January 14, 2025

Imperative Care, Inc.
Teri Nguyen
Lead Regulatory Affairs Specialist
1359 Dell Avenue
Campbell, California 95008

Re: K242672
Trade/Device Name: Zoom System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: December 16, 2024
Received: December 16, 2024

Dear Teri Nguyen:

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242672

Device Name
Zoom System

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 (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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510(k) Summary

I. SUBMITTER

Submitter's Name:	Imperative Care, Inc.
Address:	1359 Dell Avenue Campbell, CA 95008
Contact Person:	Teri Nguyen
Telephone:	408-833-4415
Email:	vtnguyen@imperativecare.com
Date of Preparation:	January 13, 2025

II. DEVICE

Proprietary Name:	Zoom™ System
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

Proprietary Name:	ZOOM (71, 55, 45, 35) Reperfusion Catheters; 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) #:	K210996

IV. REFERENCE DEVICE

Proprietary Names:	TracStar™ LDP Large Distal Platform™; Zoom™ 88 Large Distal Platform™; Zoom™ 88 Large Distal Platform™ Support
Common/Usual Name:	Catheter, Percutaneous, Neurovasculature
Classification Name:	Percutaneous Catheter
Product Codes:	QJP, DQY
Regulation:	21 CFR 870.1250
Manufacturer:	Imperative Care, Inc.
510(k) #:	K240948

V. DEVICE DESCRIPTION

The Imperative Care Zoom System consists of the following devices:

- Zoom Catheters
    - Zoom™ (71, 55, 45, 35) Catheters
- Large Distal Platform Catheters (LDP Catheters)
    - Zoom™ 88 Large Distal Platform™ (Zoom 88 LDP)
    - Zoom™ 88 Large Distal Platform™ Support (Zoom 88 LDP Support)
    - TracStar™ LDP Large Distal Platform™ (TracStar LDP)
- Zoom Aspiration Tubing and Zoom POD Aspiration Tubing
- Zoom Aspiration Pump

The Zoom Catheters and the LDP Catheters are intended to be used as a system in conjunction with the Zoom Aspiration Tubing or Zoom POD Aspiration Tubing and the Zoom Aspiration Pump (or equivalent vacuum pump) to aspirate thrombus in patients with acute ischemic stroke.

The Zoom Catheters and LDP Catheters are single lumen, braid and coil reinforced, variable stiffness catheters with a radiopaque marker and a lubricious hydrophilic coating on the distal portion of the catheter. The catheters have a luer hub on the proximal end.

Dimensions for each catheter are included on the individual device label. The Zoom Catheters are compatible with 0.014" – 0.018" guidewires. The LDP Catheters are compatible with 0.038" or smaller guidewires. An additional support catheter may be used

to assist in accessing the target vasculature. The Zoom 45, 55, and 71 Catheters are compatible with 6F guide sheaths with a minimum inner diameter of 0.088". The Zoom 35 Catheter is compatible with 5F guide sheaths with a minimum inner diameter of 0.068". The LDP Catheters are compatible with 8F or greater introducer sheaths with a minimum inner diameter of 0.115". The Zoom 71 Catheter is compatible with 5F microcatheters or intermediate catheters with a maximum outer diameter of 0.065". The Zoom 45 and 55 Catheters are compatible with 2.4F microcatheters or intermediate catheters with a maximum outer diameter of 0.031". The Zoom 35 Catheter is compatible with 1.4F microcatheters or intermediate catheters with a maximum outer diameter of 0.018". The LDP Catheters are compatible with 6F microcatheters or intermediate catheters with a maximum outer diameter of 0.083".

All catheters are 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 Catheter and the LDP Catheter and a slip fit connector that connects to the canister on the aspiration pump. The Zoom Aspiration Tubing and Zoom POD Aspiration Tubing are 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 System.

- Guidewires
- Support/Diagnostic Catheters
- Introducer Sheaths
- 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.

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 (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.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE AND REFERENCE DEVICES

The predicate devices are the Imperative Care ZOOM (71, 55, 45, 35) Reperfusion Catheters (ZOOM Reperfusion Catheters) and ZOOM Aspiration Tubing cleared under K211476 and K210996. The predicate and subject devices share the same intended use and basic technological characteristics, and equivalent performance characteristics, demonstrated through bench, animal, and clinical testing. **Table 1** provides a comparison of the subject Zoom System Catheters and the predicate ZOOM Reperfusion Catheters. **Table 2** provides a comparison of the subject Zoom Aspiration Tubing and the Zoom POD Aspiration Tubing and the predicate ZOOM Aspiration Tubing.

Table 1: Comparison of Technological Characteristics with Predicate and Reference Devices – Zoom System Catheters

Device Attribute	Predicate Device	Subject Device	Reference Device
FDA Product Classification	Class II Product Code: NRY 21 CFR 870.1250	Same as Predicate	Class II Product Code: QJP, DQY 21 CFR 870.1250
Product Name	ZOOM 71 Reperfusion Catheter ZOOM 55 Reperfusion Catheter ZOOM 45 Reperfusion Catheter ZOOM 35 Reperfusion Catheter	Zoom 71 Catheter Zoom 55 Catheter Zoom 45 Catheter Zoom 35 Catheter TracStar LDP Zoom 88 LDP Zoom 88 LDP Support	TracStar LDP Zoom 88 LDP Zoom 88 LDP Support
510(k) Number	K211476, K210996	K242672	K240948
Manufacturer	Imperative Care, Inc.	Same	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 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 TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. The Zoom 88 Large Distal Platform and Zoom 88 Large Distal Platform Support are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Device Attribute	Predicate Device	Subject Device	Reference Device
Condition Supplied	Sterile, Single Use Only	Same	Same
Sterilization Method	Ethylene Oxide (EO), SAL 10^{-6}	Same	Same
	One (1) EO Cycle	Same as Reference	Up to Two (2) EO Cycles
Inner Diameter (Distal)	0.035”-0.071”	Same as Predicate and Reference Devices	0.088”
Outer Diameter (Distal)	0.051”-0.083”	Same as Predicate and Reference Devices	0.106”
Inner Diameter (Proximal)	0.047”-0.071”	Same as Predicate and Reference Devices	0.088”
Outer Diameter (Proximal)	0.061”-0.083”	Same as Predicate and Reference Devices	0.110”
Effective Working Length	137 cm – 160 cm	Same as Predicate and Reference Devices	80 cm – 110 cm
Tip Design	Beveled distal edge, soft, flexible, atraumatic tip	Same	Same
Materials	Commonly used medical grade plastics and metals with hydrophilic coating	Same	Same
Packaged Accessories	RHV	Same	Same
Packaging Configuration	The catheter is placed in a protective polyethylene tube and then mounted, along with the RHV accessory, onto a polyethylene packaging card. The packaging card is inserted into a Tyvek® pouch which is then sealed. The sealed pouch and Instructions for Use (IFU) are placed in a shelf carton.	Same	Same

Device Attribute	Predicate Device	Subject Device	Reference Device
Aspiration Pump	Zoom Aspiration Pump	Same as Predicate Device	N/A – Not indicated for reperfusion
Shelf Life	12 Months (1 Year)	Same as Reference Device	3 Years

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

Device Attribute	Predicate Device	Subject Device
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 (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
Tubing Inner Diameter (ID)	0.110”	Same
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

VIII. PERFORMANCE DATA

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

Biocompatibility Testing

The tissue contacting materials, including raw materials, manufacturing processes and manufacturing aids, of the subject Zoom Catheters are similar to the predicate ZOOM Reperfusion Catheters (K211476 and K210996). Original testing on the predicate devices apply to the subject Zoom Catheters and additional biocompatibility testing was not required.

The subject LDP Catheters are identical to the reference LDP Catheters (K240948). There are no changes to the patient contacting materials, including raw materials, manufacturing processes, and manufacturing aids, of the subject LDP Catheters. Therefore, the original testing on the reference devices apply to the subject LDP Catheters and additional biocompatibility testing was not required.

The changes made to the Zoom Aspiration Tubing to create 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." Supporting biocompatibility testing (cytotoxicity, sensitization, and irritation / intracutaneous reactivity) was completed to confirm that the addition of the in-line clot filter component (collection pod) did not result in any significant changes to the biocompatibility of the Zoom POD Aspiration Tubing.

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 devices and predicate or reference devices do not significantly impact any performance parameters that would negatively affect the safety or effectiveness of the subject devices.

Table 3: Tests and Performance Specifications for Zoom System Catheters

Test Attribute	Specification	Results
Delivery, Compatibility, and Retraction (Trackability)	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 catheter distal tip flexibility shall be comparable to the predicate.	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 Outer Diameter (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 pressures under dynamic flow conditions.	Pass
Static Burst	The catheter shall meet criteria for static burst pressure testing.	Pass

Test Attribute	Specification	Results
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 catheters need to have acceptable flexure values for tracking in the vasculature.	Pass
Proximal Shaft Stiffness	The stiffness of the proximal shaft was evaluated to ensure comparable stiffness to the predicate.	Pass
Delivery Force	The catheters shall not be too stiff or require excessive force to safely navigate and track to the target neurovasculature.	Pass
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.	Pass
Guidewire Compatibility	The catheters shall be able to be delivered over the maximum size guidewire indicated in the product labeling.	Pass
Microcatheter/Intermediate Catheter Compatibility	The catheters shall be able to accommodate a microcatheter/intermediate catheter up to the maximum size indicated in the product labeling.	Pass
Luer Compatibility	Devices and RHV accessory shall be compatible with standard syringe luer fittings per ISO 80369-7.	Pass
Accessory Compatibility	Devices 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 competitive products and techniques.	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 catheters will be able to be delivered in a clinically relevant vascular model and effectively aspirate clots when used with the aspiration pump and aspiration tubing set when placed at appropriate locations based on the size of the catheter.	Pass

Test Attribute	Specification	Results
Lumen Integrity	The catheter lumen shall not collapse under vacuum.	Pass
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.	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 devices.	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 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
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 System devices (Zoom Catheters, LDP Catheters, Zoom Aspiration Tubing, Zoom POD Aspiration Tubing) are sterilized using validated EO processes with a sterility assurance level (SAL) 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."

Shelf Life and Packaging

Accelerated aging testing based on ASTM F1980 was previously conducted to verify packaged device performance of the subject LDP Catheters 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 POD 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 predicate devices.

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

Animal Studies

A series of subacute and chronic animal studies were conducted to evaluate the safe and effective use of the Zoom Catheters and LDP Catheters with the Imperative Care Zoom Aspiration Pump and Zoom Aspiration Tubing 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 Penumbra System was used as a control device in all completed studies. The studies concluded that:

- All vessels treated with the Zoom Catheters and the LDP 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 Zoom Catheters/LDP Catheters and control Penumbra System Reperfusion Catheter.
- The subacute and chronic pathological findings were comparable between the Zoom Catheters/LDP Catheters and control Penumbra System Reperfusion Catheter.

Clinical Study

The Imperative Care Zoom Catheters and the LDP Catheters were studied in the Imperative Trial, a prospective, multi-center, open-label, single-arm pivotal clinical investigation designed to assess the safety and effectiveness of the Zoom System in subjects diagnosed with acute ischemic stroke secondary to large vessel occlusions and undergoing a stroke mechanical neurothrombectomy procedure within 8 hours of last known well. A total of 260 evaluable subjects were enrolled across 26 clinical sites in the United States. Further details on this study can be accessed at ClinicalTrials.gov using the identifier NCT04129125.

Reconciliation of Evaluable Subjects

	Intervention/ Treatment (Day 0)	24-Hour Assessment (Day 1)	Discharge/Day 7 Assessment (Day 3-7)	90-Day Follow Up Assessment (Day 90)	Total Withdrawal, LTF, and Deaths
Evaluable Subjects	260	260	259	253	
Withdrawal	0	0	1	4	5
Lost to Follow-up (LTF)	N/A	0	0	5	5
Death	0	1*	5	27	33
Subjects Completing Each Visit	260	259	253	217	

* One subject death occurred 2 days post-procedure, but declining status prevented the 24-hour visit from being completed.

Imperative Trial Mechanical Neurothrombectomy Procedure

Mechanical neurothrombectomy was performed using the Zoom System under general anesthesia or conscious sedation, at the discretion of the investigator. The Zoom Catheters and the LDP Catheters were the primary device. An LDP Catheter was employed to access the vasculature in all cases, while its use to aspirate was according to the treating physicians' preference. Aspiration was applied through an LDP Catheter alone or in conjunction with a Zoom (71, 55, 45, or 35) Catheter either proximal to the clot or at the clot in 92% (238/260) of subjects and in 52% (124/238) of these subjects, aspiration was applied through an LDP Catheter alone or in conjunction with a Zoom (71, 55, 45, or 35) Catheter at the clot. If multiple revascularization attempts were required, the Zoom System was recommended to be used for at least the first three attempts before considering switching to any non-Zoom System device. If the modified thrombolysis in cerebral infarction (mTICI) score ≥ 2b revascularization was not achieved after three attempts with the study device, the procedure was considered a treatment failure for the primary effectiveness endpoint analysis. The subject received standard hospital/medical care after mechanical neurothrombectomy.

From the 260 subjects, the analyzed cohort includes 211 subjects of which 210 underwent concomitant aspiration mechanical neurothrombectomy with combined use of an LDP Catheter (Zoom 88 LDP, Zoom 88 LDP Support, or TracStar LDP) and a Zoom (71, 55, 45, or 35) Catheter and one underwent concomitant aspiration mechanical neurothrombectomy with two Zoom (55 + 35) Catheters. Subjects with single catheter aspiration mechanical neurothrombectomy were excluded from the analysis (n=49), including 28 subjects with direct clot aspiration applied only through the LDP Catheter (Zoom 88 LDP, Zoom 88 LDP Support, or TracStar LDP) for at least one pass and 21 subjects with direct clot aspiration applied only through the Zoom (71, 55, 45, or 35) Catheters for at least one pass. The limited sample size of 28 subjects with direct clot aspiration applied only through the LDP Catheter for at least one pass was not sufficient to establish the safety and effectiveness of the LDP Catheters for use in direct aspiration alone.

Key Inclusion Criteria

1. Age 18 and older.
2. National Institutes of health Stroke Scale (NIHSS) score ≥ 6.
3. The operator feels that the stroke can be treated with endovascular thrombectomy approaches and the interventionalist estimates that groin puncture can be achieved within 8 hours from time last seen well.
4. Pre-event modified Rankin Scale (mRS) score 0-1.
5. Large vessel occlusion of the intracranial internal carotid artery (ICA) or middle cerebral artery (MCA)-M1 and M2 segments, basilar, and vertebral arteries as evidenced by magnetic resonance angiography (MRA) or computed tomography angiography (CTA).
6. For strokes in anterior circulation, Alberta Stroke Program Early CT Score (ASPECTS) ≥ 6; for strokes in posterior circulation, pc-ASPECTS ≥8.
7. Non-contrast CT/CTA or MRI/MRA for trial eligibility performed or repeated at treating stroke center or outside medical facility within two hours of treatment initiation.
8. If indicated per American Heart Association (AHA) clinical guidelines, thrombolytic therapy should be administered as soon as possible.
9. Consenting requirements met according to local institutional review board (IRB) or ethics committee.

Key Exclusion Criteria

1. Female known to be pregnant at time of admission.
2. Patient has suffered a stroke in the past 3 months.
3. Presence of an existing or pre-existing large territory infarction.
4. Pre-existing neurological or psychiatric disease that would confound the neurological or functional evaluation, e.g., dementia with prescribed anti-cholinesterase inhibitor.
5. Known history of severe contrast allergy or absolute contraindication to iodinated contrast.
6. Clinical history, past imaging, or clinical judgement suggest that the intracranial occlusion is chronic.

7. Life expectancy of less than 6 months prior to stroke onset.
8. Clinical symptoms suggestive of bilateral stroke or stroke in multiple territories.
9. Subject participating in another clinical trial involving an investigational device or drug.
10. Known cancer with metastases.
11. Evidence of active systemic infection.
12. Any known hemorrhagic or coagulation deficiency.

Key Baseline Demographics

Characteristics	Summary
Female, % (n/N)	49% (103/211)
Age, Median (IQR)	69 years (59-79 years)
Admission NIHSS, Median (IQR)	14 (10-20)
mRS before Stroke§ 0 1	 172/210 (82%) 38/210 (18%)
Baseline ASPECTS per Core Lab, Mean ± SD	8.8 ± 1.7
Baseline pc-ASPECTS per Core Lab, Mean ± SD	9.7 ± 0.5
Baseline Core Infarct Volume per Core Lab, Mean ± SD	13 ± 25 mL
Initial Occlusion Location On CTA† ICA MCA – M1 MCA – M2 Vertebral Basilar Multiple Territories‡	 10% (20/201) 60% (120/201) 25% (50/201) 0.0% (0/201) 3.3% (7/201) 2.0% (4/201)

§ The baseline mRS for one subject was not reported.
† The baseline CTA form was not completed or did not indicate the initial occlusion location for 10 subjects resulting in a sample size of N=201 for this characteristic. The treated occlusion locations for these 10 subjects were: ICA (N=1), MCA-M1 (N=6), and MCA-M2 (N=3).
‡ In the cases with occlusions in multiple territories the following locations were treated:

- Unilateral, right MCA-M1 and right ACA
- Unilateral, right MCA-M1 and right ACA
- Bilateral, right MCA-M1 and left ICA
- Unilateral, right MCA-M1 and right ACA

Catheters Used for Concomitant Aspiration

In all but one subject, which used a combination of the Zoom 55 and Zoom 35 Catheters, concomitant aspiration within the Imperative Trial was performed using a combination of an LDP Catheter (Zoom 88 LDP, Zoom 88 LDP Support, TracStar LDP) and a smaller

diameter Zoom (71, 55, 45, or 35) Catheter. The Zoom Catheters most commonly used with the LDP Catheters on the first procedural pass were: Zoom 71 (81%, 170/211), Zoom 55 (15%, 31/211), Zoom 45 (2.4%, 5/211), and Zoom 35 (1.9%, 4/211).

Results

The primary effectiveness endpoint was independent core lab adjudicated reperfusion success, defined as achieving a mTICI score of ≥ 2b in three or fewer passes with the Zoom System (primary modality), without using additional mechanical neurothrombectomy devices or rescue therapy (e.g., intra-arterial lytics).

Core lab adjudicated reperfusion success within three or fewer passes was achieved in 84% (177/211; 95% confidence interval (CI) of 78% to 89%) of subjects, with a p-value <0.001 compared to the performance goal (PG). The performance goal of a lower bound of the two-sided 95% CI >69% was met.

Primary Effectiveness Analysis Results

Endpoint	Rate, % (n/N)	95% Confidence Interval	PG, %	P-Value
Primary Analysis mTICI ≥ 2b in three or fewer passes of Zoom System without using other devices	84% (177/211)	[78% – 89%]	> 69% for lower bound two-sided 95% CI	< 0.001
Additional Analysis mTICI ≥ 2b in three or fewer passes of Zoom System, use of any non-study devices after achieving mTICI ≥ 2b with Zoom System imputed as a failure	82% (173/211)	[76% – 87%]	> 69% for lower bound two-sided 95% CI	< 0.001

Reperfusion Success After All Passes with Zoom System and End of Procedure

Endpoint	Rate, % (n/N)	95% Confidence Interval
mTICI ≥ 2b after all passes with Zoom System	87% (183/211)	[81% – 91%]
mTICI ≥ 2b at end of procedure	91% (192/211)	[86% – 94%]

The primary safety endpoint was the rate of ECASS III defined symptomatic intracranial hemorrhage (sICH), confirmed by imaging 24 hours post-procedure and adjudicated by an independent core lab and Independent Safety Board (ISB). sICH was observed in 0.9% (2/211; 95% CI of 0.1% to 3.4%) of subjects, which meets the pre-specified performance goal of ≤ 6.0% for the observed rate.

The secondary safety endpoints included an all-cause mortality rate of 12.3% (26/211; 95% CI of 8.1% to 17.2%), a rate of all intracranial hemorrhage (ICH) within 24 hours post-procedure as adjudicated by the independent core lab of 20.0% (42/210; 95% CI of 14.8% to 26.1%), a rate of device-related serious adverse events (SAE) as adjudicated by the ISB of 1.4% (3/211; 95% CI of 0.3% to 4.1%) at 90-day follow-up, a rate of procedure-related serious vessel injury (dissections and perforations) of 0.5% (1/211; 95% CI of < 0.1% to 2.6%) and a rate of embolization in new territory (ENT) of 1.0% (2/200; 95% CI of 0.1% to 3.6%).

The median time from puncture to achieve mTICI ≥ 2b flow was 19 minutes.

Primary Safety Analysis Results

Endpoint	Rate, % (n/N)	95% Confidence Interval	PG, %
ECASS III sICH	0.9% (2/211)	[0.1% – 3.4%]	Observed rate ≤ 6.0%

Secondary Safety Endpoint Results

Endpoint	Rate, % (n/N)	95% Confidence Interval
90 Day All-Cause Mortality	12.3% (26/211)	[8.1% – 17.2%]
Core Lab Adjudicated ICH	20.0% (42/210[‡])	[14.8% – 26.1%]
Embolism in New Territory (ENT)	1.0% (2/200[§])	[0.1% – 3.6%]

[‡]Imaging for one case was inadequate for the core lab to determine if there was a hemorrhage. The site reported no hemorrhage and no neurological deterioration for this subject.
[§]ENT assessment forms were not completed for 11 subjects.

In total, 147/211 (69.7%) subjects had at least one adverse event, with 74/211 (35.1%) subjects having at least one serious adverse event.

Adverse Event Data

	Rate, % (n/N)	95% Confidence Interval
Non-Serious Adverse Event (AE)	62% (131/211)	[55% – 69%]
Serious Adverse Event (SAE)	35% (74/211)	[29% – 42%]
Device Related SAE, Adjudicated by ISB	1.4% (3/211)	[0.3% – 4.1%]
Procedure Related Serious Vessel Injury (Dissections and Perforations)	0.5% (1/211)	[< 0.1% – 2.6%]

Common Serious Adverse Events

System Organ Class	Preferred Term	Rate, % (n/N)
Cardiac disorders	Cardiac arrest	1.9% (4/211)
	Cardiac failure	1.4% (3/211)
Gastrointestinal disorders	Dysphagia	1.9% (4/211)
	Gastrointestinal haemorrhage	1.9% (4/211)
Infections and infestations	Pneumonia	2.4% (5/211)
	Urinary tract infection	1.9% (4/211)
Injury, poisoning and procedural complications	Vascular pseudoaneurysm[§§]	1.4% (3/211)
	Vessel perforation	0.5% (1/211)
Nervous system disorders	Brain oedema	1.9% (4/211)
	Cerebral artery occlusion	1.4% (3/211)
	Cerebral artery restenosis	1.9% (4/211)
	Cerebral haemorrhage	0.9% (2/211)
	Cerebrovascular accident	1.9% (4/211)
	Haemorrhagic transformation stroke	1.9% (4/211)
	Seizure	1.9% (4/211)

System Organ Class	Preferred Term	Rate, % (n/N)
Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	2.8% (6/211)
	Pneumonia aspiration	3.3% (7/211)
	Respiratory failure	3.3% (7/211)

[§§]All groin pseudoaneurysms

Direct aspiration using the LDP Catheters (Zoom 88 LDP, Zoom 88 LDP Support, TracStar LDP) alone is not supported by the Imperative Trial due to insufficient data. Aspiration through the LDP Catheter (Zoom 88 LDP, Zoom 88 LDP Support, or TracStar LDP) must be performed in conjunction with a Zoom (71, 55, 45, or 35) Catheter.

Imperative Trial Conclusions

Stroke mechanical neurothrombectomy with the Zoom System is safe and effective in subjects with large vessel occlusions within eight hours of last known well. All pre-specified performance goals were met.

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 and animal data support the safety of the device and demonstrate that the subject Zoom System performs as intended in the specified use conditions. The clinical performance data from the Imperative Trial demonstrates that the Zoom System meets the safety and effectiveness performance goals.

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