

*510(k) Summary*

1. **Device Name:** ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire
2. **Devices to Which Equivalence is Claimed:** MicroVena Niner Nitinol Guide Wire (K952860, cleared December 3, 1995) with regard to intended use and all other aspects of the proposed BMW Guide Wire are identical to the currently marketed BMW Guide Wire (K971815, cleared July 9, 1997).
3. **Intended Use:** The BMW Guide Wire is intended for general intravascular use to aid in the selective placement of interventional devices, such as catheters, in the coronary, peripheral and visceral vasculature during diagnostic and/or therapeutic procedures.
4. **Device Description:** The BMW Guide Wire is a steerable guide wire available in a nominal diameter of 0.14" in two lengths: a 190 centimeter extendible length (extendible to 335cm using the DOC® Guide Wire Extension) and a 300-centimeter exchange length.
5. **Summary of Technological Characteristics:** This notification concerns a labeling modification to modify the indications for a currently marketed device. There are no changes to the design, materials, manufacturing process, packaging process, sterilization process, or shelf life of the subject device.
6. **Summary of Substantial Equivalence:** This notification concerns a labeling modification to modify the indications for the currently marketed device. The indications are equivalent to the currently marketed MicroVena Niner Nitinol Guide Wire (K952860, cleared December 3, 1995) and all other aspects of the proposed BMW Guide Wire are identical to the currently marketed BMW Guide Wire (K971815, cleared July 9, 1997).
7. **Testing Data:**

*In Vivo Testing*

An animal study was conducted to evaluate the performance of the ACS Hi-Torque Floppy II® (K887897) and the BMW (K971815) Guide Wire when the devices were used within the coronary vein. The results of the *in vivo* animal evaluation show that the BMW Guide Wire is acceptable within the coronary vein when used with a compatible lead system. See *Appendix B* for the *in vivo* study.

8. **Conclusion:** This BMW Guide Wire with the modified indication is substantially equivalent to the currently marketed MicroVena Niner Nitinol Guide Wire (**K952860**, cleared December 3, 1995) with regard to intended use and all other aspects of the proposed BMW Guide Wire are identical to the currently marketed BMW Guide Wire (**K971815**, cleared July 9, 1997).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 10 1998

Ms. Jennifer Pae Riggs  
Sr. Regulatory Affairs Coordinator  
Guidant Corporation  
Advanced Cardiovascular Systems  
26531 Ynez Road  
P.O. Box 9018  
Temecula, CA 92591

Re: K983033

Trade Name: ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire  
Regulatory Class: II  
Product Code: DQX  
Dated: August 28, 1998  
Received: August 31, 1998

Dear Ms. Riggs:

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.

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) 594-4586. 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" (21CFR 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

**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K983033

Device Name: ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire

**Indications for Use:**

Current:

All ACS HI-TORQUE® Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

Proposed:

The HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire is intended for general intravascular use to aid in the selective placement of interventional devices, such as catheters, in the coronary and peripheral vasculature during diagnostic and/or therapeutic procedures.

*Ta h u f a*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number \_\_\_\_\_

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter \_\_\_\_\_  
(Optional Format 1-1-96)