January 28, 2022

Traverse Vascular, Inc.
℅ Prithul Bom
Most Repsonsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K214106
Trade/Device Name: QuikPass Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 28, 2021
Received: December 29, 2021

Dear Prithul Bom:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214106

Device Name
QuikPass™ Catheter

Indications for Use *(Describe)*
The QuikPass Catheter is intended to be used to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and is also intended to assist in the delivery of contrast media into the coronary and/or peripheral 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

510(k) Number: K214106

Date Prepared: December 24, 2021

Table 1. Submitter Information

Manufacturer of Record: Traverse Vascular, Inc. 535 Stevens Ave. West Solana Beach, CA 92075	Manufacturer's Contact Person: Greg Geissinger Regulatory Affairs Consultant Phone: (858) 349-8839 Email: GJGeissinger@hotmail.com

Table 2. Device Information

Trade Name:	QuikPass™ Catheter
Device Common Name:	Catheter, Percutaneous
Classification Name:	Percutaneous Catheter
Regulatory Classification:	Class II
Device Panel:	Cardiovascular
Regulation Number	21 CFR 870.1250
Product Code:	DQY

The QuikPass Catheter is comprised of similar materials and is of similar design to the corresponding components of the previously cleared predicate, Turnpike® Catheter (**Table 3**). The subject and predicate devices share similar technical requirements, perform as intended, and present no unacceptable risks to the intended patient population or end user.

Table 3. Predicate Device

Predicate Device	Manufacturer	FDA 510(k)
Turnpike® Catheter	Vascular Solutions, Inc. (now Teleflex, Inc.)	K142065

1 Device Description

The QuikPass Catheter is comprised of a proximal end containing a Luer connection and hub, a single-lumen shaft with radiopaque markers at the distal end, and a tapered distal tip with oval ports at 60° intervals.

The single-lumen shaft of the QuikPass Catheter is constructed of two polymer layers that encapsulate a braid and coil affording increased tensile strength and torque transmission. The distal 40cm of the catheter has a hydrophilic coating to aid in navigating the device through the vasculature to the target location.

The QuikPass Catheter is available in both 3 French and 4 French outer diameter sizes. Each version is available in 135cm and 150cm lengths, providing a total of four models. A list of available model numbers is provided in **Table 4** below.

Table 4. Available Model Numbers

Model Number	Size	Working Length
135-03	3 Fr	135 cm
135-04	4 Fr	135 cm
150-03	3 Fr	150 cm
150-04	4 Fr	150cm

All models of the QuikPass Catheter are sold sterile. Sterility is achieved using ethylene oxide. An image of the QuikPass Catheter is provided in **Figure 1**.

Figure 1. QuikPass Catheter

2 Indications for Use

The QuikPass Catheter is intended to be used to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and is also intended to assist in the delivery of contrast media into the coronary and/or peripheral vasculature.

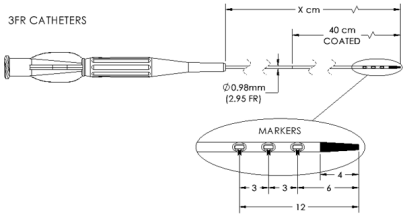
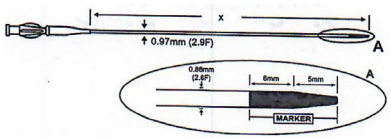
3 Comparison of Technological Characteristics with the Predicate Device

The subject and predicate devices are based on the same technological elements of using a single-lumen catheter to achieve the desired vascular access to place or exchange guidewires and to deliver diagnostic agents such as contrast media. The catheter designs are similar, come in identical working lengths, and have similar outer diameter models available.

The subject and predicate devices are both compatible with ≥ 6 French guide catheters and 0.014" guidewires. The subject and predicate devices are both sold sterile and have similar indications for use. A detailed summary of substantial equivalence between the subject and predicate devices is provided in **Table 5** below.

Table 5. Substantial Equivalence Comparison

Description	Subject Device	Predicate Device (K142065)	Conclusion
Product Name	QuikPass Catheter	Turnpike® Catheter	
Manufacturer	Traverse Vascular, Inc.	Vascular Solutions, Inc. (now Teleflex, Inc.)	
510(k) Number	To be determined	K142065	
Classification	Class II	Class II	Identical
Product Code / Regulation	DQY / 21 CFR 870.1250	DQY / 21 CFR 870.1250	Identical
Indications for Use	The QuikPass Catheter is intended to be used to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and is also intended to assist in the delivery of contrast media into the coronary and/or peripheral vasculature.	The Turnpike catheter is intended to be used to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and to subselectively infuse/deliver diagnostic and therapeutic agents.	Similar; the subject device indications for use are narrower than those of the predicate. There are therefore no new questions of safety or effectiveness.
Catheter Components	Proximal hub with Luer connection	Proximal hub with Luer connection	Identical
	Single-lumen shaft constructed of two polymer layers encapsulating a braid and coil and having a hydrophilic coating	Single-lumen shaft constructed of two polymer layers encapsulating a braid and coil and having a hydrophilic coating	Identical
	Radiopaque distal markers and ports for guidewire passage and solution infusion	Radiopaque distal tip with outlet for guidewire passage and solution infusion	Similar; minor design differences do not raise new questions of safety or effectiveness
Available Models, Sizes, and Working Length	Model #135-03: 3 Fr; 135cm Model #135-04: 4 Fr; 135cm Model #150-03: 3 Fr; 150cm Model #150-04: 4 Fr; 150cm	Model #5642: 3 Fr; 135cm Model #5643: 3 Fr; 150cm	Similar; minor design differences do not raise new questions of safety or effectiveness
Labeled Shaft Outer Diameter	Model #135-03: 2.95 Fr (0.98mm) Model #135-04: 3.95 Fr (1.32mm) Model #150-03: 2.95 Fr (0.98mm) Model #150-04: 3.95 Fr (1.32mm)	Model #5642: 2.9 Fr (0.97mm) Model #5643: 2.9 Fr (0.97mm)	Similar; minor design differences do not raise new questions of safety or effectiveness
Labeled Shaft Inner Diameter	Model #135-03: 2.10 Fr (0.70mm) Model #135-04: 3.10 Fr (1.04mm) Model #150-03: 2.10 Fr (0.70mm) Model #150-04: 3.10 Fr (1.04mm)	Model #5642: 1.26 Fr (0.42mm) Model #5643: 1.26 Fr (0.42mm)	Similar; minor design differences do not raise new questions of safety or effectiveness
Distal Tip Shape	Smooth, Rounded, Tapered	Smooth, Rounded, Tapered	Identical

Description	Subject Device	Predicate Device (K142065)	Conclusion
Distal Tip Length	4-6mm	8-10mm	Similar; minor design differences do not raise new questions of safety or effectiveness
Distal Tip Inner/Outer Diameter	OD: 1.8 Fr (0.6mm) ID: 1.2 Fr (0.4mm)	OD: 1.6 Fr (0.53mm) ID: 1.25 Fr (0.42mm)	Similar; minor design differences do not raise new questions of safety or effectiveness
Hydrophilic Coating Material, Location, Length, and Function	Hydrogel polymer, distal shaft, 40cm in length, lubricious coating	Hydrogel polymer, distal shaft, 60cm in length, lubricious coating	Similar; minor design differences do not raise new questions of safety or effectiveness
Intended Patient Population	Intended for use in adults (greater than 21 years of age)	Intended for use in adults (greater than 21 years of age)	Identical
Compatible Guidewire Diameter	0.014”	≤ 0.014”	Similar; compatible guidewire diameter for the subject device falls within the labeled range for the predicate device
Compatible Guide Catheter Size	≥ 6 Fr (≥ 1.78mm ID)	≥ 5 Fr (≥ 1.42mm ID)	Similar; compatible guide catheter diameter for the subject device falls within the labeled range for the predicate device
Catheter Images			Similar; minor design differences do not raise new questions of safety or effectiveness
Materials of Construction (Patient Contacting)	• Pebax Shaft • Metallic Braid & Coil • Polycarbonate Luer • Loctite Adhesive	• Pebax Shaft • Metallic Braid & Coil • Polycarbonate Luer • Loctite Adhesive	Similar (exact predicate formulations unknown); minor design differences do not raise new questions of safety or effectiveness
Distal Tip Material	Tungsten-loaded 35D Pebax	Tungsten loaded polymer (exact composition and durometer unknown)	Similar (exact predicate formulations unknown); minor design differences do not raise new questions of safety or effectiveness
Shaft Material	Pebax 72D = proximal Pebax 45D = mid shaft Pellethane 80A = distal shaft	Polymer jacket (exact composition and durometer unknown)	Similar (exact predicate formulations unknown); minor design differences do not raise new questions of safety or effectiveness

Description	Subject Device	Predicate Device (K142065)	Conclusion
Braid and Coil Materials	Braid: stainless steel Coil: tungsten	Braid and coil material unknown	Similar (exact predicate materials unknown); minor design differences do not raise new questions of safety or effectiveness
Proximal Hub Material	Polycarbonate	Polymer (exact composition unknown)	Similar (exact predicate materials unknown); minor design differences do not raise new questions of safety or effectiveness
Radiopaque Material	Platinum/Iridium	None	The addition of radiopaque materials meets state of the art and does not raise new questions of safety or effectiveness
Distal Side Ports	3 Fr: 3 side ports 4 Fr: 4 side ports	None	Similar; minor design differences do not raise new questions of safety or effectiveness
Package Contents	• 1 Catheter • 1 Dispenser coil	• 1 Catheter • 1 Dispenser coil	Identical
Additional Accessories Supplied	None	None	Identical
Sterilization Method / SAL	Ethylene Oxide (EO) / 10^{-6}	Ethylene Oxide (EO) / 10^{-6}	Identical
Single-Use Devices?	Yes	Yes	Identical
Shelf-Life	6 months	≥ 12 months	Similar; shelf life for the subject device falls within the labeled range for the predicate device
Over-the-Wire Delivery?	Yes	Yes	Identical

4 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

4.1 Biocompatibility

Biocompatibility testing for the QuikPass Catheter was completed in accordance with ISO 10993-1:2018, *Biological evaluation of medical devices* (FR #2-258). The QuikPass Catheter was tested for cytotoxicity, hemocompatibility, irritation, sensitization, pyrogenicity, and acute systemic toxicity. The QuikPass Catheter biocompatibility testing met all requirements.

4.2 Sterilization, Shelf-Life and Packaging

The QuikPass Catheter is subjected to ethylene oxide (EO) sterilization to meet a sterility assurance level (SAL) of 10^{-6}. Testing was performed to demonstrate that the devices have acceptable levels of EO residuals, bioburden, and endotoxin.

Accelerated aging was performed per ASTM F1980, *Standard Guide for Accelerated Aging of Sterile Barrier Systems of Medical Devices* (FR #14-497) to validate package sterility and device performance after 6-months of accelerated aging shelf life.

Device packaging was validated in accordance with ASTM D4169-16, *Standard Practice for Performance Testing of Shipping Containers and Systems* (FR #14-499) for simulated distribution testing, with ASTM D4332-14, *Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing* (FR #5-99) followed for environmental conditioning. Package integrity was validated per ASTM F1886, *Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection* (FR #14-501), ASTM F2096, *Standard Test Method for Determining Gross Leaks in Packaging by Internal Pressurization* (FR #14-359), and ASTM F88, *Standard Test Method for Seal Strength of Flexible Barrier Materials* (FR #14-482).

4.3 Bench Testing

Performance of the QuikPass Catheter was assessed via design verification testing performed in accordance with ISO 10555-1:2013, *Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements* (FR #6-408). Aged and non-aged samples were tested for a variety of characteristics, including visual defects, appropriate dimensions, compatibility with guidewires and guide catheters, pressurization, vacuum, tracking, kink resistance, coating lubricity, coating durability, torsion, bend, tensile strength, coating integrity, particulate, radiopacity, and corrosion.

5 Conclusions

The QuikPass Catheter is comprised of similar materials and is of similar design to the corresponding components of the predicate device. The subject and predicate devices share similar technical requirements, perform as intended, and present no unacceptable risks to the intended patient population or end user. The non-clinical bench data support the safety of the device and demonstrate that the QuikPass Catheter performs as intended in the specified use conditions. The non-clinical testing demonstrates that the device is as safe, as effective, and performs as well as or better than the predicate device.