



April 23, 2021

Imperative Care, Inc.
Kristin Ellis
Regulatory Affairs Manager
1359 Dell Avenue
Campbell, California 95008

Re: K210996

Trade/Device Name: ZOOM (71, 55, 45, 35) Reperfusion Catheters; ZOOM Aspiration Tubing
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: April 1, 2021
Received: April 2, 2021

Dear Kristin Ellis:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531 - 542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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

Indications for Use

510(k) Number (if known)

K210996

Device Name

ZOOM (71, 55, 45, 35) Reperfusion Catheters; ZOOM Aspiration Tubing

Indications for Use (Describe)

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 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.

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

A. Submitter Information

Submitter's Name:	Imperative Care, Inc.
Address:	1359 Dell Avenue Campbell, CA 95008
Contact Person:	Kristin Ellis
Telephone:	408-857-0934
Email:	kellis@imperativecare.com
Date of Preparation:	April 1, 2021

B. Subject Device

Proprietary Name:	ZOOM (71, 55, 45, 35) Reperfusion Catheters; ZOOM Aspiration Tubing
Common/Usual Name:	Catheter, Thrombus Retriever
Classification Name:	Catheter, Percutaneous
Product Code:	NR Y
Regulation:	21 CFR 870.1250

C. Predicate Device

Proprietary Name:	ZOOM (71, 55, 45, 35) Reperfusion Catheters; ZOOM Aspiration Tubing
Common/Usual Name:	Catheter, Thrombus Retriever
Classification Name:	Catheter, Percutaneous
Product Code:	NR Y
Regulation:	21 CFR 870.1250
Manufacturer:	Imperative Care Inc.
510(k) #:	K202182

D. Device Description:

The ZOOM™ Reperfusion Catheter is a single lumen, braid and coil reinforced, variable stiffness catheter that facilitates removal of thrombus/clot from the neurovasculature when connected to a vacuum source, such as the ZOOM Aspiration Pump, using the ZOOM Aspiration Tubing.

The ZOOM Reperfusion Catheter is offered in various working lengths and nominal inner diameters (ID) and outer diameters (OD) as shown in **Table 1**.

Table 1: ZOOM Reperfusion Catheter Sizes

Product Name	Model Number	Distal Diameter		Proximal Diameter		Nominal Usable Catheter Length	Hydrophilic Coating Length
		Inner	Outer	Inner	Outer		
ZOOM 71	ICRC071137	0.071"	0.083"	0.071"	0.083"	137 cm	35cm
ZOOM 55	ICRC055137	0.055"	0.069"	0.067"	0.080"	137 cm	35cm
ZOOM 45	ICRC045144	0.045"	0.060"	0.064"	0.080"	144 cm	65cm
ZOOM 35	ICRC035158	0.035"	0.051"	0.047"	0.061"	160 cm	90cm

The ZOOM Reperfusion Catheter is comprised of a hollow cylindrical tube which is bonded to a standard luer fitting. The wall of the tube is constructed using a combination of metal coils/braids and medical grade polymers.

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

The ZOOM Reperfusion Catheter is packaged with an accessory Rotating Hemostasis Valve (RHV). The RHV is designed to be attached to the proximal luer of the catheter and helps the user maintain hemostasis.

The ZOOM Aspiration Tubing is offered in one model with the features indicated in **Table 2**.

Table 2: ZOOM Aspiration Tubing Model

Product Name	Model Number	Tubing ID	Tubing Length
ZOOM Aspiration Tubing	TAT102B	0.110" Minimum	104"

The ZOOM Aspiration Tubing is comprised of a hollow cylindrical tube which is bonded to a standard luer fitting that connects to the ZOOM Reperfusion 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 are intended to be used with the ZOOM Reperfusion Catheter and Aspiration Tubing.

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

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

E. 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 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.

F. Predicate Comparison:

The predicate device for the ZOOM Reperfusion Catheter and Aspiration Tubing in this Special 510(k) is the prior generation of ZOOM Reperfusion Catheter and Aspiration Tubing cleared under 510(k) K202182 with the same device names. **Table 3** presented below provides a comparison of the similarities and differences between the subject and predicate ZOOM Reperfusion Catheter and Aspiration Tubing.

The comparison between the subject ZOOM Reperfusion Catheters and predicate ZOOM Reperfusion Catheters demonstrates that the subject ZOOM Reperfusion Catheters is substantially equivalent to the predicate ZOOM Reperfusion Catheters and that there are no new safety or effectiveness concerns. This conclusion is based on all devices sharing the same intended use, basic technological characteristics, and performance characteristics.

Table 3: Subject and Predicate Device Comparison

Device Attribute	ZOOM Reperfusion Catheters (Predicate Device – K202182)	ZOOM Reperfusion Catheters (Subject Device)
FDA Product Classification	Class II, NRY, 21 CFR 870.1250	Same
Intended Use	Revascularization of patients with acute ischemic stroke.	Same
Indications for Use	See Section E.	Same
Condition Supplied	Sterile and Single Use	Same
Sterilization Method	Ethylene Oxide (EO), SAL 10 ⁻⁶	Same
Nominal Distal Inner Diameter	0.035” – 0.071”	Same
Max Distal Outer Diameter	0.053” – 0.085”	Same
Nominal Proximal Inner Diameter	0.047” – 0.071”	Same
Max Proximal Outer Diameter	0.062” – 0.085”	Same
Effective Length	137 - 158cm	137 - 160cm
Tip Design	Beveled edge, soft, flexible, and atraumatic	Same
Tip Length	0.5 – 0.8cm	Same
Coating	Hydrophilic coating	Same
Materials	Commonly used medical grade plastics & metals with hydrophilic coating.	Same

Device Attribute	ZOOM Reperfusion Catheters (Predicate Device – K202182)	ZOOM Reperfusion Catheters (Subject Device)
Packaged Accessories	Rotating Hemostasis Valve (RHV)	Same
Packaging Configuration	The catheter is placed in a protective polyethylene tube and then mounted, along with the accessories, onto a polyethylene packaging card. The packaging card is inserted into a Tyvek® pouch which is then sealed. The sealed pouch and IFU are placed in a carton box.	Same
Aspiration Pump	ZOOM Aspiration Pump	Same
Device Attribute	ZOOM Aspiration Tubing (Predicate Device – K202182)	ZOOM Aspiration Tubing (Subject Device)
Indications for Use	See Section E	Same
Condition Supplied	Sterile and Single Use	Same
Sterilization Method	Ethylene Oxide (EO), SAL 10 ⁻⁶	Same
Tubing ID	0.110” Minimum	Same
Tubing Length	104”	Same
Flow Control Mechanism	Flow Control Clamp	Same

G. Performance Data Supporting Substantial Equivalence:

Bench testing was completed to evaluate the differences between the subject ZOOM Reperfusion Catheters and predicate ZOOM Reperfusion Catheters. Performance specifications and test methods were based primarily on catheter performance standard ISO

10555-1 and a summary of the evaluated performance specifications is presented in **Table 4** below.

The test results were reviewed and found to demonstrate that the differences between the subject ZOOM Reperfusion Catheters and predicate ZOOM Reperfusion Catheters do not significantly impact any performance parameters that would negatively affect the safety or effectiveness of the subject ZOOM Reperfusion Catheters and Aspiration Tubing.

Table 4: Tests and Performance Specifications for ZOOM Reperfusion Catheter

Test Attribute	Specification
Visual	Free of kinks, breaks, separation or particulate (greater than 0.25mm ²). No exposed metal.
Dimensional (Effective Length)	All defined catheter dimensions are within the specified tolerances.
Catheter Bond Strength	The catheter shall have sufficient bond strengths to remain intact throughout a procedure.
Flowrate – Positive (Forward) Pressure	The catheter lumen shall allow for a minimum flowrate comparable to competitive products.
Flowrate – Vacuum Pressure	The flowrate under a vacuum shall be similar to or greater than competitive devices.
Freedom from Leakage – Positive Pressure	No liquid leakage from the hub or catheter shaft at 46psi for 30 seconds
Freedom from Leakage – Negative Pressure	No air leakage into a 20cc syringe when vacuum pulled for 15 seconds.
Dynamic Burst Pressure	Catheter does not burst under pressures that could be seen when performing contrast injections with a standard 10cc syringe.
Tip Flexibility	The flexibility of the catheter tip shall be comparable to competitive products and allow for easily tracking the device to the desired target anatomy.
Corrosion Resistance	No visible corrosion present on devices after saline immersion followed by 30 minutes in boiling water followed by 48 hours in 37°C water bath.

There were no changes to the Zoom Aspiration Tubing or Zoom Aspiration Pump and no changes to the subject and predicate ZOOM Reperfusion Catheters that would impact compatibility with these components. Therefore, no additional performance testing was required for the Zoom Aspiration Tubing or Zoom Aspiration Pump.

H. Biocompatibility Testing:

There are no changes to materials compared to the predicate device. Therefore, the original testing on the predicate devices applies to the subject devices and additional biocompatibility testing was not required.

I. Sterilization:

The ZOOM Reperfusion Catheters and Aspiration Tubing are both sterilized using validated EO processes with a sterility assurance level of 1×10^{-6} . The sterilization processes were validated per the overkill method described in recognized consensus standard ISO 11135, "Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices." There were no changes to the ZOOM Reperfusion Catheters that would impact the validated EO process.

J. Shelf Life and Packaging:

Accelerated aging testing based on ASTM F1980 was previously conducted to verify packaged device performance. A minimum shelf life was established based on this testing and is indicated by the expiration date provided on the product labeling. There were no changes to packaging compared to the predicate ZOOM Reperfusion Catheters. In addition, there were no changes to the ZOOM Reperfusion Catheters that would impact the packaging validation.

K. Conclusions:

Where differences were identified between the subject ZOOM Reperfusion Catheters and predicate ZOOM Reperfusion Catheters, a risk assessment was completed to determine if the difference would result in new safety or effectiveness concerns. As appropriate, previous bench and laboratory testing was evaluated for applicability and either the

rationale for no impact was documented or verification and validation was repeated as required. As appropriate, bench and laboratory testing were conducted to support this assessment.

Based on the results of the risk assessments and associated bench and laboratory testing, the subject ZOOM Reperfusion Catheters and predicate ZOOM Reperfusion Catheters are substantially equivalent and there are no new safety or effectiveness concerns. The subject ZOOM Reperfusion Catheters and predicate ZOOM Reperfusion Catheters share the same intended use, basic technological characteristics, and equivalent performance characteristics.