



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 16 2000

Mr. R. Edward Winters  
Advanced Biomedical Devices, Inc.  
3 Dundee Park  
P.O. Box 2087  
Andover, MA 01810

Re: K981936  
ABD-VariSoft Guide Wire and Extension  
Regulatory Class: II (two)  
Product Code: DQX  
Dated: November 13, 1999  
Received: November 18, 1999

Dear Mr. Winters:

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.  
Acting Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN) : K981936

DEVICE NAME: ABD VARISOFT STEERABLE GUIDE WIRE  
AND ABD VARISOFT GUIDE WIRE EXTENSION

INDICATIONS FOR USE:

**INTENDED USE.** The VariSoft Guide Wire is intended to facilitate the placement of balloon dilatation catheters during PTCA and/or PTA. The VariSoft Guide Wire is not intended for use in the cerebral vasculature.

**INTENDED USE.** The ABD VariSoft Guide Wire Extension is intended to provide the necessary length to allow the exchange of one dilatation catheter for another while maintaining the position of the ABD VariSoft Steerable Guide Wire in the coronary artery. After the dilatation catheter exchange has been completed, the ABD VariSoft Guide Wire Extension can be detached and the ABD VariSoft Steerable Guide Wire can be used as a conventional steerable guide wire.

(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  
(per 21 CFR 80-1.109)

OR Over-The-Counter-Use

(optional format 1-2-96)

Christopher Witten  
(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K981936