K030201

MAR 2 6 2003

Section 6
Summary of Safety and Effectiveness

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Pursuant to Section 12, Safe Medical Devices Act of 1990)

1. Identifying Information:

   1.1. Submitters Name: Medtronic AVE, Inc.
   37A Cherry Hill Drive
   Danvers, MA 01923

   1.2. Contact Person: Fred L. Boucher R.A.C., (978) 777-0042

2. Classification Name: Device, Coronary Saphenous Vein Graft, Temporary, for Embolization Protection
   (21 CFR Part 870.1250)

3. Proprietary Name: Export Catheter

4. Name of Predicate Devices:

   4.1. Export Catheter, K023303

   4.2. GuardWire Temporary Occlusion and Aspiration System, K014223 and K013913

   4.3. Medtronic Genius Guide Catheter, K010579

5. Description:

   The Export Catheter is a single lumen catheter that has guidewire access holes on the distal end of the catheter that mimic a single operator guidewire rail. This design, called the "Dual-Trak single lumen" is best described as a single lumen catheter that has wire entry and exit holes on the distal segment of the catheter. This allows a single lumen catheter to be advanced over a wire without the need for a separate wire lumen. The result is a single lumen catheter that has a smaller outer diameter compared to a dual lumen catheter yet can be advanced over a wire like a dual lumen catheter. To accomplish this feature the distal segment of the catheter is distorted so that the catheter in this portion is no longer round.

The access holes are carefully formed in the tip section. This allows the GuardWire to be placed in the distal tip and exit the catheter a short distance down the shaft, thus forming a small rail for the catheter to track over. An aspiration syringe is provided, as is an aspiration line. These are attached to the proximal end of the Export to facilitate blood and debris being evacuated from the site into the syringe.

6. Intended-Use:

The indication for use for the stand-alone Export Catheter is:

The Export Aspiration Catheter is indicated for use with the GuardWire Temporary Occlusion and Aspiration System in coronary saphenous vein bypass grafts to:

- Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures.
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

The current submission identifies, as did the predicate K023303 that the device will be offered in two different configurations, as a stand-alone device and as a component of the GuardWire Temporary Occlusion and Aspiration System.

When the Export Catheter is packaged with a GuardWire Temporary Occlusion and Aspiration System, the device will be marketed under the indications for use of that system.

When the Export Catheter is included in the GuardWire 2.5-5 Temporary Occlusion and Aspiration System this system will be labeled as shown below:

The PercuSurge GuardWire Temporary Occlusion & Aspiration System is indicated for use in the coronary saphenous vein bypass grafts (2.5-5.0mm) to:

- Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures.
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.

- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.
- The safety and effectiveness of the device as an embolic protection system has not been established in treating patients with acute myocardial infarction.
- The safety and effectiveness of the device as an embolic protection system has not been established in treating native coronaries.

When the Export Catheter is included in the GuardWire 3-6 Temporary Occlusion and Aspiration System the indications for that system will be labeled as shown below:

The PercuSurge GuardWire Temporary Occlusion & Aspiration System is indicated for use in the coronary saphenous vein bypass grafts to:

- Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures.
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

7. Technology:

The Export Catheters is manufactured in a similar manner, using similar processes and materials, as the legally marketed predicate devices identified in this submission. In addition to being technologically equivalent to the predicate devices, the intended use of the device has not changed.

The proposed Export Catheter has been subjected to in vitro bench testing and it has been determined that it is substantially equivalent to the current Export Catheter available in the GuardWire Temporary Occlusion and Aspiration System or as an accessory to the previously mentioned System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2003

Mr. Fred L. Boucher, R.A.C.
Sr. Regulatory Affairs Manager
Medtronic AVE, Inc.
37A Cherry Hill Drive
Danvers, MA 01923

Re: K030201
Trade/Device Name: Export Aspiration Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: NFA
Dated: February 21, 2003
Received: February 24, 2003

Dear Mr. Boucher:

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 Office of Compliance at (301) 594-4646. 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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K030201

Device Name: Export Aspiration Catheter

Indications for Use:

The indication for use for the stand-alone Export Catheter is:

The Export Aspiration Catheter is indicated for use with the GuardWire Temporary Occlusion and Aspiration System in coronary saphenous vein bypass grafts to:

- Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures.
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030201

510(k) Number: K030201

Device Name: Export Aspiration Catheter

Indications for Use (continued):

When the proposed modified device is included in the GuardWire 2.5-5 Temporary Occlusion and Aspiration System cleared under K013913 the indications for that system will not change. This system will be labeled as shown below:

The PercuSurge GuardWire Temporary Occlusion & Aspiration System is indicated for use in the coronary saphenous vein bypass grafts (2.5-5.0mm) to:

- Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures.
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.
- The safety and effectiveness of the device as an embolic protection system has not been established in treating patients with acute myocardial infarction.
- The safety and effectiveness of the device as an embolic protection system has not been established in treating native coronaries.

When the proposed device is included in the GuardWire 3-6 Temporary Occlusion and Aspiration System (cleared under K003992 and K014223) the indications for that system will not change. This system will be labeled as shown below:

The PercuSurge GuardWire Temporary Occlusion & Aspiration System is indicated for use in the coronary saphenous vein bypass grafts to:

- Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures.
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.