February 9, 2022

Vascular Solutions LLC
Beka Vite
Regulatory Manager
6464 Sycamore Court N
Maple Grove, Minnesota 55369

Re: K212167
Trade/Device Name: R350 guidewire, Spectre guidewire, Raider guidewire, Bandit guidewire, Warrior guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: July 9, 2021
Received: July 12, 2021

Dear Beka Vite:

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)*
K212167

Device Name
R350 guidewire; Spectre guidewire; Raider guidewire; Bandit guidewire; Warrior guidewire

Indications for Use *(Describe)*
The R350 guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

The Spectre guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

The Raider guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

The Bandit guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

The Warrior guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting 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: K212167

SUBMITTER'S NAME / CONTACT PERSON

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

Contact Person
Beka Vite
Regulatory Manager
Tel: 763-656-4326

General Information	
Trade Name	R350 guidewire Spectre guidewire Raider guidewire Bandit guidewire Warrior guidewire
Common / Usual Name	Catheter guidewire
Classification Name	21 CFR 870.1330, DQX, Catheter guidewire, Class II
Predicate Device	ASAHI Fielder XT guidewire, K171933 (Asahi Intecc Co., Ltd.)
Reference Device	R350 guidewire, K151234 Spectre guidewire, K163444 Raider guidewire, K173532 Warrior guidewire, K180128 Bandit guidewire, K181647

DEVICE DESCRIPTION

R350 Guidewire:
The R350 guidewire is an extended length (350 cm) guidewire with a 0.013" maximum outer diameter (OD) (0.012" nominal OD). It is composed of a nitinol alloy mandrel with a straight, radiopaque 5 cm gold-coated tungsten coil distal tip. The proximal 150 cm of the R350 guidewire has a polytetrafluoroethylene (PTFE) coating, while the distal 200 cm has a hydrophilic coating.

Spectre Guidewire:
The Spectre guidewire is a nitinol and stainless-steel guidewire with a 0.014" diameter and straight shapeable tip. It is available in 200 cm and 300 cm lengths. The distal 25 cm of the guidewire has a spring coil with a 3 cm platinum coil on the distal tip that is visible under fluoroscopic methods. The distal 42 cm of the guidewire has a hydrophilic coating and the proximal portion has a PTFE coating.

Raider Guidewire:
The Raider guidewire is a stainless-steel core guidewire with a maximum outer diameter of 0.014" and a straight, shapeable tip. It is available in 200 cm and 300 cm lengths. The distal portion of the guidewire includes a radiopaque coil and is covered with a polymer jacket and hydrophilic coating. The proximal portion has a PTFE coating. The 200 cm model has a modified proximal end to allow for guidewire extension.

Warrior Guidewire:
The Warrior guidewire is a stainless-steel core guidewire with a 0.014" diameter that tapers to a 0.009" diameter distal tip. It is available in 200 cm and 300 cm lengths. The distal 20 cm of the guidewire has a spring coil, of which the distal 2.5 cm is visible under fluoroscopic methods. The guidewire has a straight shapeable tip with a tip load of 14 grams. The distal portion of the guidewire has a hydrophilic coating and the proximal portion has a PTFE coating. The 200 cm model has a modified proximal end to allow for guidewire extension.

Bandit Guidewire:
The Bandit guidewire is a 0.014" diameter stainless steel core guidewire with a 0.008" diameter tapered distal tip. It is available in 200 cm and 300 cm lengths. The distal portion of the guidewire includes a radiopaque coil and is covered with a polymer jacket and hydrophilic coating. The proximal portion has a PTFE coating. The 200 cm length is compatible with a guidewire extension.

INTENDED USE

The R350 guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

The Spectre guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

The Raider guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

The Bandit guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

The Warrior guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).

Comparison of Technological Characteristics with the Predicate Device and Reference Device

The subject guidewires and predicate device have the same intended use, and each consist of a metallic core with a proximal PTFE and distal lubricious coating. The reference devices have the same operating principles and technological characteristics as the subject devices with the exception of length and PTFE coating supplier. The standard-length version was changed from 190 cm to 200 cm for the Spectre,

Raider, and Warrior guidewires, and the PTFE coating supplier was changed for the Spectre and Warrior guidewires.

A comparison of the subject and predicate device technological characteristics are provided in the following table. Questions related to clinical performance have been evaluated through design verification and validation testing, including an IDE Clinical Study.

Comparison of Technological Characteristics			
Characteristic	**Subject Guidewires**		**Predicate Guidewire (Fielder XT – K171933)**
Indications for Use	Spectre	The Spectre guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).	ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA), including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).
	Raider	The Raider guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).	
	Warrior	The Warrior guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).	
	Bandit	The Bandit guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).	
	R350	The R350 guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature, including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).	

Comparison of Technological Characteristics			
Characteristic	**Subject Guidewires**		**Predicate Guidewire (Fielder XT – K171933)**
Anatomical Location	Spectre	Coronary and Peripheral Vasculature	
	Raider		
	Warrior		
	Bandit		
	R350		
Wire Diameter	Spectre	0.014”	0.014”
	Raider		
	Warrior		
	Bandit		
	R350	0.013”	
Device Length	Spectre	200 cm 300 cm	190 cm 300 cm
	Raider	200 cm 300 cm	
	Warrior	200 cm 300 cm	
	Bandit	200 cm 300 cm	
	R350	350 cm	
Tip Type and Shape	Spectre	Straight, Shapeable	Tapered, Straight
	Raider	Straight, Shapeable	
	Warrior	Tapered, Straight, Shapeable	
	Bandit	Tapered, Straight, Shapeable	
	R350	Straight	
Wire Material (Core)	Spectre	Nitinol, Stainless Steel	Stainless Steel
	Raider	Stainless Steel	
	Warrior	Stainless Steel	
	Bandit	Stainless Steel	
	R350	Nitinol	
Coating Material	Spectre	PTFE Hydrophilic	PTFE Coating Hydrophilic Coating Over Polymer Jacket
	Raider	PTFE Hydrophilic Polymer Jacket	
	Warrior	PTFE Hydrophilic	
	Bandit	PTFE Hydrophilic Polymer Jacket	
	R350	PTFE Hydrophilic	
Tip Material	Spectre	Platinum-Tungsten, Stainless Steel	Platinum-Nickel
	Raider	Platinum-Tungsten, Stainless Steel	
	Warrior	Platinum-Tungsten, Stainless Steel	
	Bandit	Platinum-Tungsten, Stainless Steel	
	R350	Gold-Coated Tungsten	

Comparison of Technological Characteristics		
Characteristic	**Subject Guidewires**	**Predicate Guidewire (Fielder XT – K171933)**
Sterilization Method	Spectre	EO
	Raider	
	Warrior	
	Bandit	
	R350	

PERFORMANCE DATA

With the exception of additional coating integrity tests and a biocompatibility assessment to evaluate the change in the PTFE coating supplier, no new biocompatibility, sterilization, packaging, shelf-life, or bench tests were performed to support the expanded indications. The existing tests performed on the reference devices, along with the clinical data described below, support the subject devices with the expanded indication.

CLINICAL DATA

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 Catheter Device Usage	
Catheter	**Number (%) of Subjects with Device Used**
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 guidewires are suitable for their intended use 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 guidewires with the expanded indication are substantially equivalent to the predicate devices.

CONCLUSION

The Spectre, Raider, Warrior, Bandit, and R350 guidewires are substantially equivalent to the predicate device.