K082935

VisionWire Coronary Guidewire 510(k) Premarket Notification

DEC 0 4 2008

1. GUIDEWIRE 510(K) SUMMARY

Name and Address of Applicant:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Device Name:

Proprietary Name:	VisionWire Coronary Guidewire
Classification:	Class II (21 CFR 870.1330)
Classification Name:	Wire, Guide, Catheter
Product Code:	DQX

Date Prepared: September 30, 2008

General Description:

The VisionWire coronary guidewire is a transvenous wire with sensing and stimulation capabilities. The VisionWire is intended to be used to facilitate the positioning of left ventricular (LV) pacing leads, with compatible guidewire lumen, within the coronary venous system during the implantation of an implantable pulse generator (IPG) or Implantable Cardioverter Defibrillator (ICD) for Cardiac Resynchronization Therapy (CRT). The VisionWire is used as a guide to position the over-the-wire (OTW) lead, especially in angled or tortuous veins. Prior to lead positioning, the VisionWire can be used to perform comparative intraoperative measurements of various pacing sites within the coronary venous system. Thus the physician can identify an appropriate pacing site for a LV lead.

The VisionWire coronary guidewire is a disposable medical device designed for single use only.

Predicate Device:

BIOTRONIK proposes the following guidewires and catheter, cleared through 510(k) notification, as the predicate devices for the VisionWire coronary guidewire:

- Guidant's HI-TORQUE WHISPER – Guidewires (Models 6726, 6737, 6738, 4482, 4483, 4581, 4586, 4583, and 4588), #K030019, cleared on 01-24-2003 and HI-TORQUE WHISPER VIEW Guidewire (Model #4631-4639), #K061453, cleared on 06-22-2006
- Medtronic Performr Electrode Catheter, #K964272, cleared on 01-23-1997

Indications for Use:

The VisionWire coronary guidewire is intended for the following applications:

- Its positioning in the coronary vascular system (probing coronary vessel anatomy)
- Connection to an external pacing system analyzer in order to perform the following intraoperative tests in several places e.g. of the coronary sinus:
  - Measuring the left ventricular threshold
  - Measuring the intracardiac signals
  - Temporary pacing of the left ventricle
- As a guidewire for positioning compatible over-the-wire (OTW) pacing leads in the coronary sinus

Name and Address of Manufacturing Site:

Brivant Ltd.
Parkmore West Business Park
Galway, Ireland

Manufacturer's Establishment Registration Number / Owner's Number:

3006010712 / 9083703

Manufacturing Site Contact Person and Phone Number:

Conan Campbell
Quality Engineer
Brivant Ltd.
Parkmore West Business Park
Galway, Ireland
(353) 91 358 376

510(k) Contact Person and Phone Number:

Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
(888) 345-0374

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 4 2008

Biotronik, Inc.
c/o Mr. Jon Brumbaugh
6024 Jean Road
Lake Oswego, Oregon 97035

Re: K082935
Trade/Device Name: VisionWire Coronary Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 30, 2008
Received: October 1, 2008

Dear Mr. Brumbaugh:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochney

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 (if known): K082935

Device Name: VisionWire Coronary Guidewire

Indications for Use:

The VisionWire coronary guide wire is intended for the following applications:

- Its positioning in the coronary vascular system (probing coronary vessel anatomy)
- Connection to an external pacing system analyzer in order to perform the following intraoperative tests in several places e.g. of the coronary sinus:
  - Measuring the left ventricular threshold
  - Measuring the intracardiac signals
  - Temporary pacing of the left ventricle
- As a guide wire for positioning compatible over-the-wire (OTW) pacing leads in the coronary sinus

Prescription Use ✓ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Vo Mason

(Division Sign-Off)
Division of Cardiovascular Devices

510(K) Number K082935