April 2, 2024

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

Re: K233975
Trade/Device Name: Zoom 6F Insert Catheters
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: February 20, 2024
Received: February 21, 2024

Dear Nguyen Teri:

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.

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,

Samuel G. Raben -S

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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.

Submission Number *(if known)*

K233975

Device Name

Zoom 6F Insert Catheter (Zoom SIM);
Zoom 6F Insert Catheter (Zoom VTK);
Zoom 6F Insert Catheter (Zoom VRT)

Indications for Use *(Describe)*

The Zoom 6F Insert Catheters are indicated for use in delivering radiopaque media to selected sites in the peripheral vascular system in conjunction with routine diagnostic procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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A. Submitter Information

Submitter's Name:	Imperative Care, Inc.
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Email:	kellis@imperativecare.com

Date of Preparation:	March 26, 2024

B. Subject Device

Proprietary Names:	Zoom™ 6F Insert Catheter
Common/Usual Name:	Diagnostic Intravascular Catheter
Classification Name:	Catheter, Intravascular, Diagnostic
Product Code:	DQO
Regulation:	21 CFR 870.1200

C. Predicate Device

Proprietary Name:	Impress Angiographic Catheter
Common/Usual Name:	Diagnostic Intravascular Catheter
Classification Name:	Catheter, Intravascular, Diagnostic
Product Code:	DQO
Regulation:	21 CFR. 870.1200
Manufacturer:	Merit Medical Systems, Inc.
510(k) #'s:	K191608

D. Device Description:

The Imperative Care Zoom™ 6F Insert Catheters are single lumen, braid reinforced, variable stiffness catheters. The catheters feature a standard luer hub on the proximal end, a radiopaque distal shaft and tip, and a tapered distal tip provided pre-shaped with various curve configurations. The curve configurations are designed to selectively engage arteries from the access sites such as the femoral, radial, and brachial arteries. The Zoom 6F Insert Catheter outer diameter is 0.082" (2.08 mm), the inner diameter is 0.041" (1.04 mm), and the tapered distal tip outer diameter is 0.061" (1.55 mm). The catheters are offered in working lengths of 137 cm, 139 cm, 140 cm, and 143 cm and come in three different tip configurations: VRT, SIM and VTK. The Zoom 6F Insert Catheters are compatible with standard luer lock devices (e.g., syringes), ≤ 0.038" diameter guidewires, ≥ 180 cm length guidewires, ≥ 6F introducer sheaths and ≥ 0.088" inner diameter guide catheters.

Accessory devices required, but not supplied, include:

- Guidewires
- Introducer Sheaths
- Guide Catheters
- RHV/Standard Luer Lock Devices

E. Indications for Use:

The Zoom 6F Insert Catheters are indicated for use in delivering radiopaque media to selected sites in the peripheral vascular system in conjunction with routine diagnostic procedures.

F. Principles of Operation:

The subject Zoom 6F Insert Catheters are advanced into the vasculature by a physician trained in endovascular techniques and experienced in endovascular procedures. Use of the Zoom 6F Insert Catheters relies on standard angiographic techniques.

G. Predicate Comparison:

The predicate devices are the Merit Medical Impress Angiographic Catheters (K191608). The predicate and subject devices share the same intended use, basic technological characteristics, and similar performance characteristics, demonstrated through bench and laboratory testing. As shown in **Table 1**, all fundamental technological characteristics of the subject device are substantially equivalent to the predicate device Merit Medical Impress Angiographic Catheter FDA-cleared under K191608.

Table 1: Comparison of Subject and Predicate Device

Description	Predicate Device Merit Medical Impress Angiographic Catheter (K191608)	Subject Device Zoom 6F Insert Catheter
FDA Device Classification	Class II	**Same**
Regulation Number	21 CFR 870.1200	**Same**
FDA Device Code	DQO	**Same**
Indications for Use	Angiographic catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Angiographic catheters with marker bands may also be used for anatomical measurements.	The Zoom 6F Insert Catheter is indicated for use in delivering radiopaque media to selected sites in the peripheral vascular system in conjunction with routine diagnostic procedures.
Contraindications	None known	**Same**
Materials	Commonly used medical grade plastics & metals.	**Same**
Inner Diameter	0.046"	0.041”
Outer Diameter	5F (0.066”)	6F (0.082”)
Effective Length	40cm to 125cm	137cm, 139cm, 140cm, 143cm
Guide Wire Compatibility	Compatible with 0.035” (VERT) and 0.038" (SIM and VTK) diameter guidewires or smaller.	Compatible with 0.038” diameter guidewires or smaller and ≥ 180 cm length
Introducer Sheath/Guide Catheter Compatibility	Compatible with 5F (0.066”) Introducer Sheath	Compatible with 0.088” Inner Diameter guide catheter or larger
Luer Compatibility	Compatible with standard luer lock devices	**Same**

Description	Predicate Device Merit Medical Impress Angiographic Catheter (K191608)	Subject Device Zoom 6F Insert Catheter
Tip Shape	Provided in a variety of tip shapes, including: - VTK - VERT - SIM2	**Same**
Shaft Lumen Construction	Braided configurations	**Same**
Packaged Accessories	None	**Same**
Condition Supplied	Sterile and Single Use	**Same**
Sterilization Method	Ethylene Oxide	**Same**
Sterility Assurance Level (SAL)	10^{-6}	**Same**
Packaging Configuration	Pouch Backing Card Shelf Carton Shipper Box	**Same**
Radiopacity	With and without radiopaque marker band, distal shaft is radiopaque	No radiopaque marker band, distal shaft is radiopaque
Hydrophilic Coating	With and without hydrophilic coating	Without hydrophilic coating
Maximum Dynamic Burst Pressure	1200 psi	**Same**
Flow Rate	5F SIM 2, 100cm length: 814 psi (57 kg/cm2) at 15 mL/sec 5F VERT, 100cm length: 888 psi (62 kg/cm2) at 15 mL/sec 5F VTK, 125cm length: 1030 psi (72 kg/cm2) at 14 mL/sec	1065 psi (75 kg/cm^2) at 10 mL/sec

H. Performance Data Supporting Substantial Equivalence:

Bench and Laboratory (*In-vitro*) testing was completed to evaluate the subject device, Zoom 6F Insert Catheter. Performance specifications and test methods were based primarily on catheter performance standard ISO 10555-1. A summary of the evaluated performance specifications is presented in **Table 2**.

The test results were reviewed and found to demonstrate that the differences between the subject Zoom 6F Insert Catheter and predicate Impress Angiographic Catheters do not significantly impact any performance parameters that would adversely affect the safety or effectiveness of the subject Zoom 6F Insert Catheter.

Table 2: Tests and Performance Specifications

Test Attribute	Specification	Results
Visual	The external surface of the effective length of the device shall be defect free when removed from packaging.	Pass
Effective Length	Effective lengths of the catheters are within the specified tolerances.	Pass
Guidewire compatibility	The catheters shall be compatible with guidewire specified in labeling.	Pass
Dimensional (Proximal OD, Midsection OD, Maximum OD)	All defined catheter dimension shall be within specified tolerances.	Pass
Shape/Curve Retention	The device shall be offered with the SIM, VERT, and VTK tip shapes.	Pass
Distal Tip	The distal tip shall be a smooth taper and contain a radiused edge.	Pass
Radiopacity	At least the shaped portion of the device shall be visible under fluoroscopy during use.	Pass
Flexibility and Kink Resistance	The device must be capable of being inserted into the access site, selecting the target vessel a minimum and being retracted without damage to the device.	Pass
Flexibility and Kink Resistance	The device shall be able to bend to a minimum radius specified radius at all locations without kinking.	Pass

Test Attribute	Specification	Results
Tensile Strength	Each junction of the device must meet the specified minimum tensile requirement.	Pass
Torque Strength	The device shall withstand 720 degree rotation without separation of any portion of the device.	Pass
Freedom from Leakage	The device shall not leak liquid when a pressure of 300 kPa minimum is applied and maintained for 30 seconds.	Pass
Freedom from Leakage	Air shall not leak into the hub assembly or device shaft during aspiration when vacuum is applied using a 10 mL syringe for 10 seconds.	Pass
Proximal Stiffness (Pushability)	The proximal shaft of the catheters shall have sufficient stiffness that the user can easily push the catheter to the target anatomy.	Pass
Dynamic Flow	The device shall remain free of leak and rupture, when used with a power injector set to a determined maximum pressure setting and maximum commanded flow rate.	Pass
Burst Strength	The device shall exceed the peak pressure present in the catheter at maximum flow conditions as determined per ISO 10555-1.	Pass
Flowrate, Positive	The device shall provide a flow rate which complies with ISO 10555-1.	Pass
Luer Compatibility	Device shall contain a female hub luer which complies with ISO 80369-7.	Pass
Corrosion	The metallic components of the device intended for fluid path contact shall be free of corrosion throughout the use of the device.	Pass
Particulate	The amount of particulate matter that comes off the shaft during simulated use testing shall be characterized and compared to competitive products.	Pass

I. Biocompatibility Testing:

Biocompatibility testing was performed on a representative finished Zoom 6F Insert Catheter to evaluate all direct patient contacting components of the device. This testing was conducted to ensure that the components and raw materials used in the subject Zoom 6F Insert Catheters and the manufacturing processes and sterilization processes result in a biocompatible product. Test results confirmed the subject Zoom 6F Insert Catheters met biological safety requirements per ISO 10993-1 for externally communicating medical devices with circulating blood contact for less than 24 hours.

J. Sterilization:

The Zoom 6F Insert Catheters are sterilized using a validated Ethylene Oxide (EtO) process with a sterility assurance level (SAL) of 10^{-6} 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".

K. Shelf Life and Packaging:

Accelerated aging testing based on ASTM F1980 was conducted to verify packaged device performance. A real time aging equivalent of 13 months was used to support 1-year expiration dating. Device performance was verified by functional and performance testing.

Packaging and sterile barrier integrity through transportation has been verified. Aging testing has also been performed that supports the sterile barrier integrity following 13 months of accelerated aging.

L. Conclusions:

Imperative Care has completed comprehensive design verification and validation testing to ensure the subject device is biocompatible, performs as intended, meets all necessary performance attributes, and performs consistently throughout its labeled expiration dating. The results of design verification and validation testing did not raise any new issues or different questions of safety and effectiveness.

Based on the results of bench and laboratory testing, the subject device described in this submission is substantially equivalent to the predicate device.