August 28, 2026

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

Re: K261176
Trade/Device Name: Zoom 4S Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: July 24, 2026
Received: July 27, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261176

Please provide the device trade name(s).

Zoom 4S Catheter

Please provide your Indications for Use below.

The Zoom 4S Catheter is indicated for the introduction of interventional devices into the neuro vasculature.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

510(k) #: K261176

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:	July 24, 2026

II. DEVICE

Proprietary Names:	Zoom™ 4S Catheter
Common/Usual Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter
Regulatory Class:	II
Product Code:	QJP
Regulation:	21 CFR 870.1250

III. PREDICATE DEVICE

Proprietary Name:	AXS Vecta 46 Intermediate Catheter
Common/Usual Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter
Product Code:	QJP
Regulation:	21 CFR 870.1250
Manufacturer:	Stryker Neurovascular
510(k) #:	K202752

IV. REFERENCE DEVICE

Proprietary Names:	Zoom System (Zoom™ 4S Catheter)
Common/Usual Name:	Catheter, Thrombus Retriever
Classification Name:	Percutaneous Catheter
Product Code:	NRY
Regulation:	21 CFR 870.1250
Manufacturer:	Imperative Care, Inc.
510(k) #:	K252046

V. DEVICE DESCRIPTION

The Zoom™ 4S Catheter 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 compatible with guide catheters that have a minimum inner diameter of 0.071" and 0.014"-0.035" guidewires. A microcatheter with a maximum outer diameter of 0.040" may be used with the Zoom™ 4S Catheter to assist in accessing the target vasculature.

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 Zoom™ 4S Catheter and used to control hemostasis during use with other devices.

VI. INDICATIONS FOR USE

The Zoom™ 4S Catheter is indicated for the introduction of interventional devices into the neuro vasculature.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE AND REFERENCE DEVICES

The subject, predicate, and reference devices have similar technological characteristics, and equivalent performance characteristics, as demonstrated through bench testing. **Table 1** provides a comparison of the subject Zoom 4S Catheter, predicate AXS Vecta 46 Intermediate Catheter (K202752), and reference Zoom 4S Catheter (K252046).

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: QJP 21 CFR 870.1250	Class II Product Code: QJP 21 CFR 870.1250	Class II Product Code: NRY 21 CFR 870.1250
Product Name	AXS Vecta 46 Intermediate Catheter	Zoom 4S Catheter	Zoom System (Zoom 4S Catheter)
510(k) Number	K202752	K261176	K252046
Manufacturer	Stryker Neurovascular	Imperative Care, Inc.	Imperative Care, Inc.
Indications for Use	The AXS Vecta Intermediate Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the neurovascular system. The AXS Vecta Intermediate Catheter is also indicated for use as a conduit for retrieval devices.	The Zoom 4S Catheter is indicated for the introduction of interventional devices into the neuro vasculature.	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, 4S, 45, 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

Description	Predicate Device	Subject Device	Reference Device
			(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
Inner Diameter (Distal)	0.046”	0.045”	Same as Subject Device
Outer Diameter (Distal)	0.056”	0.060” max	Same as Subject Device
Inner Diameter (Proximal)	0.046”	0.045”	Same as Subject Device
Outer Diameter (Proximal)	0.058”	0.062” max	Same as Subject Device
Effective Working Length	125cm 146cm 153cm 160cm	125cm 144cm 160cm	Same as Subject Device
Tip Design	Square edge, soft, flexible, and atraumatic	Angled edge, flexible, and atraumatic	Same as Subject Device
Materials	Commonly used medical grade plastics & metals with hydrophilic coating	Same	Same
Packaged Accessories	Peel-away Introducer, Rotating Hemostasis Valve	Rotating Hemostasis Valve (RHV)	Same as Subject Device
Packaging Configuration	Pouch Backing Card Shelf Carton Shipper Box	Same	Same
Shelf Life	3 years	1 year	Same as Subject Device

VIII. PERFORMANCE DATA

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

Biocompatibility Testing

The device design, materials and manufacturing of the subject Zoom 4S Catheter and the reference Zoom 4S Catheter are identical, and the patient contact type and duration per International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process" is the same. Therefore, biocompatibility is unchanged from K252046.

Non-clinical Bench Testing

As the subject and reference devices are technologically identical, applicable performance testing previously completed on the reference device has been leveraged to support the substantial equivalence determination. A summary of the evaluated applicable performance specifications is presented in **Table 2**. 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 there are no differences between the subject device and predicate device that would adversely affect the safety or effectiveness of the subject device, and to support a determination of substantial equivalence to the legally marketed predicate device.

Table 2: 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 neurological model without incurring any damage to the catheter.	Pass
Distal 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

Test Attribute	Specification	Results
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 strengths 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 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
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	Devices and accessories shall be compatible with standard syringe luer fittings per ISO 80369-7.	Pass
Accessory Compatibility	Devices shall be compatible with an RHV.	Pass

Test Attribute	Specification	Results
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
Flowrate – Positive (forward) Pressure	The catheter lumen shall allow for a minimum flowrate comparable to comparator products.	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

The device design (including packaging) and shelf life of the subject Zoom 4S Catheter and the reference Zoom 4S Catheter are identical and are therefore unchanged from K252046.

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 issues. 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. Therefore, the subject Zoom 4S catheter is substantially equivalent to the predicate device.