K111395

510 (K) Summary

AUG - 1 2011

PrimeWire PRESTIGE® Plus Pressure Guide Wire

Date Prepared: July 7, 2011

Submitted by: Volcano Corporation
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Device Name: PrimeWire PRESTIGE® Plus Pressure Guide Wire

Classification name:

	Class
➢ 870.1330 Catheter guide wire	II
➢ 870.2870 Catheter tip pressure transducer	II

Predicate Device:

The Volcano PrimeWire PRESTIGE® Plus Pressure Guide Wire is substantially equivalent to the following:

510(k) Number	Product Name	Clearance Date
K100930	PrimeWire PRESTIGE® Pressure Guide Wire	April 30, 2010

Device Description:

The PrimeWire PRESTIGE® Plus pressure guide wire is a steerable guide wire with a pressure transducer mounted 3 cm proximal to the tip. The PrimeWire PRESTIGE® Plus guide wire measures pressure when used with the SmartMap®, s5™ Family, and ComboMap® systems. The PrimeWire PRESTIGE® Plus guide wire has a diameter of 0.014" (0.36 mm) and is available in lengths of 185 cm or 300 cm, and also in straight or pre-shaped tips. The PrimeWire PRESTIGE® Plus guide wire is packaged preconnected to the connector with a torque device to facilitate navigation through the vasculature.

Intended Use:

The PrimeWire PRESTIGE® Plus Pressure Guide Wire Device is indicated for use to measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.

Device Technological Characteristics and Comparison to Predicate Device:

The Volcano Corporation PrimeWire PRESTIGE® Plus Pressure Guide Wire Device is substantially equivalent to the predicate device, PrimeWire PRESTIGE® Pressure Guide Wire.

The PrimeWire PRESTIGE® Plus Pressure Guide Wire Device uses the same fundamental scientific technology and has the same intended use as that of the predicate device.

Performance Data:

Applicable testing was performed in accordance with the Design Verification Plan including a Risk Analysis addressing the impact of enhancements to the device and components. The test results indicate the PrimeWire PRESTIGE® Plus Pressure Guide Wire is comparable to the predicate device.

Summary of Performance Characteristics

Design Input Description	Design Change	Required Testing, Leveraged or *Justification*
Working Length - product shall come in 185cm and 300 cm lengths	No change from predicate device.	Testing
Flexible Distal Length - length of flexible section shall be ~ 30 cm in length	No change from predicate device.	Testing
Distal Radiopaque Length - length of distal tip shall be 3.0 cm	No change from predicate device.	Testing

Design Input Description	Design Change	Required Testing, Leveraged or *Justification*
Maximum outer diameter of .0145"	No change from predicate device.	*Justification – 100% verified in manufacturing*
The distal 1.0 cm of the wire shall be equivalent stiffness to the predicate device tip.	No change from predicate device.	Testing
Better torqueability than predicate device in distal or tortuous anatomy.	Replaced silicon-based coating with hydrophilic coating	Testing
Maintain lubricity within the body throughout procedure (approx. 60 minutes).	Replaced silicon-based coating with hydrophilic coating	Testing
Particulate generation in simulated use shall meet USP 788: Maximum of 3000 particles ≥ 10 microns; maximum of 300 particles ≥ 25 microns.	Replaced silicon-based coating with hydrophilic coating	Testing
Sensor Housing to Core Tensile shall be ≥ 1.0 pounds.	No change from predicate device.	Testing
Tip Tensile ≥ 1.0 pounds.	No change from predicate device.	Testing
Turns to Failure ≥ 10 turns	No change from predicate device.	Testing
Wire connector must withstand 10 insertions in connector.	No change from predicate device.	Testing
Sensor shall have same accuracy as predicate device	No change from predicate device.	*Leveraged from previously cleared predicate device and 100% verified in manufacturing*
Sensor drift shall not exceed 5 mmHG in 10 minutes		
Subjecting PLUS to clinically relevant tortuosity shall not cause erratic output		
3 year shelf life	Replaced silicon-based coating with hydrophilic coating	Testing
Biocompatibility	Replaced silicon-based coating with hydrophilic coating	Testing
Packaging	No change from predicate device.	*Leveraged from previously cleared predicate device*
Sterilization	No change from predicate device.	*Leveraged from previously cleared predicate device*

Biocompatibility Studies:

The biocompatibility of the PrimeWire PRESTIGE® Plus was verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices and FDA Memorandum # G95-1. Test results confirmed biocompatibility of the pressure wire was tested as an external communicating, circulating blood contact, limited exposure (<24 hrs) device.

The following table summarizes biocompatibility test results on the following PrimeWire PRESTIGE® Plus materials:

Test Description	Results
Cytotoxicity Study using the Colony Assay Extraction Method	Pass
ISO Intracutaneous Study (Irritation Test), Extract 0.9% NaCl	Pass
ISO Intracutaneous Study (Irritation Test), Extract Sesame Oil	Pass
ISO Systemic Toxicity Study, Sesame Oil	Pass
ISO Systemic Toxicity Study, 0.9% NaCl	Pass
ISO Maximum Sensitization Study, Extract Sesame Oil	Pass
ISO Maximum Sensitization Study, Extract 0.9% NaCl	Pass
Pyrogen Study, Material Mediated, 0.9% NaCl	Pass
ASTM Partial Thromboplastin Time – Plasma Extract	Pass
ASTM Hemolysis CMF PBS Extract	Pass
C3a Complement Activation (Hemocompatibility), Normal Human Serum Extract	Pass
SC5b-9 Complement Activation (Hemocompatibility), Human Serum Extract	Pass
In Vivo Thromboresistance Study, Peripheral Vessel / Jugular Vein (vessel to be determined based on device evaluation) (Note: the control device will be identified in the NAMSA protocol before test execution)	Pass
Preliminary Extraction, Japanese MHLW	Pass
Exaggerated Extraction Method 1 or 2, Japanese MHLW (test type depends on preliminary extraction results)	Pass
Maximum Sensitization Study, Method 1 or 2, MHLW (test type depends on preliminary extraction results)	Pass

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Conclusion:

The Volcano PrimeWire PRESTIGE® Plus Pressure Guide Wire Device has the same performance specifications, fundamental scientific technology and intended use as that of the predicate device, PrimeWire PRESTIGE® Pressure Guide Wire. The design enhancements to the device do not raise any new questions regarding safety or efficacy. The performance data and a declaration of conformity with design controls support a determination of continuing substantial equivalence of the modified device to the predicate device.

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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

Volcano Corporation
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Senior Director, Regulatory Affairs
3661 Valley Centre Drive Suite 200
San Diego, CA 92130

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Re: K111395
Trade/Device Name: PrimeWire PRESTIGE® Plus Pressure Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II
Product Code: DQX
Dated: July 12, 2011
Received: July 13, 2011

Dear Ms. Pourazar:

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 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

510(k) Number (if known): K111395

Device Name: PrimeWire PRESTIGE® Plus Pressure Guide Wire Device

Indications for Use:

The PrimeWire PRESTIGE® Plus Pressure Guide Wire Device is indicated for use to measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.

Prescription Use ____x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111395