March 3, 2021

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

Re: K203764
Trade/Device Name: TracStar Large Distal Platform, ZOOM 88 Large Distal Platform, ZOOM 88-T Large Distal Platform
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: December 21, 2020
Received: December 23, 2020

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203764

Device Name
TracStar™ Large Distal Platform
ZOOM™ 88 Large Distal Platform
ZOOM™ 88-T Large Distal Platform

Indications for Use *(Describe)*
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.

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, K203764

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:	December 21, 2020

B. Subject Device

Proprietary Names:	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

C. Predicate Device

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) #'s:	K180169

D. Device Description:

The Imperative Care Large Distal Platform (LDP) Catheters include the TracStar™ LDP, Zoom™ 88 LDP and Zoom™ 88-T LDP. The LDP Catheters are 0.038" 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 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.

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 device is the Imperative Care EagleRay Access Catheters cleared under K180169. The predicate and subject devices share the same intended use, basic technology characteristics, and the same performance characteristics, demonstrated through bench and laboratory testing as shown in **Table 1**.

Table 1: Comparison of Subject and Predicate Device

Device Attribute	Subject device	Predicate device
FDA Product Classification	Class II, QJP and DQY, 21 CFR 870.1250	Class II, DQY, 21 CFR 870.1250
Product Name	TracStar Large Distal Platform ZOOM 88 Large Distal Platform ZOOM 88-T Large Distal Platform	EagleRay Long Sheath and EagleRay Access Catheter
510(k) Number	K203764	K180169
Indications for Use	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
Sterilization Method	Ethylene Oxide (EtO), SAL 10^{-6}	Same
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	80 - 110cm	Same
Tip Design	Beveled distal edge, soft, flexible, atraumatic tip.	Same
Coating	Hydrophilic coating	Same
Materials	Commonly used medical grade plastics & metals with hydrophilic coating.	Same
Packaged Accessories	Rotating Hemostasis Valve (RHV)	RHV and Catheter Introducer

Device Attribute	Subject device	Predicate device
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

H. Performance Data Supporting Substantial Equivalence:

Bench and Laboratory (in-vitro) testing evaluated the similarities and differences between the subject and predicate Imperative Care Inc., Large Distal Platform (LDP) Catheters. The test results were reviewed and found to demonstrate that any differences between the subject and predicate devices do not significantly impact any catheter performance parameters that would affect safety or efficacy. A summary of the supportive data is presented in **Table 2**. These tests were performed per company approved protocols, test methods, and performance standards.

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
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

Test Attribute	Specification	Results
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
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 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 $1x10^{-6}$ 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 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 efficacy 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 efficacy concerns. As confirmed through the results of bench and lab testing, the subject device and predicate device share the same intended use, basic technological characteristics, and performance characteristics.