K100930



## 510 (K) Summary

## PrimeWire PRESTIGE™ Pressure Guide Wire

**Date Prepared:** April 2, 2010

**Submitted by:** Volcano Corporation
3661 Valley Centre Dr.
Suite 200
San Diego, CA 92130

APR 30 2010

**Contact person:** Marilyn Pourazar
Director of Regulatory Affairs

**Phone number:** (858) 720-4116

**Facsimile number:** (858) 720-0335

**Device Name:** PrimeWire PRESTIGE™ 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™ Pressure Guide Wire is substantially equivalent to the following:

| 510(k) Number | Product Name | Clearance Date |
|---|---|---|
| K021209 | SmartWire/SmartMap Pressure System | May 17, 2002 |
| K070487 | SmartWire II Pressure Guide Wire | March 16, 2007 |
| Letter to File | PrimeWire Pressure Guide Wire | June 26, 2008 |
| Letter to File | PrimeWire Pressure Guide Wire | April 6, 2009 |

**Device Description:**

The PrimeWire PRESTIGE™ Pressure Guide Wire is a steerable guide wire with a pressure transducer mounted 3 cm proximal to the tip. The PrimeWire PRESTIGE™ guide wire measures pressure when used with the SmartMap, s5 Family, and ComboMap

systems. The PrimeWire PRESTIGE™ guide wire has a diameter of 0.014" (0.36 mm) and is available in lengths of 185 cm and 300 cm, with straight or pre-shaped tips. The PrimeWire PRESTIGE™ guide wire is packaged preconnected to the connector with a torque device to facilitate navigation through the vasculature.

**Intended Use:**

The PrimeWire PRESTIGE™ 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™ Pressure Guide Wire Device is substantially equivalent to the predicate devices, Volcano SmartWire II/PrimeWire Pressure Guide Wires.

The modified PrimeWire PRESTIGE™ 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 modifications to the device and components. The test results indicate the revised product is comparable to the predicate device.

**Conclusion:**

The Volcano PrimeWire PRESTIGE™ Pressure Guide Wire Device has the same performance specifications, fundamental scientific technology and intended use as that of the predicate devices, Volcano SmartWire II/PrimeWire Pressure Guide Wires.

Modifications 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Volcano Corporation
c/o Ms. Marilyn Pourazar
Director of Regulatory Affairs
3661 Valley Centre Dr., Suite 200
San Diego, CA 92130

APR 30 2010

Re: K100930
Device Name: PrimeWire PRESTIGE™ Pressure Guide Wire, Models 8185, 8185J, 8300, 8300J
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (Two)
Product Code: DQX
Dated: April 2, 2010
Received: April 5, 2010

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

K100930



**510(k) Number (if known):** _____

**Device Name:** PrimeWire PRESTIGE™ Pressure Guide Wire Device

**Indications for Use:**

The PrimeWire PRESTIGE™ 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.

The intended use and indications for use of the modified device as described in its labeling have not changed. The fundamental scientific technology of the modified device has not changed.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____X_____ OR Over-the-Counter Use _____

(Per 21 CFR 801.19)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100930