June 6, 2024

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

Re: K240948
Trade/Device Name: TracStar LDP Large Distal Platform; Zoom 88 Large Distal Platform; Zoom 88 Large Distal Platform Support
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: April 5, 2024
Received: April 8, 2024

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 (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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K240948

Device Name
TracStar™ LDP Large Distal Platform™
Zoom™ 88 Large Distal Platform™
Zoom™ 88 Large Distal Platform™ Support

Indications for Use *(Describe)*
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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:	June 4, 2024

B. Subject Device

Proprietary Names:	TracStar™ LDP Large Distal Platform™ Zoom™ 88 Large Distal Platform™ Zoom™ 88 Large Distal Platform™ Support
Common/Usual Name:	Guide Catheter
Classification Name:	Catheter, Percutaneous, Neurovasculature
Product Code:	QJP DQY
Regulation:	21 CFR 870.1250

C. Predicate Device

Proprietary Name:	TracStar™ LDP Large Distal Platform™ Zoom™ 88 Large Distal Platform™ Zoom™ 88 Large Distal Platform™ Support
Common/Usual Name:	Guide Catheter
Classification Name:	Catheter, Percutaneous, Neurovasculature
Product Code:	QJP DQY
Regulation:	21 CFR. 870.1250
Manufacturer:	Imperative Care, Inc.
510(k) #'s:	K231168

D. Device Description:

The Imperative Care Large Distal Platform™ (LDP) Catheters include the Zoom™ 88 Large Distal Platform™, Zoom™ 88 Large Distal Platform™ Support, and TracStar™ LDP Large Distal Platform. The LDP Catheters are 0.038" diameter or smaller guidewire compatible single lumen guide catheters that provide access to peripheral, coronary and neuro vasculature. The catheters are comprised of a hollow cylindrical tube bonded at the proximal end 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 each catheter has a hydrophilic coating to enhance tracking through tortuous vasculature. An

angled distal soft tip facilitates smooth tracking past vessel branches. A radiopaque marker provides visual confirmation of the distal tip location under fluoroscopy. The LDP Catheters have an inner diameter (ID) of 0.088" (6F compatible), and a maximum outer diameter (OD) of 0.110". The LDP guide catheters are packaged with a rotating hemostasis valve (RHV) that is attached to the proximal luer to help maintain hemostasis.

Accessory devices required, but not supplied include:

- Guidewires
- Support/diagnostic catheters
- Introducer sheaths

E. Indications for Use:

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.

F. Principles of Operation:

The LDP Catheters may be used with support catheters to assist in accessing the target vasculature. During use, the male luer of the RHV is attached to the proximal luer of the LDP Catheter to create a continuous lumen through the catheter and to the RHV ports. The female luer is typically connected to a saline drip line while the LDP Catheter is advanced through the vasculature. Use of the LDP Catheter relies on standard percutaneous interventional techniques, including access site preparation, introducing the catheter portion of the device, advancing the catheter under fluoroscopy, withdrawing the catheter, and closing the access site.

G. Predicate Comparison:

The predicate devices are the Imperative Care 0.088" ID Large Distal Platform (LDP) Catheters cleared under K231168. The predicate and subject devices share the same intended use, basic technological characteristics, and the same performance characteristics, demonstrated through bench and laboratory testing as shown in **Table 1.**

Table 1: Comparison of Subject and Predicate Devices

Device Attribute	Predicate device	Subject device
FDA Product Classification	Class II, QJP and DQY, 21 CFR 870.1250	Same
Product Name	• TracStar LDP Large Distal Platform • Zoom 88 Large Distal Platform • Zoom 88 Large Distal Platform Support	Same
510(k) Number	K231168	K240948
Indications for Use	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.	Same
Condition Supplied	Sterile and Single Use	Same
Sterilization Method	Ethylene Oxide (EtO), SAL 10^{-6}	Same
	Single Cycle	Up to Two (2) Cycles
Inner Diameter (Distal)	0.088”	Same
Outer Diameter (Distal)	0.106”	Same
Inner Diameter (Proximal)	0.088”	Same
Outer Diameter (Proximal)	0.110”	Same
Effective Length	TracStar LDP: 80 – 105 cm Zoom 88 LDP: 100 – 110 cm Zoom 88 LDP Support: 100 cm	TracStar LDP: 80 – 105 cm Zoom 88 LDP: 110 cm Zoom 88 LDP Support: 100 cm
Tip Design	Beveled distal edge, soft, flexible, atraumatic tip	Same

Device Attribute	Predicate device	Subject device
Distal Catheter Shaft	Reinforced with metals and polymers	Same
Proximal Catheter Shaft	Reinforced with metals and polymers	Same
Coating	Hydrophilic coating	Same
Materials	Commonly used medical grade plastics & metals with hydrophilic coating	Same
Packaged Accessories	Rotating Hemostasis Valve (RHV)	Same
Packaging Configuration	The catheters are placed in a protective polyethylene tube, mounted with accessory RHV onto a polyethylene packaging card, placed into a pouch, sealed and labeled. The sealed pouch and IFU are placed in a labeled shelf carton box.	Same
Shelf life	12 months	36 months

H. Performance Data Supporting Substantial Equivalence:

Bench and laboratory (in-vitro) testing was completed to evaluate the differences between the subject LDP Catheters and predicate LDP 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 2**.

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

Table 2: Tests and Performance Specifications

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 neurological model without incurring any damage to the catheter.	Pass

Test Attribute	Specification	Results
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 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
Burst Pressure	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 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

Test Attribute	Specification	Results
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
Interventional Device Compatibility (internal)	The catheters shall be able to accommodate other interventional devices (e.g., support catheter, diagnostic 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
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

I. Biocompatibility Testing:

There are no changes to patient contacting materials, including raw materials, manufacturing processes, and manufacturing aids 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.

J. Sterilization:

The LDP Catheters are sterilized using a validated EtO process with a sterility assurance level of $1x10^{-6}$ 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 previously conducted to verify packaged device performance of the predicate LDP Catheters. The subject LDP Catheters undergo the same packaging and similar sterilization processing as the predicate LDP Catheters. The construction of the subject LDP Catheters is the same as the predicate LDP Catheters including raw materials, manufacturing processes, and manufacturing aids. Verification testing of the subject LDP Catheters followed the same test methods as the predicate LDP Catheters. Bench testing of the subject LDP Catheters and packaging supports a three (3) year shelf life.

L. Conclusions:

Where differences were identified between the subject and predicate devices, 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.

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