May 28, 2025

Imperative Care, Inc.
Michael Wong
Lead Regulatory Affairs Specialist
1359 Dell Avenue
Campbell, California 95008

Re: K243047
Trade/Device Name: Zoom 7X Catheter; Zoom Aspiration Tubing; Zoom POD Aspiration Tubing
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: April 29, 2025
Received: April 29, 2025

Dear Michael Wong:

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)*
K243047

Device Name
Zoom 7X Catheter; Zoom Aspiration Tubing; Zoom POD Aspiration Tubing

Indications for Use *(Describe)*
The Zoom 7X Catheter, with the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing, and 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, 35) Catheter and the TracStar LDP Large Distal Platform, 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.

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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K243047 – 510(k) Summary

I. SUBMITTER

Submitter's Name:	Imperative Care, Inc.
Address:	1359 Dell Avenue Campbell, CA 95008
Contact Person:	Michael Wong
Telephone:	925-337-1530
Email:	mwong@imperativecare.com
Date of Preparation:	May 23, 2025

II. DEVICE

Proprietary Names:	Zoom™ 7X Catheter; Zoom Aspiration Tubing; Zoom POD Aspiration Tubing
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:	ZOOM 71 Reperfusion Catheter; ZOOM Aspiration Tubing
Common/Usual Name:	Catheter, Thrombus Retriever
Classification Name:	Percutaneous Catheter
Product Code:	NRY
Regulation:	21 CFR 870.1250
Manufacturer:	Imperative Care, Inc.
510(k) #:	K211476

IV. DEVICE DESCRIPTION

The Zoom™ 7X 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, such as the Zoom Aspiration Pump, using the Zoom Aspiration Tubing or the Zoom POD Aspiration Tubing.

The Zoom 7X 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 Zoom 7X 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 Zoom 7X 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 7X Catheter is also packaged with two (2) introducer sheath accessories. The introducer is intended to assist with insertion of the Zoom 7X Catheter into the RHV or the guide catheter.

The Zoom Aspiration Tubing and the Zoom POD Aspiration Tubing are comprised of a hollow cylindrical tube which is bonded to a standard luer fitting that connects to the Zoom 7X Catheter and a slip fit connector that connects to the canister on the aspiration pump. The Zoom Aspiration Tubing is made of common medical grade polymers.

In addition to the accessories discussed above, the adjunctive devices and supplies listed below could be used with the Zoom 7X Catheter, Zoom Aspiration Tubing, and Zoom POD Aspiration Tubing.

- Guidewires
- Support/Diagnostic Catheters
- Aspiration Pump*
    - Capable of achieving pressure between -20inHg to max vacuum (-29.9 inHg)
    - Airflow rating of 0 – 23 LPM
    - IEC 60601-1 Compliant

*Imperative Care offers the Zoom Aspiration Pump which meets the indicated criteria.

V. INDICATIONS FOR USE

The Zoom 7X Catheter, with the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing, and 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, 35) Catheter and the TracStar LDP Large Distal Platform, 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The predicate device is the Imperative Care ZOOM 71 Reperfusion Catheter and ZOOM Aspiration Tubing cleared under K211476. The predicate and subject devices share the same intended use, basic technological characteristics, and equivalent performance characteristics, demonstrated through bench testing. **Table 1** provides a comparison of the subject Zoom 7X Catheter and the predicate ZOOM 71 Reperfusion Catheter. **Table 2** provides a comparison of the subject Zoom Aspiration Tubing and Zoom POD Aspiration Tubing and the predicate ZOOM Aspiration Tubing.

Table 1: Comparison of Technological Characteristics with Predicate Device – Zoom 7X Catheter

Device Attribute	Predicate Device	Subject Device
FDA Product Classification	Class II Product Code: NRY 21 CFR 870.1250	Same as Predicate
Product Name	ZOOM 71 Reperfusion Catheter	Zoom 7X Catheter
510(k) Number	K211476	K243047
Manufacturer	Imperative Care, Inc.	Same
Intended Use	Revascularization of patients with acute ischemic stroke.	Same
Indications for Use	The ZOOM Reperfusion Catheters, with the ZOOM Aspiration Tubing and ZOOM 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 Zoom 7X Catheter, with the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing, and 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.

Device Attribute	Predicate Device	Subject Device
Condition Supplied	Sterile, Single Use Only	Same
Sterilization Method	Ethylene Oxide (EO), Sterility Assurance Level (SAL) 10^{-6}	Same
	One (1) EO cycle	Up to two (2) EO cycles
Nominal Distal Inner Diameter	0.071”	Same
Maximum Distal Outer Diameter	0.085”	Same
Nominal Proximal Inner Diameter	0.071”	Same
Maximum Proximal Outer Diameter	0.086”	Same
Effective Working Length	137 cm	Same
Tip Design	Beveled edge, soft, flexible, atraumatic	Pre-shaped tip, beveled edge, soft, flexible, atraumatic
Tip Length	0.5 – 0.8 mm (point to point) 0.4 – 0.7 mm (line to line)	Same
Distal Catheter Shaft	Reinforced with metals and polymers	Same
Coating	Hydrophilic coating	Same
Materials	Commonly used medical grade plastics and metals with hydrophilic coating	Same
Packaged Accessories	One (1) Rotating Hemostasis Valve (RHV)	One (1) RHV Two (2) Introducer sheaths
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 shelf carton.	Same

Device Attribute	Predicate Device	Subject Device
Aspiration Pump	Zoom Aspiration Pump or equivalent	Same
Shelf Life	12 Months (1 Year)	Same

Table 2: Comparison of Technological Characteristics with Predicate Device – Zoom and Zoom POD Aspiration Tubing

Device Attribute	Predicate Device (K211476)	Subject Device (K243047)
Product Name	ZOOM Aspiration Tubing	Zoom Aspiration Tubing; Zoom POD Aspiration Tubing
Indications for Use	The ZOOM Aspiration Tubing is intended to connect the ZOOM Reperfusion Catheter to the ZOOM Canister of the ZOOM Aspiration Pump and to allow the user to control the fluid flow.	The Zoom Aspiration Tubing and the Zoom POD Aspiration Tubing are intended to connect the Zoom (7X, 71, 55, 45, 35) Catheter and the TracStar LDP Large Distal Platform, 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 and Single Use	Same
Sterilization Method	EO, SAL 10^{-6}	Same
Nominal Tubing Inner Diameter	0.110”	Same
Nominal Working Length	104”	Zoom Aspiration Tubing: 104” Zoom POD Aspiration Tubing: 117”
Flow Control Mechanism	External Pinch Clamp	Same
Clot Filter	N/A – does not have a clot filter	Zoom Aspiration Tubing: N/A Zoom POD Aspiration Tubing: in-line clot filter
Packaging Configuration	The Zoom Aspiration Tubing is coiled and placed inside a labeled pouch and sealed. The sealed pouch and IFU are placed in a labeled shelf carton box.	Same
Shelf Life	43 months	Same

VII. PERFORMANCE DATA

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

Non-Clinical Bench Testing

A summary of the evaluated design and performance specifications for the Zoom 7X Catheter is listed below. 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 device do not significantly impact any performance parameters that would negatively affect the safety or effectiveness of the subject device.

Table 3: Performance Tests for the Zoom 7X Catheter

Test Attribute	Acceptance Criterion	Results
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.	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
Tip Flexibility	The catheter distal tip flexibility shall be comparable to the predicate.	Pass

Test Attribute	Acceptance Criterion	Results
Visual Inspection	The catheter shall meet visual inspection criteria. The printing on the strain relief must be legible.	Pass
Dimensional (ID, Distal OD, Tip Length)	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
Dynamic Burst	The catheter must withstand pressure testing 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
Luer Compatibility	Device and accessories shall be compatible with standard syringe luer fittings per ISO 80369-7.	Pass
Accessory Compatibility	Device shall be compatible with an RHV.	Pass

Test Attribute	Acceptance Criterion	Results
Coating - Particulate	The amount of particulate matter generated during simulated use testing shall be determined and comparable to competitive products.	Pass
Coating – Lubricity, Durability, and Integrity	Coating must be lubricious with a specified average pull force. There were no coating anomalies or significant wear 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

The performance of the Zoom Aspiration Tubing is supported by testing conducted in K211476. A summary of the key performance specifications for the Zoom POD Aspiration Tubing is listed below. The test results were reviewed and found to demonstrate that the differences between the subject device and predicate device do not significantly impact any performance parameters that would negatively affect the safety or effectiveness of the subject device.

Table 4: Performance Tests for the Zoom POD Aspiration Tubing

Test Attribute	Acceptance Criterion	Results
Visual Inspection	The Zoom POD Aspiration Tubing shall meet visual inspection criteria.	Pass
Dimensional (Working Length)	The working length is within the specified tolerances.	Pass
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 predicate 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

Test Attribute	Acceptance Criterion	Results
Clot Filter Functionality (Zoom POD only)	The clot filter should be able to be opened and closed without causing leak.	Pass

Sterilization

The subject Zoom 7X Catheter, Zoom Aspiration Tubing, and Zoom POD Aspiration Tubing are sterilized using validated EO processes with a sterility assurance level of 10^{-6}. The sterilization processes were 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."

Packaging and Shelf Life

Accelerated aging testing based on ASTM F1980 was conducted to verify packaged device performance of the subject Zoom 7X Catheter, Zoom Aspiration Tubing, and Zoom POD Aspiration Tubing. A minimum shelf life was established based on the 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 predicate device.

Packaging and sterile barrier integrity following a transportation challenge has been verified for the packaging configuration used for the Zoom 7X Catheter, Zoom Aspiration Tubing, and Zoom POD Aspiration Tubing. Aging testing has also been performed that supports the sterile barrier integrity following aging.

Biocompatibility

With the exception of the minor modifications to the Zoom 7X Catheter distal shaft, there are no changes to the patient contacting materials, including raw materials, manufacturing processes and manufacturing aids of the subject Zoom 7X Catheter compared to the predicate ZOOM 71 Reperfusion Catheter. Following a risk assessment, it was determined that the original testing on the predicate (K211476) device applies to the subject Zoom 7X Catheter and additional biocompatibility testing of the Zoom 7X Catheter was not required.

To further support the safety of the new introducer sheath accessory, biocompatibility tests were completed for this component categorized as an external communicating device with indirect blood contact for a limited (≤ 24 hour) duration, in accordance with the FDA guidance document, "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".

Table 5: Biocompatibility Test Summary – Introducer Sheath

Test	Test Method	Extraction Methods/Conditions	Acceptance Criteria	Results
Cytotoxicity	ISO 10993-5	Test device extracted with MEM with 5% serum at 37ºC for 24 hours.	Test article extracts must yield grade 2 or lower.	**Pass, Non-cytotoxic**
Sensitization	ISO 10993-10	Test device extracted with both NS and SSO at 50ºC for 72 hours.	Test article extracts must yield grade 0.	**Pass, Non-sensitizing**
Intracutaneous Reactivity	ISO 10993-23	Test device extracted with both NS and SSO at 50ºC for 72 hours.	Test article extracts must yield a difference between the test extract overall mean score and corresponding control overall mean score of 1.0 or less.	**Pass, Non-irritating**
Acute Systemic Toxicity	ISO 10993-11	Test device extracted with both NS and SSO at 50ºC for 72 hours.	None of the animals treated with the test article extracts must show a significantly greater reactivity than animals treated with the control article.	**Pass, Non-toxic (acute systemic)**
Material-Mediated Pyrogenicity	ISO 10993-11	Test device extracted with NS at 50ºC for 72 hours.	Test article extract must yield <0.5ºC rise in individual animal temperature.	**Pass, Non-pyrogenic**
Indirect Hemolysis	ASTM F756-17	Test device extracted in PBS at 50ºC for 72 hours.	Test article extract must result in a hemolytic index of <2%.	**Pass, Non-hemolytic**

The changes made to the Zoom Aspiration Tubing that resulted in the Zoom POD Aspiration Tubing (Zoom POD) were evaluated for the Zoom POD in accordance with the FDA guidance document, “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". Using a risk assessment approach, it was determined that the biocompatibility assessments provided for previously cleared devices (K210996, K242672) apply to the subject Zoom and Zoom POD Aspiration Tubing and no additional testing of these components is required.

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.

VIII. CONCLUSION

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 was performed. The non-clinical testing demonstrates that the subject Zoom 7X Catheter, Zoom Aspiration Tubing, and Zoom POD Aspiration Tubing perform as intended.

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