February 9, 2022

Vascular Solutions LLC
Rebecca Astrup
Sr. Regulatory Product Specialist
6464 Sycamore Court N
Maple Grove, Minnesota 55369

Re: K212211
Trade/Device Name: Turnpike catheter, Turnpike Spiral catheter, Turnpike LP catheter, Turnpike Gold catheter, GuideLiner V3 catheter, TrapLiner catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 14, 2021
Received: July 15, 2021

Dear Rebecca Astrup:

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)*
K212211

Device Name
Turnpike Catheter; Turnpike LP Catheter; Turnpike Spiral Catheter; Turnpike Gold Catheter; GuideLiner V3 Catheter; TrapLiner Catheter

Indications for Use *(Describe)*
Turnpike catheters: The Turnpike catheters are intended to be used to access discrete regions of the coronary and/or peripheral vasculature. They may be used to facilitate placement and exchange of guidewires and to subselectively infuse/ deliver diagnostic and therapeutic agents, and to assist in crossing de novo coronary chronic total occlusions (CTO).

GuideLiner V3 catheter: GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, to facilitate placement of interventional devices, and to assist in crossing de novo coronary chronic total occlusions (CTO).

TrapLiner catheter: The TrapLiner catheter is intended for use in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, to facilitate placement of interventional devices, to facilitate the exchange of an interventional device while maintaining the position of a guidewire within the vasculature, and to assist in crossing de novo coronary chronic total occlusions (CTO).

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

[As required by 21 CFR 807.92]

Date Prepared: February 9, 2022

510(k) Number: K212211

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions LLC
6464 Sycamore Court North
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Becky Astrup
Sr. Regulatory Product Specialist
Tel: 763-762-2601
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General Information

Trade Name	Turnpike catheter Turnpike Spiral catheter Turnpike LP catheter Turnpike Gold catheter GuideLiner V3 catheter TrapLiner catheter
Common / Usual Name	Catheter
Classification Name	21 CFR 870.1250, DQY, Percutaneous catheter, Class II
Predicate Device	K171933, Asahi Corsair Pro microcatheter (Asahi Intecc Co., LTD)
Reference Devices	K191560, Turnpike catheter (Vascular Solutions LLC) K172090, GuideLiner V3 catheter (Vascular Solutions LLC) K161901, TrapLiner catheter (Vascular Solutions LLC)

Device Description

Turnpike catheters:

The Turnpike catheters are single lumen catheters designed for use in the coronary and peripheral vasculature. The catheter shaft is constructed of two polymer layers that encapsulate a braid and a dual-layer coil. The distal 60 cm of the Turnpike catheters are hydrophilic coated, and all models are compatible with 0.014" guidewires and 5F guide catheters. The turnpike catheters are available in four configurations: Turnpike, Turnpike Spiral, Turnpike Gold, and Turnpike LP.

GuideLiner V3 catheters:

The GuideLiner V3 catheter is a rapid-exchange guide extension catheter designed for use in the coronary and peripheral vasculature. It is available in five sizes – 5F, 5.5F, 6F, 7F, and 8F. All sizes of the GuideLiner V3 catheter have a 150 cm working length, consisting of a 125 cm long stainless steel pushwire shaft followed distally by a 25 cm long full-round, silicone-wiped guide extension segment. The distal 17 cm of the 125 cm pushwire shaft is covered with a semicircular shaped polymer that meets the proximal end of the full-round guide extension segment.

TrapLiner catheters:

The TrapLiner catheter is a rapid-exchange guide extension catheter with a trapping balloon on the distal end of the pushrod. The stainless steel hypotube pushrod is covered on the distal end by a semi-circular polymer ('half-pipe') and transitions to a hydrophilic coated full-round polymer guide extension section. There are two radiopaque marker bands on the guide extension segment, one on the distal tip and one on the collar. The Nylon trapping balloon (3.1 mm diameter) is located proximal to the half-pipe and has a single radiopaque gold marker under the proximal end of the balloon. The balloon is reflowed, and an adhesive is applied on each end. The TrapLiner catheter has an over-molded Nylon hub on the proximal end to facilitate balloon inflation.

Intended Use

All devices are intended to be used to access discrete regions of the coronary and/or peripheral vasculature. The indications for use are as follows.

Turnpike catheters:

The Turnpike catheters are intended to be used to access discrete regions of the coronary and/or peripheral vasculature. They may be used to facilitate placement and exchange of guidewires, to subselectively infuse/deliver diagnostic and therapeutic agents, and to assist in crossing de novo coronary chronic total occlusions (CTO).

GuideLiner V3 catheters:

GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/ or peripheral vasculature, to facilitate placement of interventional devices**,** and to assist in crossing de novo coronary chronic total occlusions (CTO).

TrapLiner catheters:

The TrapLiner catheter is intended for use in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, to facilitate placement of interventional devices, to facilitate the exchange of an interventional device while maintaining the position of a guidewire within the vasculature, and to assist in crossing de novo coronary chronic total occlusions (CTO).

Technological Characteristics Comparison

The Turnpike Catheter, GuideLiner V3 Catheter, TrapLiner Catheter, and Corsair Pro Microcatheter have the same intended use. The Turnpike Catheter, GuideLiner V3 Catheter, TrapLiner Catheter, and Corsair Pro Microcatheter are both manufactured with a polymer layers and include a coil segment with a radiopaque tip and a lumen compatible with 0.014" guidewires.

The tables below compare the technological characteristics of each subject device with the predicate device. The Turnpike, GuideLiner V3, and TrapLiner catheters are substantially equivalent to the predicate device with respect to indications for use and technological characteristics. Furthermore, the Turnpike, GuideLiner V3, and TrapLiner catheters are identical in design and technological characteristics to each reference device.

	Subject Device **Turnpike Catheter**	***Predicate Device*** **Asahi Corsair Pro microcatheter** (K171933)
Product Classification	21 CFR 870.1250 Percutaneous Catheter	
Product Code	DQY	
Intended Use/Indications	The Turnpike catheters are intended to be used to access discrete regions of the coronary and/or peripheral vasculature. They may be used to facilitate placement and exchange of guidewires, to subselectively infuse/deliver diagnostic and therapeutic agents, and to assist in crossing de novo coronary chronic total occlusions (CTO).	This product is intended to provide support to facilitate the placement of guidewires in the coronary and peripheral vasculatures, and can be used to exchange one guidewire for another. This product is also intended to assist in the delivery of contrast media into the coronary, peripheral, and abdominal vasculatures, and to assist in crossing de novo coronary chronic total occlusions (CTO). This device should not be used in the neurovasculature.
Device Description	Single lumen guidewire support catheter with radiopaque tip	
Anatomical Location	Coronary and Peripheral Vasculature	
Guidewire Compatibility	≤ 0.014"	
Guide Catheter Compatibility	≥5F	
Working Length	135 cm, 150 cm	
Coating Length	60 cm	
Proximal Shaft OD	0.038"	0.037"
Distal Shaft OD	0.029" – 0.038"	0.034"

	Subject Device **Turnpike Catheter**	***Predicate Device*** **Asahi Corsair Pro microcatheter** (K171933)
Distal Tip OD	0.021" – 0.028"	0.017"
Materials	Materials compatible with ISO 10993, commonly used for the manufacture of medical devices.	
Sterilization	Ethylene Oxide, SAL 10^{-6}	

	Subject Device **GuideLiner V3 Catheter**	***Predicate Device*** **Asahi Corsair Pro microcatheter** (K171933)
Product Classification	21 CFR 870.1250 Percutaneous Catheter	
Product Code	DQY	
Intended Use/Indications	GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/ or peripheral vasculature, to facilitate placement of interventional devices, and to assist in crossing de novo coronary chronic total occlusions (CTO).	This product is intended to provide support to facilitate the placement of guidewires in the coronary and peripheral vasculatures, and can be used to exchange one guidewire for another. This product is also intended to assist in the delivery of contrast media into the coronary, peripheral, and abdominal vasculatures, and to assist in crossing de novo coronary chronic total occlusions (CTO). This device should not be used in the neurovasculature.
Device Description	Single lumen rapid exchange catheter with radiopaque tip	Single lumen guidewire support catheter with radiopaque tip
Anatomical Location	Coronary and Peripheral Vasculature	
Guidewire Compatibility	≤ 0.014"	
Guide Catheter Compatibility	5 Fr: ID ≥0.056" (1.42 mm) 5.5 Fr: ID ≥0.066" (1.68 mm) 6 Fr: ID ≥0.070" (1.78 mm) 7 Fr: ID ≥0.078" (1.98 mm) 8 Fr: ID ≥0.088" (2.24 mm)	≥5F
Working Length	150 cm	135 cm, 150 cm
Coating Length	25 cm	60 cm
Shaft ID	0.046" – 0.071"	0.018" (0.45 mm)
Shaft OD	0.053" – 0.085"	Proximal: 0.037" Distal: 0.034"
Materials	Materials compatible with ISO 10993, commonly used for the manufacture of medical devices.	
Sterilization	Ethylene Oxide, SAL 10^{-6}	

	Subject Device **TrapLiner Catheter**	***Predicate Device*** **Asahi Corsair Pro microcatheter** (K171933)
Product Classification	21 CFR 870.1250 Percutaneous Catheter	
Product Code	DQY	
Intended Use/Indications	The TrapLiner catheter is intended for use in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, to facilitate placement of interventional devices, to facilitate the exchange of an interventional device while maintaining the position of a guidewire within the vasculature, and to assist in crossing de novo coronary chronic total occlusions (CTO).	This product is intended to provide support to facilitate the placement of guidewires in the coronary and peripheral vasculatures, and can be used to exchange one guidewire for another. This product is also intended to assist in the delivery of contrast media into the coronary, peripheral, and abdominal vasculatures, and to assist in crossing de novo coronary chronic total occlusions (CTO). This device should not be used in the neurovasculature.
Device Description	Rapid-exchange guide extension catheter with trapping balloon	Single lumen guidewire support catheter with radiopaque tip
Anatomical Location	Coronary and Peripheral Vasculature	
Guidewire Compatibility	≤ 0.014"	
Guide Catheter Compatibility	6 Fr: ID ≥0.070" (1.78 mm) 7 Fr: ID ≥0.078" (1.98 mm) 8 Fr: ID ≥0.088" (2.24 mm)	≥5F
Working Length	150 cm	135 cm, 150 cm
Coating Length	11.5 cm	60 cm
Materials	Materials compatible with ISO 10993, commonly used for the manufacture of medical devices.	
Sterilization	Ethylene Oxide, SAL 10^{-6}	

Questions related to clinical performance have been evaluated for the subject devices through design verification and validation testing, including an IDE clinical study.

Performance Data

No physical changes have been made to the subject devices compared to the reference devices; therefore, comparisons of bench, biocompatibility, packaging, and sterilization testing are not necessary. Clinical testing has been performed to evaluate the technological differences when comparing the subject devices to the predicate device for the CTO indication.

Clinical Tests:

A prospective, multi-center, single-arm study of 150 subjects was performed to evaluate the safety and effectiveness of Vascular Solutions' specialized guidewires, microcatheters, and guide extensions in patients undergoing CTO-PCI. The objective of the study was to evaluate angiographic confirmation of placement of any guidewire beyond the CTO, in the true vessel lumen, in patients undergoing CTO PCI in which at least one study guidewire and one Turnpike catheter were used.

Device Use

A total of 566 study-guidewires (55% of the total number of guidewires used; used in all 150 subjects) and 457 non-study guidewires (45% of the total; used on 112 subjects) were used in the CTO-PCI Study. A detailed breakdown of study device wire use is provided in the following table.

Guidewire Device Usage	
Guidewire	**Number (%) of Subjects with Device Used**
Spectre	129 (86.0%)
Raider	102 (68.0%)
Warrior	35 (23.3%)
Bandit	68 (45.3%)
R350	39 (26.0%)

At least one Turnpike catheter and one study guidewire were used in all cases, and a GuideLiner catheter or TrapLiner catheter was used in all cases where a guide extension was required (64% of cases). A breakdown of Turnpike catheter use by model is provided in the following table.

Turnpike Catheter Device Usage	
Catheter	**Number (%) of Subjects with Device Used**
Turnpike	33 (22.0%)
Turnpike Spiral	94 (62.7%)
Turnpike Gold	1 (0.7%)
Turnpike LP	85 (56.7%)

Study device procedural technique is provided in the following table.

Procedural Technique – n (%)	
Wire escalation	86 (57.3%)
Dissection/re-entry	23 (15.3%)
Wire externalization	21 (14.0%)
Safety	15 (10.0%)
Stabilization and/or support	7 (4.7%)
Delivery	5 (3.3%)
Reverse CART	4 (2.7%)
Crossing	2 (1.3%)
Not specified	2 (1.3%)
CTO RCA and RPL	1 (0.7%)
Donor vessel	1 (0.7%)
Knuckled	1 (0.7%)
Workhorse	1 (0.7%)

Primary Endpoint

The primary endpoint for the study was defined as procedure success through discharge or 24 hours post-procedure, whichever came first. Procedure success was defined as angiographic visualization of any guidewire in a position either distal or proximal to the occlusion depending on the route of access, and absence of in-hospital MACE (cardiac death, target lesion revascularization, or post-procedural MI defined as CK-MB ≥ 3x ULN).

Summary of Primary Endpoint Analysis

The study primary endpoint result (75.3%) met the predetermined performance goal.

Category	Study Results % (n/N)
Overall Primary Endpoint Met	75.3% (113/150)
Components of Primary Endpoint	
Angiographic Visualization of any guidewire distal/proximal to CTO in the true vessel lumen	94.7% (142/150)
Absence of in-hospital MACE	80.7% (121/150)

Secondary Endpoint

The secondary endpoints include:

- Frequency of successful recanalization (defined as angiographic confirmation of crossing CTO and restoring blood flow to the affected area).
- Frequency of MACE through discharge or 24 hours post-procedure, whichever comes first (in-hospital follow-up), and at 30 days post-procedure (MACE components are also reported separately).
- Frequency of clinically significant perforation (defined as any perforation resulting in hemodynamic instability and/or requiring intervention including pericardiocentesis, embolization, prolonged balloon occlusion, stent graft, or comparable therapy).
- Procedural success according to crossing technique.
- Technical success.

Summary of Secondary Endpoint Analysis

Parameter	Study Results % (n/N)
Successful recanalization	140 (93.3%)
MACE	29 (19.3%)
In-Hospital	29 (19.3%)
30-Day	0 (0.0%)
Clinically Significant Perforations	16 (10.7%)
Procedure Success by Crossing Technique	
Antegrade	69 (85.2%) (69/81)
Retrograde	1 (50.0%) (1/2)
Combined Antegrade and Retrograde	43 (64.2%) (43/67)
Technical Success	140 (93.3%)

MACE includes all MIs defined as CK-MB ≥ 3x ULN.

In a multicenter, prospective registration trial, procedural success was achieved in a high lesion complexity patient population (e.g. 94.7% severely calcified lesions) using contemporary technique and application of dedicated CTO guidewires, microcatheters and guide catheter extensions. No new safety or effectiveness issues were raised during the study. These results demonstrate that the subject catheters are suitable for their intended use to assist in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO). The clinical data raised no new questions of safety and effectiveness compared to the predicate devices, supporting that the subject catheters with the expanded indication are substantially equivalent to the predicate devices.

Conclusion

The Turnpike Catheter, GuideLiner V3 Catheter, and TrapLiner Catheter are substantially equivalent to the predicate device.