October 30, 2025

Imperative Care, Inc.
Peter Taylor
Principal Regulatory Affairs Specialist
1359 Dell Avenue
Campbell, California 95008

Re: K252046
Trade/Device Name: Zoom System (Zoom 4S Catheter)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: September 26, 2025
Received: September 29, 2025

Dear Peter Taylor:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252046

Device Name
Zoom System (Zoom 4S Catheter)

Indications for Use *(Describe)*
The Zoom System, when used with the Zoom Aspiration Pump (or equivalent vacuum pump), is 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 last known well. Patients who are ineligible for intravenous thrombolytic drug therapy or who have not responded to thrombolytic drug therapy are candidates for treatment.

The Zoom Aspiration Tubing and the Zoom POD Aspiration Tubing are intended to connect the Zoom (7X, 71, 55, 45, 4S, 35) Catheter and the Zoom 88 Large Distal Platform, the Zoom 88 Large Distal Platform Support, or the TracStar LDP Large Distal Platform to the Zoom Canister or Zoom DuoPort Canister of the Zoom Aspiration Pump (or equivalent vacuum pump) and to allow the user to control the fluid flow.

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.

510(k) Summary

K252046

I. SUBMITTER

Submitter's Name:	Imperative Care, Inc.
Address:	1359 Dell Avenue Campbell, CA 95008
Contact Person:	Peter Taylor
Telephone:	831-227-4810
Email:	ptaylor@imperativecare.com
Date of Preparation:	October 24, 2025

II. DEVICE

Proprietary Name:	Zoom™ System (Zoom™ 4S Catheter)
Common/Usual Name:	Catheter, Thrombus Retriever
Classification Name:	Percutaneous Catheter
Regulatory Class:	II
Product Code:	NRY
Regulation	21 CFR 870.1250

III. PREDICATE DEVICE

Proprietary Name:	Zenith Flex Aspiration System (046 Zenith Flex Catheter)
Common/Usual Name:	Catheter, Thrombus Retriever
Classification Name:	Percutaneous Catheter
Product Code:	NRY
Regulation:	21 CFR 870.1250
Manufacturer:	InNeuroCo, Inc.
510(k) #:	K190338

IV. REFERENCE DEVICE

Proprietary Name:	Zoom™ System
Common/Usual Name:	Catheter, Thrombus Retriever
Classification Name:	Percutaneous Catheter
Product Code:	NRY
Regulation:	21 CFR 870.1250
Manufacturer:	Imperative Care Inc.
510(k) #:	K242672

V. DEVICE DESCRIPTION

The Zoom 4S Catheter, a new catheter within the Zoom System, is a single lumen, braid and coil reinforced, variable stiffness catheter with a radiopaque marker and a lubricious hydrophilic coating on the distal portion of the catheter. The Zoom 4S Catheter has a luer hub on the proximal end. The Zoom 4S Catheter is intended to be used in conjunction with the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing and Zoom Aspiration Pump (or equivalent vacuum pump) to aspirate thrombus.

Dimensions of the Zoom 4S Catheter are included on the individual device label. The Zoom 4S Catheter is compatible with 0.035" or smaller guidewires. An additional support catheter may be used to assist in accessing the target vasculature. The Zoom 4S Catheter is compatible with guide sheaths having a minimum inner diameter of 0.071".

The Zoom 4S Catheter is packaged with an accessory Rotating Hemostasis Valve (RHV). The RHV is intended to be attached to the proximal hub of the catheter and used to control hemostasis during use with other devices.

The Zoom Aspiration Tubing and the Zoom POD Aspiration Tubing (Zoom POD) are comprised of a hollow cylindrical tube which is bonded to a standard luer fitting that connects to the Zoom 4S Catheter and a slip fit connector that connects to the canister on the aspiration pump. The Zoom Aspiration Tubing and Zoom POD are made of common medical grade polymers.

In addition to the accessories discussed above, the adjunctive devices and supplies listed below are intended to be used with the Zoom 4S Catheter.

- Guidewires
- Support/Diagnostic Catheters
- Introducer Sheaths
- Aspiration Pump*
    - Capable of achieving pressure between -20inHg to max vacuum (-29 inHg)

- Airflow rating of 0 – 23 LPM
- IEC 60601-1 Compliant

*Imperative Care offers the Zoom Aspiration Pump which meets the indicated criteria. The Zoom Aspiration Pump is used with the Zoom Canister or Zoom DuoPort Canister.

VI. INDICATIONS FOR USE

The Zoom System, when used with the Zoom Aspiration Pump (or equivalent vacuum pump), is 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 last known well.

Patients who are ineligible for intravenous thrombolytic drug therapy or who have not responded to thrombolytic drug therapy are candidates for treatment.

The Zoom Aspiration Tubing and the Zoom POD Aspiration Tubing are intended to connect the Zoom (7X, 71, 55, 45, 4S, 35) Catheter and the Zoom 88 Large Distal Platform, the Zoom 88 Large Distal Platform Support, or the TracStar LDP Large Distal Platform to the Zoom Canister or Zoom DuoPort Canister of the Zoom Aspiration Pump (or equivalent vacuum pump) and to allow the user to control the fluid flow.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE AND REFERENCE DEVICES

The predicate device is the Zenith Flex Aspiration System (046 Zenith Flex Catheter) cleared under K190338. The predicate and subject devices share the same intended use, basic technological characteristics, and equivalent performance characteristics, as demonstrated through bench testing. **Table 1** provides a comparison of the subject Zoom 4S Catheter and the predicate 046 Zenith Flex Catheter.

Table 1: Comparison of Technological Characteristics with Predicate and Reference Devices

Description	Predicate Device	Subject Device	Reference Device
FDA Product Classification	Class II Product Code: NRY 21 CFR 870.1250	Same	Same
Product Name	Zenith Flex Aspiration System (046 Zenith Flex Catheter)	Zoom System (Zoom 4S Catheter)	Zoom System (Zoom 71, 55, 45, 35 Catheters, TracStar LDP, Zoom 88 LDP, Zoom 88 LDP Support)
510(k) Number	K190338	K252046	K242672
Manufacturer	InNeuroCo, Inc	Imperative Care, Inc.	Imperative Care, Inc.
Indications for Use	The Zenith Flex Aspiration System, including the 046 Zenith Flex Catheter, Aspiration Tubing Set, and VC-701 Cliq Aspirator Pump, is indicated 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 failed IV t-PA therapy are candidates for treatment.	The Zoom System, when used with the Zoom Aspiration Pump (or equivalent vacuum pump), is 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 last known well. Patients who are ineligible for intravenous thrombolytic drug therapy or who have not responded to thrombolytic drug therapy are candidates for treatment. The Zoom Aspiration Tubing and the Zoom POD Aspiration Tubing are intended to connect the Zoom (7X, 71, 55, 45, 4S, 35) Catheter and	The Zoom System, when used with the Zoom Aspiration Pump (or equivalent vacuum pump), is 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 last known well. Patients who are ineligible for intravenous thrombolytic drug therapy or who have not responded to thrombolytic drug therapy are candidates for treatment. The Zoom Aspiration Tubing and the Zoom POD Aspiration Tubing are intended to connect the Zoom (71, 55, 45, 35) Catheter and the TracStar LDP Large Distal Platform,

Description	Predicate Device	Subject Device	Reference Device
	Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.	the Zoom 88 Large Distal Platform, the Zoom 88 Large Distal Platform Support, or the TracStar LDP Large Distal Platform to the Zoom Canister or Zoom DuoPort Canister of the Zoom Aspiration Pump (or equivalent vacuum pump) and to allow the user to control the fluid flow.	the Zoom 88 Large Distal Platform, or the Zoom 88 Large Distal Platform Support to the Zoom Canister of the Zoom Aspiration Pump (or equivalent vacuum pump) and to allow the user to control the fluid flow.
Condition Supplied	Sterile, Single Use Only	Same	Same
Sterilization Method	Ethylene Oxide (EO), SAL 10^{-6}	Same	Same
	One (1) EtO Cycle	Same as Reference	Up to Two (2) EtO Cycles
Inner Diameter (Distal)	0.046”	0.045”	0.035” - 0.088”
Outer Diameter (Distal)	0.056”	0.060” max	0.051” – 0.107” max
Inner Diameter (Proximal)	0.046”	0.045”	0.047” – 0.088”
Outer Diameter (Proximal)	0.058”	0.062” max	0.061” – 0.110” max
Effective Working Length	153cm 160cm	125cm 144cm 160cm	80cm – 160cm
Tip Design	Square edge, soft, flexible, and atraumatic	Same as Reference	Angled edge, flexible, and atraumatic
Materials	Commonly used medical grade plastics & metals with hydrophilic coating	Same	Same
Packaged Accessories	Peel-away Introducer Rotating Hemostasis Valve (RHV)	Same as Reference	RHV
Packaging Configuration	Pouch Backing Card Shelf Carton	Same	Same

Description	Predicate Device	Subject Device	Reference Device
	Shipper Box		
Aspiration Pump	VC-701 Cliq Aspirator Pump	Same as Reference	Zoom Aspiration Pump
Shelf Life	3 Years	1 Year	3 Years

VIII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

Testing was conducted in accordance with the 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”,” and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process” to confirm that the specific materials, manufacturing, and sterilization processes used for the Zoom 4S Catheter result in a biocompatible product.

Table 2: Biocompatibility Test Summary

Test	Test Method	Extraction Method/Conditions	Acceptance Criteria	Results
Cytotoxicity	ISO 10993-5	Test device extracted in MEM with 5% serum at 37 ± 1°C for 24 hours. Triplicate culture wells incubated with test device extract. The wells were incubated at 37°C in 5% CO2 for 48 hours. The cells were examined microscopically to evaluate cellular characteristics and percent lysis.	Sample extracts must yield cell lysis grade 2 or lower.	**PASS** Non-cytotoxic
Sensitization	ISO 10993-10	Extracts were prepared at 50 ± 2°C for 72 ± 2 hours. Guinea pigs exposed to test device extracts at day 0 (Induction I) and 1 week (Induction II). A challenge condition was tested 2 weeks after Induction II. Observations for dermal reactions were conducted at 24 and 48 hours after patch removal.	Test group shall yield grade <1 score on Magnusson and Kligman scale (provided control grade <1).	**PASS** Non-sensitizing
Irritation	ISO 10993-23	Extracts were prepared at 50 ± 2°C for 72 ± 2 hours. Rabbits are injected with extracts of test device. Injection sites examined/scored for erythema and edema at 24, 48 and 72 hours after injections.	The difference in the mean test article and mean control score must be grade 1.0 or lower.	**PASS** Non-irritating (both extracts)
Material Mediated Pyrogenicity	ISO 10993-11	Extracts were prepared at 50 ± 2°C for 72 ± 2 hours. Test device extract was injected in the marginal ear vein. Body temperatures recorded at 0 hour and then at 30 min intervals between 1-3 hours post injection.	Sample extracts must not cause a total rise in body temperature of ≥0.5°C.	**PASS** Non-pyrogenic
Acute Systemic Toxicity	ISO 10993-11	Extracts were prepared in saline and sesame oil at 50 ± 2°C for 72 ± 2 hours. Mice are injected with extracts of test device. Animals are observed for signs of toxicity	Sample extracts must not cause the following: • Test animal showed significantly greater reaction than the corresponding control animal	**PASS** Non-toxic (both extracts)

Test	Test Method	Extraction Method/Conditions	Acceptance Criteria	Results
		immediately after injection, 1, 4, 24, 48 and 72 hours after injections. The animals were weighed daily for three days after dosing.	• > 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	
Hemocompatibility: ASTM Hemolysis	ISO 10993-4	Direct Contact: Test device incubated in PBS and diluted blood. % hemolysis is measured. Extract Method: 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
Hemocompatibility: Complement Activation	ISO 10993-4	Performed 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 for 60 minutes and tested for SC5b at 30 ± 1 minutes using EIA kit.	The concentrations of SC5b-9 in the test devices are statistically similar to the reference device (Zoom 45).	**PASS** No significant differences
Hemocompatibility: Partial Thromboplastic Time (PTT) Test	ISO 10993-4	Test device and comparator device is incubated in human blood plasma at 37 ± 1°C for 60 ± 5 minutes and then PTT reagent and calcium chloride was added. Time until the formation of clots is measured.	Test device clotting time is not statistically different than both the comparator article and negative controls.	**PASS** Test device clotting time similar to comparator device and negative control
Hemocompatibility: Thrombogenicity	ISO 10993-4	Performed in triplicate. Test and control device are placed in a flow loop using blood from 3 different sheep for 4 ± 0.5 hours at 37 ± 2°C. % thrombus formation score is measured.	The device must receive a thrombus formation score of 0, 1, or 2. After 4 hours, the device must have similar or lesser	**PASS** Thromboresistant

Test	Test Method	Extraction Method/Conditions	Acceptance Criteria	Results
			thrombogenic potential when compared to the reference device (Zoom 45).	

Non-clinical Bench Testing

A summary of the evaluated design and performance specifications is presented in **Table 3** and **Table 4**. Performance specifications and test methods were based primarily on catheter performance standard ISO 10555-1. The test results were reviewed and found to demonstrate that the differences between the subject device and predicate or reference devices do not significantly impact any performance parameters that would negatively affect the safety or effectiveness of the subject device.

Table 3: Tests and Performance Specifications for the Zoom 4S Catheter

Test Attribute	Specification	Results
Delivery (Trackability), Compatibility, and Retraction	The catheter shall be able to be delivered, deployed, and retracted per the IFU within a simulated neurovascular model without incurring any damage to the catheter.	Pass
Tip Flexibility	The flexibility of the catheter tip shall be comparable to competitive products.	Pass
Visual Inspection	The catheter shall meet visual inspection criteria. The printing on the strain relief must be legible.	Pass
Dimensional (Distal ID, Proximal ID, Distal OD, Proximal OD)	All defined catheter dimensions are within the specified tolerances.	Pass
Catheter Bond Strength	The catheter shall have sufficient bond strength to remain intact throughout a procedure.	Pass
Freedom from Leakage – Positive Pressure	The catheter must remain leak free under specified test conditions.	Pass
Freedom from Leakage – Negative Pressure	The catheter must remain leak free under specified test conditions.	Pass
Dynamic Burst	The catheter must withstand pressure under dynamic flow conditions.	Pass
Static Burst	The catheter shall meet criteria for static burst pressure testing.	Pass

Catheter Torque Strength	With the catheter tip constrained from movement, the proximal end was rotated until failure. The catheter shall not be damaged when rotated at least two (2) full rotations (720 degrees).	Pass
Kink Resistance	There shall be no kinking of the catheter shaft around respective clinically relevant minimum bend radii in distal tip, medial, and proximal locations.	Pass
Flexibility	The catheter needs to have acceptable flexure values for tracking in the vasculature.	Pass
Compatibility with Other Devices (External)	The catheter shall be able to be delivered through the minimum introducer sheath or guide catheter size indicated in the product labeling.	Pass
Guidewire Compatibility	The catheter shall be able to be delivered over the maximum size guidewire indicated in the product labeling.	Pass
Microcatheter / Intermediate Catheter Compatibility	The catheter shall be able to accommodate a microcatheter/intermediate catheter up to the maximum size indicated in the product labeling.	Pass
Luer Compatibility	The device and accessories shall be compatible with standard syringe luer fittings per ISO 80369-7.	Pass
Accessory Compatibility	The device shall be compatible with an RHV.	Pass
Coating - Particulate	The amount of particulate matter generated during simulated use testing shall be determined and compared to a competitive product.	Pass
Coating – Lubricity, Durability and Integrity	Coating must be lubricious with a specified average pull force. No coating anomalies or significant wear shall be observed post simulated use.	Pass
Clot Retrieval	The device shall be able to aspirate a variety of clot types in a range of vessel diameters.	Pass
Lumen Integrity	The catheter lumen shall not collapse under vacuum.	Pass
Flowrate – Positive (Forward) Pressure	The catheter lumen shall allow for a minimum flowrate comparable to comparator products.	Pass
Flowrate – Negative (Vacuum) Pressure	The minimum flowrate under a vacuum shall be similar to or greater than comparator products.	Pass

Table 4: Tests and Performance Specifications for Zoom System Aspiration Tubing

Test Attribute	Specification	Results
Vacuum Force at Catheter Tip	The vacuum force delivered by the aspiration tubing to the tip of the catheter should be comparable to the vacuum force delivered by the reference aspiration tubing.	Pass
Connector Compatibility	The aspiration tubing connectors shall securely connect to the pump canister lid and standard luer fittings.	Pass
Lumen Collapse Test	The tubing lumen shall not collapse under vacuum.	Pass
Flow Control Functionality	The flow control mechanism shall allow users to start and stop flow multiple times when the connected pump is running at maximum vacuum.	Pass
Freedom From Leakage	The vacuum pressure delivered at the tip of the aspiration tubing shall be consistent with the pressure generated by the pump.	Pass
Tensile Strength	The bonds between the tubing and connectors shall be sufficiently strong to ensure the tubing remains intact during use.	Pass
Clot Filter Functionality (Zoom POD only)	The clot filter should be able to be opened and closed without causing leak.	Pass
Aspiration Flowrate	Minimum aspiration catheter flowrate shall be achieved with the Zoom Aspiration Tubing and Zoom POD Aspiration Tubing.	Pass

Sterilization

The Zoom 4S Catheter is sterilized using validated EO processes with a minimum sterility assurance level (SAL) of 10^{-6}. The sterilization process was validated per the overkill method in accordance with ISO 11135, "Sterilization of Health-Care Products - Ethylene Oxide - Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices."

Shelf Life and Packaging

Accelerated aging testing based on ASTM F1980 was conducted to verify packaged device performance of the Zoom 4S Catheter and Zoom Aspiration Tubing. Accelerated aging testing based on ASTM F1980 was conducted to verify packaged device performance of

the subject Zoom Catheters and Zoom Aspiration Tubing. A minimum shelf life was established based on these testing and is indicated by the expiration date provided on the product labeling. Verification testing of the subject devices followed the same test methods as the reference devices.

Packaging and sterile barrier integrity following transportation challenge has been verified for the packaging configurations used for the Zoom 4S Catheter and Zoom Aspiration Tubing within the Zoom System. Aging testing has also been performed that supports the sterile barrier integrity following aging.

Animal Study

Substantial equivalence was established based on non-clinical testing presented above.

Clinical Study

Substantial equivalence was established based on non-clinical testing presented above.

IX. CONCLUSIONS

Where differences were identified between the subject and predicate devices, a risk assessment was completed to determine if the differences would result in new safety or effectiveness concerns. As appropriate, bench and laboratory testing were evaluated for applicability and either the rationale for no impact was documented or verification and validation was repeated as required. The non-clinical bench data supports the safety of the device and demonstrates that the subject Zoom 4S Catheter performs as intended in the specified use conditions.

Based on the non-clinical data presented above, the subject and predicate devices are substantially equivalent and there are no new questions of safety or effectiveness. The subject device and predicate device share the same intended use, basic technological characteristics, and performance characteristics.