August 18, 2022

Vascular Solutions LLC
Steph Pahl
Regulatory Product Specialist
6464 Sycamore Court N
Maple Grove, Minnesota 55369

Re: K220647
Trade/Device Name: GuideLiner Coast, 5.5F (5270); GuideLiner Coast, 6F (5271); GuideLiner Coast, 7F (5272); GuideLiner Coast, 8F (5273)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 4, 2022
Received: March 7, 2022

Dear Steph Pahl:

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,

for 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)*
K220647

Device Name
GuideLiner Coast, 5.5F (5270);
GuideLiner Coast, 6F (5271);
GuideLiner Coast, 7F (5272); GuideLiner Coast, 8F (5273)

Indications for Use *(Describe)*
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).

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

[As required by 21 CFR 807.92]

Date Prepared: August 18, 2022

510(k) Number: K220647

Submitter's Name / Contact Person

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

Contact Person
Steph Pahl
Sr. Regulatory Product Specialist
Tel: 763-762-2641
Fax: 763-251-0363

General Information

Trade Name	GuideLiner Coast catheter
Common / Usual Name	Catheter
Classification Name	21 CFR 870.1250, DQY, Percutaneous catheter, Class II
Predicate Device	K212211, GuideLiner V3 catheter and TrapLiner catheter (Vascular Solutions)

Device Description

The GuideLiner Coast catheter is a rapid-exchange guide extension catheter designed for use in the coronary and peripheral vasculature. It is available in four sizes – 5.5F, 6F, 7F, and 8F. All sizes of the GuideLiner Coast 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, hydrophilic coated 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.

Intended Use

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

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).

Technological Characteristics Comparison

The key technological differences between the GuideLiner Coast catheter and the predicate device are the introduction of a new hydrophilic coating material, a reduction in coating length, and the colors of the hub resin and hot stamp foil ink.

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate device have been evaluated through performance and biocompatibility tests to provide evidence of substantial equivalence for the GuideLiner Coast catheter.

Bench Tests:

The device performance was verified through the following tests:

- Deliverability
- Hydrophilic Coating Evaluation
- Tensile Strength
- Hub Markings

Device samples passed the following biocompatibility tests performed in accordance with ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis
- Complement Activation

Conclusions

The differences between the GuideLiner Coast catheter and the predicate GuideLiner V3 catheter have been evaluated through bench data. The bench data raised no new questions of safety and effectiveness compared to the predicate device, supporting that the GuideLiner Coast catheter is substantially equivalent to the predicate device.