

## 11. 510(k) Summary

### 11.1 Submitter Information

BIOTRONIK, Inc.  
 6024 Jean Road  
 Lake Oswego, OR 97035-5369  
 (800) 547-0394  
 Contact: David Makanani, Vice President, Clinical and Regulatory Affairs  
 Notification Prepared June 26, 1998

### 11.2 Device Name

Trade Name:	Galeo HS 014
	Galeo S 014
	Galeo M 014
	Galeo F 014
	Galeo HF 014
	Galeo S/J 014
	Galeo M/J 014
	Galeo F/J 014
	Galeo ES 014
	Galeo EW 014
Common Name:	guide wire
Classification Name:	catheter guide wire

### 11.3 Predicate Devices

The Galeo guide wire is substantially equivalent in material, design, function, and intended use to the following devices:

Guidant ACS Hi-Torque guide wire  
 Medtronic Mustang guide wire

### 11.4 Device Description

BIOTRONIK Galeo Guide Wires are coronary vascular guide wires with a nominal diameter of 0.014"/0.36 mm and a nominal length of 175 cm. The BIOTRONIK Galeo Guide Wire Family consists of nine coronary guide wires of various flexibilities and one extension wire. Galeo has a straight configuration with five levels of stiffness: Highly Stiff (HS), Stiff (S), Medium (M), Flexible (F), and Highly Flexible (HF). There are also three stiffness variations available with a pre-formed J-tip: Floppy (F), Medium (M), and Stiff (S). Galeo ES (Extra Support) offers enhanced support during intracoronary vascular procedures.

All Galeo Guide Wires (175 cm) are extendable to over-the-wire exchange length using the Galeo Extension Wire (EW).

The distal coil areas of the BIOTRONIK Galeo guide wires are treated with a silicone-based coating that makes the distal section of the guide wire more lubricious than the bare metal surface. The proximal wire section is coated with PTFE.

The distal 3.0 cm of the Galeo Guide Wire responds easily to manual forming or shaping. The Galeo Guide Wire offers different grades of radioopacity over its distal stainless steel and platinum coil section. The 27 cm stainless steel coil section (27 cm in length) is radiolucent; the platinum coil section (3.0 cm) is highly radioopaque.

The proximal end of the guide wire is slightly tapered and allows the attachment of the extension wire Galeo EW. The combination of Galeo and Galeo EW results in an overall wire length of 325 cm.

### 11.5 Intended Use

Galeo guidewires are intended for use in vascular interventional procedures to facilitate the placement of catheters within the coronary arteries.

### 11.6 Comparison to Predicate Devices

The Galeo guide wires are functionally equivalent to market-released guide wires. In specific, the materials used and design are similar to the Guidant ACS Hi-Torque (K973494, Dec. 12, 1997) series with the exception of the coating of the distal coil region. This coating is similar between the Galeo series and the Medtronic Mustang guide wire (K961917, Nov. 20, 1996).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 8 1999

Mr. David M. Makanani  
Biotronik, Inc.  
6024 Jean Road  
Lake Oswego, OR 97035-5369

Re: K982272  
Biotronik Galeo Guide Wire  
Regulatory Class: II (two)  
Product Code: 74 DQX  
Dated: November 20, 1998  
Received: November 23, 1998

Dear Mr. Makanani:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

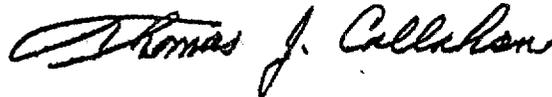
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K982272

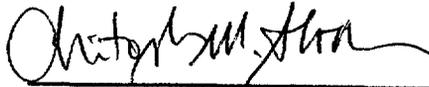
Device Name: BIOTRONIK GALEO GUIDE WIRES

**Indications For Use:**

Galeo Guidewires are intended for use in vascular interventional procedures to facilitate the placement of catheters within the coronary arteries.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K982272

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use