May 17, 2022

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

Re: K220807
Trade/Device Name: Imperative Care Radial 088 Access System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: March 16, 2022
Received: March 18, 2022

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)*
K220807

Device Name
Imperative Care Radial 088 Access System

Indications for Use *(Describe)*
The Imperative Care Radial 088 Access System 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.

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K220807: 510(k) Summary

A. Submitter Information

Submitter's Name:	Imperative Care, Inc.
Address:	1359 Dell Avenue Campbell, CA 95008
Contact Person:	Kristin Ellis, RAC
Telephone:	(408) 857-0934
Email:	kellis@imperativecare.com
Date of Preparation:	May 12, 2022

B. Subject Device

Proprietary Name:	Imperative Care Radial 088 Access System
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
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):	K212224

D. Device Description:

The Imperative Care Radial 088 Access System (Radial 088 Access System) consists of a single lumen catheter (Radial 088 Access Catheter) and a 6F Dilator intended to provide ease of access to the peripheral, coronary and neuro vasculature using a transradial access (TRA) approach.

The Radial 088 Access Catheter consists of a single lumen, braid and coil reinforced, variable stiffness catheter constructed using medical grade polymers. The catheter features include a standard luer hub on the proximal end and an atraumatic angled tip on the distal end. The distal section is covered in a lubricious hydrophilic coating for ease of tracking through tortuous vasculature to reach the target location. The distal tip has a radiopaque marker to provide the user with visual confirmation of the distal tip location during

tracking and placement under fluoroscopy.

The Radial 088 Access Catheter is offered in working lengths of 95 cm, 105 cm, and 110 cm. The catheter has a proximal and distal inner diameter (ID) of 0.088" and is compatible with ≤ 0.038" diameter guidewires and 6F interventional devices having a minimum device length of 120 cm. The catheter has a distal outer diameter (OD) of 0.107" (2.7 mm) and a proximal OD of 0.110" (2.8 mm); the luer hub on the proximal end is compatible with Rotating Hemostasis Valves (RHVs) having a standard luer connector.

The 6F Dilator is a single lumen dilator with a tapered tip constructed of medical grade polymers. The 6F Dilator includes a standard luer hub on the proximal end which is compatible with standard luer lock devices (e.g., syringes). The 6F Dilator has an ID of 0.039" minimum, an OD of 0.083"-0.086" and is offered in a working length of 130 cm (± 2 cm).

Accessories and supplies required, but not supplied, include:

- Rotating Hemostatic Value (RHV)
- Guidewires
- Support/diagnostic catheters
- Heparinized saline

E. Indications for Use:

The Imperative Care Radial 088 Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

F. Principles of Operation:

Use of the Radial 088 Access System 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.

During use, the male luer of an ancillary RHV is attached to the proximal luer of the Radial 088 Access Catheter to create a continuous lumen through the catheter and to the RHV ports. The female luer of an ancillary RHV is typically connected to a saline drip line while an ≤ 0.038" guidewire and other ancillary devices (such as support catheters) are used to gain vascular access facilitating advancement of the Radial 088 Access Catheter through the vasculature. Under fluoroscopy, the Radial 088 Access Catheter is advanced to the desired position, where it is used as a conduit to access the target site.

G. Predicate Comparison:

As shown in **Table 1**, the subject and predicate devices share the same intended use.

The differences in technological characteristics compared to the predicate device, for ease of tracking through tortuous vasculature, a range of working lengths designed to reach target anatomy, and the addition of the dilator, do not raise new questions of safety and effectiveness.

Table 1: Comparison of Subject and Predicate Devices

Device Attribute	Subject Device	Predicate Device
Product Name	Imperative Care Radial 088 Access System	TracStar LDP Large Distal Platform
510(k) Number	K220807	K212224
Device Classification	Class II	Same
Regulation Number and Name	21 CFR §870.1250 Percutaneous Catheter	Same
Product Code	DQY, QJP	Same
Indications for Use	The Imperative Care Radial 088 Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Condition Supplied	Provided sterile, for single use only.	Same
Sterilization Method	Ethylene Oxide (EtO) gas	Same
Catheter Effective Working Length	95 cm 105 cm 110 cm	80 cm 90 cm 95 cm 105 cm
Catheter Inner Diameter (Distal and Proximal)	0.088”	Same
Catheter Outer Diameter (Distal)	0.107”	Same
Catheter Outer Diameter (Proximal)	0.110”	Same
Catheter Tip Configuration	Atraumatic, angled tip	Same
Shaft Lumen	Single-lumen, braid and coil reinforced shaft, variable stiffness	Same

Device Attribute	Subject Device	Predicate Device
Hydrophilic Coating	Distal portion of the catheter contains a hydrophilic coating to reduce friction during use.	Same
Accessories Provided in Product Package	6F Dilator	Rotating Hemostasis Valve (RHV)
Dilator Effective Length	130 cm ± 2 cm	N/A
Dilator ID	0.039" minimum	N/A
Dilator OD	0.083"-0.086"	N/A
Dilator Tip Configuration	Atraumatic, taper	N/A
Packaging Configuration	The catheters are placed in a protective polyethylene tube (which is attached to the packaging card), then the 6F Dilator is mounted onto a polyethylene packaging card The packaging card is inserted into a Tyvek® pouch which is then sealed. The sealed pouch and Instructions for Use (IFU) are placed in a shelf carton.	The catheters are placed in a protective polyethylene tube and then mounted, along with the RHV, 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 shelf carton.

H. Performance Data Supporting Substantial Equivalence:

Bench and Laboratory (*in-vitro*) testing was completed to evaluate the differences between the subject device, Radial 088 Access System, and the predicate. Performance specifications and test methods were based primarily on catheter performance standard ISO 10555-1. A summary of the evaluated performance tests and specifications is presented in **Table 2** and **Table 3**.

The test results were reviewed and found to demonstrate that the differences between the subject Radial 088 Access Catheter and predicate TracStar LDP catheters do not significantly impact any performance parameters that would adversely affect the safety or effectiveness of the subject Radial 088 Access System.

Table 2: Catheter Tests and Performance Specifications

Test Attribute	Specification	Results
Dimensional Inspection	All defined catheter dimensions are within the specified tolerances.	Pass

Test Attribute	Specification	Results
Delivery, Compatibility, and Retraction (Trackability)	The catheter shall be able to be delivered and retracted per the IFU using radial access in 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. Catheter remains patent after removal of the dilator.	Pass
Catheter Torque Strength	No separation of any portion of the catheter when rotated at least two (2) full rotations (720 degrees). No damage to the catheter when hand rotated during insertion.	Pass
Luer Compatibility	Devices shall be compatible with standard syringe luer fittings per ISO 80369-7.	Pass
Guidewire Compatibility	The catheters shall be able to be delivered over the maximum size guidewire indicated in the product labeling.	Pass
Dilator Compatibility	The catheter should remain patent after removal of the dilator to allow for the introduction of interventional devices.	Pass
Interventional Device Compatibility	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
Direct Puncture	The catheter with dilator can be inserted without incurring any damage to the catheter or causing catheter tip roll back.	Pass
Accessory Compatibility	Devices shall be compatible with an RHV.	Pass
Stability	The catheter provides enough support to maintain its position when interventional device is advanced to target location.	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
Coating Integrity/Particulate	The amount of particulate matter that comes off the hydrophilic coated shaft during simulated use testing shall be determined and compared to competitive products and techniques.	Pass

Table 3: Dilator Tests and Performance Specifications

Test Attribute	Specification	Results
Dimensional Inspection	All defined dilator dimensions are within the specified tolerances.	Pass
Radiopacity	The distal tip of dilator can be seen under fluoroscopy during use.	Pass
Dilator Bond Strength	The dilator shall have sufficient bond strength to remain intact throughout a procedure.	Pass
Luer Compatibility	The dilator shall be compatible with standard luer lock fittings per ISO 80369-7.	Pass
Guidewire Compatibility	The dilator shall be able to be delivered over the maximum size guidewire indicated in the product labeling.	Pass
Direct Puncture	The dilator can be inserted without incurring any damage.	Pass

I. Biocompatibility Testing:

There are no changes to patient contacting materials of the catheter component of the Radial 088 Access System, compared to the predicate device. Therefore, the original testing on the predicate devices applies to the Radial 088 Access Catheter and additional biocompatibility testing was not required. Biocompatibility testing was successfully completed to support the biological safety of the 6F Dilator component of the Radial 088 Access System.

Table 4: Biocompatibility Testing – 6F Dilator

Test	Results	Conclusion
Cytotoxicity (ISO MEM* Elution)	The test article had no reactivity.	Non-cytotoxic
Sensitization (Magnusson-Klingman Method)	The extracts of the test article elicited no reaction at the challenge following the induction phase.	Non-sensitizer
Irritation/Intracutaneous Reactivity (ISO Intracutaneous Irritation Test)	The test article sites did not show any significantly greater biological reaction than the sites injected with the control article. The differences in the mean test and control scores of the dermal observations were less than 1.0.	Non-irritant
Acute Systemic Toxicity (ISO Acute Systemic Injection Test)	None of the animals treated with sample extracts of the test article showed a significantly greater biological reaction than animals treated with sample extracts of the control article.	Non-toxic

Test	Results	Conclusion
Hemocompatibility (Complement Activation)	The test device had statistically similar SC5b-9 concentrations when compared to the predicate device and negative controls.	Pass
Hemocompatibility (ASTM Hemolysis, Direct Contact Method)	The difference between the hemolytic indexes of the test sample and the negative control equals 0 percent.	Non-hemolytic
Hemocompatibility (ASTM Hemolysis, Extract Method)	The difference between the hemolytic indexes of the test sample and the negative control equals 0.15 percent.	Non-hemolytic
Hemocompatibility (*in-vitro* Blood Loop Assay)	The test device received acceptable thrombus formation scores.	Thromboresistant
Material Mediated Pyrogenicity (ISO Material Mediated Rabbit Pyrogen)	No individual temperature rise of ≥ 0.5°C at the observed time points.	Non-pyrogenic

*MEM=Minimal Essential Media

J. Sterilization:

The Radial 088 Access System is sterilized using a validated 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 F1980-16 was conducted to verify packaged device performance. The devices were exposed to accelerated aging conditions equivalent to 13 months real time aging to support a 1-year shelf life. Device performance was verified by functional and performance testing. A summary of the completed packaging tests is presented below in **Table 5**.

Table 5. Packaging Validation Summary

Test	Test Method	T=0 Results	T=1 year Results
Packaging Visual Inspection	ASTM F1886	Pass	Pass
Pouch Integrity Test – Gross Leak Detection	ASTM F2096	Pass	Pass
Pouch Seal Strength – Peel Strength	ASTM F88	Pass	Pass
Label Integrity	Imperative Care Internal	Pass	Pass

L. Conclusions:

The differences between the subject device and the predicate devices do not raise new questions of safety and effectiveness.

Imperative Care has completed comprehensive design verification and validation testing to evaluate the differences and to ensure that the Radial 088 Access System is biocompatible, performs as intended, meets all necessary performance attributes, and performs consistently throughout the device shelf life.

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