K096062

SEP 27 2010

510(k) Summary

As required by section 807.92

Company Name	Cardiosolutions Inc.
Address	75 Mill St. Stoughton, MA 02072 Phone: 781-344-0801 Fax: 781-344-0803
Contact Person	Michele Lucey
Date	September 23, 2010
Trade Name	Percu-Pro™ GuideWire
Common Name	Cardiovascular Guidewire
Classification Name	Catheter Guidewire
Product Code	DQX
Regulation #	21 CFR 870.1330
Class	2
Panel	Circulatory System Devices Panel
Predicate Devices	TechDevice Guidewire (K053251) TFX Guidewire (K963320)
Device Description	The Percu-Pro™ GuideWire is constructed of a stainless steel core wire The proximal end of the core and is finished with a PTFE jacket. The coil covered distal end of the core is tapered to a ribbon tip to increase flexibility and is finished with a silver brazed ball tip. The guidewire is provided sterile and is a single use device.
Intended Use	The Percu-Pro™ GuideWire is intended to facilitate the placement of devices during diagnostic and interventional vascular procedures in the peripheral vasculature. The guidewire is not intended for use in coronary arteries or for neurovascular use.
Pre-Clinical Safety and Performance Testing	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices, However, pre-clinical safety and performance testing was conducted in accordance with protocols based on the requirements of industry standards and guidance documents. Preclinical testing conducted included biocompatibility and hemocompatibility, tensile strength, torque strength, resistance to fracture, torqueability, and tip flexibility.
Substantial Equivalence	The Percu-Pro™ GuideWire is equivalent to the predicate devices in terms of intended use, design, materials, technology, and performance. There are no differences between devices which would raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 27 2010

Cardiosolutions, Inc.
c/o Ms. Michele Lucey
Vice President, Regulatory Affairs & Quality Assurance
75 Mill Street
Stoughton, MA 02072

Re: K094062
Trade/Device Name: Percu-Pro™ GuideWire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: September 6, 2010
Received: September 8, 2010

Dear Ms. Lucey:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 094062

SEP 27 2010

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Percu-Pro™ Guidewire

Indications for Use:

The Percu-Pro™ Guidewire is intended to facilitate the placement of devices during diagnostic and interventional vascular procedures in the peripheral vasculature. The guidewire is not intended for use in coronary arteries or for neurovascular use.

Prescription Use ___X___ AND/OR Over-The_Counter Use_____

(PLEASE DO NOTR WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K094062