



Food and Drug Administration
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January 22, 2016

Tatara Vascular, LLC
% Jill Munsinger
Regulatory Consultant
JMCS, LLC
11470 Kenyon Ct. NE
Blaine, Minnesota 55449

Re: K152497

Trade/Device Name: PW Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 15, 2015
Received: December 18, 2015

Dear Jill Munsinger:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K152497

Device Name: PW Guidewires

Indications For Use:

The PW Guidewires are intended to facilitate placement of balloon dilatation catheters or other intravascular devices during percutaneous transluminal coronary angioplasty (PCTA) and percutaneous transluminal angioplasty (PTA). The PW Guidewires are not to be used in cerebral blood vessels.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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This 510(k) summary is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K152497

Applicant Information:

Date Prepared: January 20, 2016

510(k) Owner: Tatara Vascular, LLC
Address: 10000 Cedar Ave. GCIC-10
Cleveland, OH 44106

Facsimile Number: (216) 445-6514

Regulatory Correspondent: Jill Munsinger
Phone Number: 651-270-0572
E-mail: jill.munsinger@outlook.com

Device Information:

Classification: Class II Percutaneous Guidewire
Trade Name: PW Guidewires
Common Name: Percutaneous Guidewire
Classification Name: Percutaneous Guidewire

Predicate Devices:

The Tatara Vascular, LLC PW Guidewire is substantially equivalent in intended use, method of operation and technical aspects to the following predicate devices:

K041531 - Asahi Confianza Pro Guidewire
K052339 - Asahi MiracleBros Guidewire

Device Description:

The Tatara Vascular, LLC PW Guidewires are steerable guidewires with a maximum diameter of 0.014" (0.36mm) and nominal length of 180cm. The wires are constructed from a stainless steel solid core wire with two grind profiles that distinguish the gram stiffness of the wire. The core wire transitions to an angled tip of either 0.30mm or 0.75 mm in length. The distal end of the guidewires have a radiopaque coil. A hydrophilic coating is applied to the distal portion of the guidewires. The proximal portion of the guidewires is coated with polytetrafluoroethylene (PTFE).

Intended Use:

The PW Guidewires are intended to facilitate placement of balloon dilatation catheters or other intravascular devices during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The PW Guidewires are not to be used in cerebral blood vessels.

Comparison to Predicate Device(s):

Comparison of the Tatara Vascular, LLC PW Guidewires and predicate devices show that the technological characteristics (indications, components, design, materials, sterilization method, and operating principles) of the PW Guidewires are identical or similar to the currently marketed predicate devices. The following table outlines the comparison of the PW Guidewires to the predicate devices.

Characteristic	PW Guidewires	Asahi Confianza Pro	Asahi MiracleBros
510(k) Number	TBD	K041531	K052339
Indications for Use	...to facilitate placement of balloon dilatation catheters or other intravascular devices during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The PW Guidewires are not to be used in cerebral blood vessels.	Same	Same
Sterilization	Ethylene Oxide to SAL 10^{-6}	Same	Same
Target Body Location	Coronary and peripheral vasculature. Not cerebral vasculature.	Same	Same
Core Wire Material	Stainless steel	Same	Same
Nominal Outer Diameter	0.014" (0.36mm)	Same	Same
Overall length	180 cm	180 cm and 300 cm	180 cm and 300 cm
Proximal Coating	PTFE	Same	Same
Distal Coating	Hydrophilic	Same	Hydrophobic
Tip Load	5g, 12g	9.3g, 12.4g	3.9g, 4.4g, 8.8g, 13g
Tip Radiopacity	2.5cm	20cm	11cm
Tip Outer Diameter	0.26mm	0.23mm	0.36mm

Non-clinical laboratory testing was performed on the Tatara Vascular, LLC PW Guidewires to demonstrate the device would perform as intended. The following tests and assessments were performed:

- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Tip Load
- Coating Adhesion
- Simulated Use
- Resistance to Wire Fracture
- Dimensional Verification
- Catheter Compatibility
- Radiopacity Testing

The *in vitro* bench tests demonstrated that the Tatara Vascular, LLC PW Guidewires met the required acceptance criteria and performed in a similar manner to the predicate devices. Performance data demonstrate that the device will function as intended and has an equivalent performance profile as the predicate devices.

Biocompatibility tests were also conducted to demonstrate the materials of the Tatara Vascular, LLC PW Guidewires were suitable for human use. The materials necessary to construct the PW Guidewires are similar to the predicate devices and were evaluated in accordance with ISO 10993-1. The results of the biocompatibility evaluations demonstrated the materials of the PW Guidewires are suitable for their intended use.

Summary:

Based upon the intended use, descriptive information, and performance evaluation provided in this pre-market notification, the Tatara Vascular, LLC PW Guidewires have been shown to be substantially equivalent to currently marketed predicate devices.