



September 20, 2021

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

Re: K212224

Trade/Device Name: TracStar LDP Large Distal Platform; Zoom 88 Large Distal Platform  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: QJP, DQY  
Dated: September 1, 2021  
Received: September 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](mailto: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)

K212224

Device Name

TracStar LDP Large Distal Platform

Zoom 88 Large Distal Platform

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 is 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.

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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: September 1, 2021

### B. Subject Device

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

### C. Predicate Device(s)

Proprietary Name: TracStar™ Large Distal Platform  
 ZOOM™ 88 Large Distal Platform  
 ZOOM™ 88-T Large Distal Platform  
 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): K203764

Proprietary Name: EagleRay Long Sheath  
 EagleRay Access Catheter  
 Common/Usual Name: Guide Catheter  
 Classification Name: Catheter, Percutaneous  
 Product Code: DQY  
 Regulation: 21 CFR. 870.1250  
 Manufacturer: Imperative Care Inc.  
 510(k): K180169

### D. Device Description:

The Imperative Care Large Distal Platform (LDP) Catheters include the TracStar™ LDP Large Distal Platform and Zoom™ 88 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. LDP Catheters have an inner diameter of 0.088” (6F compatible), and a maximum outer diameter 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 is 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 LDP Catheters cleared under K203764 and K180169. 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**. Modifications include dimensional updates, additional axial and radial reinforcements, and manufacturing process improvements.

**Table 1: Comparison of Subject and Predicate Devices**

<b>Device Attribute</b>	<b>Subject device</b>	<b>Predicate devices</b>	
FDA Product Classification	Class II, QJP and DQY, 21 CFR 870.1250	Class II, QJP and DQY, 21 CFR 870.1250	Class II, DQY, 21 CFR 870.1250
Product Name	TracStar LDP Large Distal Platform Zoom 88 Large Distal Platform	TracStar Large Distal Platform ZOOM 88 Large Distal Platform ZOOM 88-T Large Distal Platform	EagleRay Long Sheath EagleRay Access Catheter
510(k) Number	K212224	K203764	K180169
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 is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The TracStar Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.  The ZOOM 88 and ZOOM 88-T Large Distal Platform are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The EagleRay Long Sheath and EagleRay Access Catheter are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Condition Supplied	Sterile and Single Use	Same	Same
Sterilization Method	Ethylene Oxide (EtO), SAL 10 <sup>-6</sup>	Same	Same
Inner Diameter (Distal)	0.088"	Same	Same
Outer Diameter (Distal)	0.106"	Same	Same
Inner Diameter (Proximal)	0.088"	Same	Same
Outer Diameter (Proximal)	0.110"	Same	Same

Device Attribute	Subject device	Predicate device(s)	
Effective Length	80 - 110cm	Same	Same
Tip Design	Beveled distal edge, soft, flexible, atraumatic tip	Same	Same
Distal Catheter Shaft	Additional polymer reinforcement	Reinforced with metals and polymers	Reinforced with metals and polymers
Proximal Catheter Shaft	Additional radial reinforcement	Reinforced with metals and polymers	Reinforced with metals and polymers
Coating	Hydrophilic coating	Same	Same
Materials	Commonly used medical grade plastics & metals with hydrophilic coating	Same	Same
Packaged Accessories	Rotating Hemostasis Valve (RHV)	Same	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	Same

#### 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 tests and 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**

<b>Test Attribute</b>	<b>Specification</b>	<b>Results</b>
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
Flexibility and Kink Resistance	There shall be no kinking of shaft (permanent deformation) after simulated use.	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
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
Catheter Bond Strength	The catheter shall have sufficient bond strengths to remain intact throughout a procedure.	Pass
Freedom from Leakage – positive pressure	No liquid leakage from the hub or catheter shaft at 46psi for 30 seconds	Pass
Freedom from Leakage – negative pressure	No air leakage into a 20cc syringe when vacuum pulled for 15 seconds.	Pass
Dynamic Burst Pressure	Catheter does not burst under pressures that could be seen when performing contrast injections with a standard 10cc syringe.	Pass
Static Burst Pressure	Catheter does not burst under pressures that could be seen when performing contrast injections with a standard 10cc syringe.	Pass



Test Attribute	Specification	Results
Catheter Torque Strength	With the catheter tip held in a static position, there shall be no separation of any portion of the catheter when rotated at the hub at least two (2) full rotations (720 degrees).	Pass
Kink Resistance	There shall be no kinking of the catheter shaft (permanent deformation) after wrapping around anatomically relevant bend radii.	Pass
Pushability	The proximal shaft of the catheters shall have sufficient stiffness that the user can easily push the catheter to the target anatomy without buckling.	Pass
Access Force	Catheters shall not require excessive force to safely navigate and track to the target anatomy.	Pass

#### **I. Biocompatibility Testing:**

There are no changes to patient contacting 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.

#### **J. Sterilization:**

The LDP Catheters are sterilized using a validated EtO process with a sterility assurance level of  $1 \times 10^{-6}$  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 a 1-year shelf life claim. Device performance was verified by functional and performance testing.

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

**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 device and predicate devices share the same intended use, basic technological characteristics, and performance characteristics.