath.
Radiopacity	The radiopaque marker on the catheter can be seen under fluoroscopy during use.
Vacuum Force at Catheter Tip	The vacuum force at the tip of the catheter should be comparable to the vacuum force at the tip of the predicate devices.
Aspiration Volume	The volume of fluid aspirated when using the catheter should be comparable to the predicate devices.

In addition to the above tests which support that the MantaRay Reperfusion Catheter performs as intended when used in conjunction with the Imperative Care Aspiration Pump and Aspiration Tubing Set, Imperative Care also confirmed that performance testing has been completed for the Imperative Care Aspiration Pump (K180115) and Imperative Care Aspiration Tubing Set individually. Testing completed for the Imperative Care Aspiration Pump is summarized in K180115. Testing for the Imperative Care Aspiration Tubing includes: connector compatibility, lumen collapse resistance, flow control switch functionality, freedom from leakage, and tensile strength.

H. Biocompatibility Testing:

Biocompatibility testing was performed on all direct and indirect patient contacting components of the MantaRay Reperfusion Catheter. This testing was conducted to ensure that the components and raw materials used in the proposed MantaRay Reperfusion Catheter, 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 MantaRay Reperfusion Catheter is in direct contact with circulating blood and the average length of an endovascular procedure is typically less than 2 hours, the test devices were evaluated for the tests recommended in the patient contact category: External communicating device, blood path direct, limited contact duration.

A summary of the selected biocompatibility tests performed for the MantaRay Reperfusion Catheter is presented for reference below and on the following pages in **Table 5**. All test results passed, indicating that the MantaRay Reperfusion Catheter is biocompatible for its intended use.

Table 5: 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

Imperative Care also confirmed that the Imperative Care Aspiration Tubing Set is biocompatible for its intended use. Biological evaluation of the aspiration tubing was conducted pursuant to 21 CFR Part 58, Good Laboratory Practices and following 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 aspiration tubing does not have any patient contact, it was evaluated for the tests recommended for skin contacting devices to cover a worst-case scenario where the aspiration tubing may be handled by someone who isn't wearing gloves. All test results passed, indicating that the aspiration tubing is biocompatible for the intended use.

I. Sterilization:

The MantaRay Reperfusion Catheter is 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 6**.

Table 6: 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.

Imperative Care also confirmed that sterilization validation has been completed for the Imperative Care Aspiration Tubing Set, which is provided sterile via Ethylene Oxide (EtO) and with a sterility assurance level of $1x10^{-6}$. The sterilization process was validated per the overkill and equivalence method described in recognized consensus standard 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." All requirements for EtO sterilization validation per the methods indicated in ISO 11135 were completed and all test results passed.

J. 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.

All device component performance was verified by repeating a subset of the functional tests previously presented in Section G of this 510(k) summary.

Packaging and sterile barrier integrity through transportation has been verified for the packaging configuration used for the MantaRay Reperfusion Catheter. 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 7**.

Table 7: Packaging Validation Summary

Test	Test Method	T0 Results (Pass/Fail)	1-Year Shelf Life 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

Imperative Care also confirmed that shelf life testing and packaging validation has been completed for the Imperative Care Aspiration Tubing Set. Accelerated aging testing based on ASTM F1980 was conducted to verify performance of the aspiration tubing and the packaging. A real time aging equivalent of 24 months was used for this testing and will allow for labeling of the aspiration tubing with a 23 month shelf life.

K. Animal Studies

A series of subacute and chronic animal studies were conducted to evaluate the safe and effective use of the MantaRay Reperfusion Catheter with the Imperative Care Aspiration Pump and Aspiration Tubing Set in a porcine model. Testing included worst case positioning of the catheter in a "wedged" position, retrieval of various types of clots, and evaluation of various aspiration pressures. The predicate Penumbra System was used as a control device in all completed studies. The studies concluded that:

- All vessels treated with the MantaRay Reperfusion Catheters were patent, with no perforation, dissection or thrombosis following completion of the procedure.
- The subacute and chronic vascular response was histologically comparable between the MantaRay Reperfusion Catheter and predicate Penumbra System Reperfusion Catheter.
- The subacute and chronic pathological findings were comparable between the MantaRay Reperfusion Catheter and predicate Penumbra System Reperfusion Catheter.

L. Physician Validation Study

A user validation study was developed and conducted per recommendations in the FDA guidance document titled "*Applying Human Factors and Usability Engineering to Medical Devices"*. As part of the study, active US physicians experienced in interventional neuroradiology and neurovascular surgery were asked to complete clot retrieval procedures under fluoroscopic visualization in a tortuous neurovascular simulated use model using both the subject MantaRay Reperfusion Catheter with the Imperative Care Aspiration Pump and Aspiration Tubing Set and the predicate Penumbra System. The order in which each physician tested the subject and predicate devices was randomized to reduce bias.

The results of the clot retrieval procedures for the subject and predicate devices were analyzed and compared. The analysis found no significant differences between the subject and predicate devices that would negatively impact safety or effectiveness.

M. Conclusions:

Where differences were identified between the subject MantaRay Reperfusion Catheter with the Imperative Care Aspiration Pump and Aspiration Tubing Set and the predicate Penumbra System, a risk assessment was completed to determine if the difference would result in new safety or effectiveness concerns regarding the use of the device. As appropriate, testing (bench, lab, and animal) was conducted to support this assessment.

Based on the results of the conducted risk assessments and associated testing, it is concluded that MantaRay Reperfusion Catheters with the Imperative Care Aspiration Pump and Aspiration Tubing Set is substantially equivalent to the predicate Penumbra System and that there are no new safety or effectiveness concerns associated with the identified differences. This conclusion was determined based on the fact that the subject and predicate devices share the same intended use, basic technology characteristics, and equivalent performance characteristics, as confirmed through bench, lab, and animal testing.