



MAR 11 1999

K983927

VI. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter Information:

Name: Arterial Vascular Engineering Massachusetts, Inc.
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Date of Preparation: December 1, 1998

B. Device Name

Trade Name: GT1 Floppy guide wire
 GT1 Hi-Per Flex guide wire
 GT1 Light Support guide wire
Common Name: Guide Wire
Classification Name: Guide Wire for PTCA Catheter

C. Predicate Device Name(s): Commander Series Guide Wires
 Commander Floppy
 Commander Hi-Per Flex
 Commander Light Support

AVE Massachusetts, Inc.

Concord Road

Billerica, MA 01821-9666

Tel: 978 667-2511

www.avei.com

Amendment to K983927 - 510(k) Premarket Notification for the AVE GT1 Guide Wires

December 1, 1998

D. Device Description & Intended Use:

The GT1 Floppy, GT1 Hi-Per Flex, and GT1 Light Support Guide Wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. The GT1 Floppy, GT1 Hi-Per Flex, and GT1 Light Support Guide Wires are not intended for use in the cerebral vasculature.

E. Technological Characteristics Summary

The GT1 guide wires, covered under this 510(k), are very similar to their Commander Series guide wire counterparts regarding materials and construction. They utilize the same packaging materials and method of sterilization as the Commander Series guide wires.

The indications for use are the same for both the GT1 and Commander Series guide wires: GT1 Floppy, GT1 Hi-Per Flex, and GT1 Light Support Guide Wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. The GT1 Floppy, GT1 Hi-Per Flex, and GT1 Light Support Guide Wires are not intended for use in the cerebral vasculature.

The new devices (GT1 guide wires) are compared to marketed devices (Commander Series guide wires).

1. Does the New Device Have the Same Indication Statements?

Yes. The proposed GT1 Floppy, GT1 Hi-Per Flex, and GT1 Light Support Guide Wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. The GT1 Floppy, GT1 Hi-Per Flex, and GT1 Light Support Guide Wires are not intended for use in the cerebral vasculature. This indication statement is the same as the indication statement for the Commander Series guide wires.

The new devices have the same Intended Use and May be “Substantially Equivalent”.

2. Does the New Device Have the Same Technological Characteristics, e.g., Design, Materials, Etc.?

No. Although the overall design of the GT1 guide wires is similar with respect to the components and dimensional properties, there have been modifications to some of the materials of construction. The new materials have been qualified through biocompatibility testing and bench testing.

3. Could the New Characteristics Affect Safety or Effectiveness?

Yes. The effect on safety and effectiveness is due to the material differences. The differences in materials are unlikely to affect safety as biocompatibility was verified through testing (see summary in Section III and results in Appendix 1). The effectiveness of the guide wire, however, can be affected by changes to materials since these material differences could affect the guide wires mechanical properties. Bench testing was conducted on the GT1 Floppy and GT1 Hi-Per Flex guide wires and compared to the predicate devices. This bench testing supports the effectiveness of the GT1 guide wires. The proposed GT1 guide wires have the same performance requirements as their Commander Series guide wire counterparts (see below and Appendix 2).

4. Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?

No. The minor material differences do not raise new types of safety or effectiveness questions as the same biocompatibility and mechanical properties questions need to be addressed as for the predicate devices.

5. Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics?

Yes. The necessary biocompatibility and mechanical properties tests have been used based on the required properties of guide wires as discussed in the Principles of Operation in Section III E are well-established.

6. Are Performance Data Available to Assess Effects of New Characteristics?

Yes. The GT1 Floppy and GT1 Hi-Per Flex guide wires were tested for safety and performance based on the required properties of guide wires as discussed in Section III E, Principles of Operation. Biocompatibility testing was conducted on guide wires that contain the same materials of construction as the GT1 guide wires. All GT1 guide wires have the same materials of construction. The performance requirements for the GT1 Floppy, GT1 Hi-Per Flex, and GT1 Light Support guide wires are identical to their Commander Floppy, Commander Hi-Per Flex, and Commander SR-1 Light Support counterparts. Testing was conducted on the GT1 Floppy and GT1 Hi-Per Flex guide wires as representative samples to support this 510(k). A summary of this testing is provided in Part C below. Results for the performance testing may be found in Appendix 2; results for the biocompatibility tests are summarized in Section III and the NAmSA reports are presented in Appendix 1.

7. Do Performance Data Demonstrate Equivalence?

Yes. The performance of the GT1 Floppy and GT1 Hi-Per Flex guide wires was statistically equivalent to, better than, or between the performances of the currently sold Commander Series guide wire counterparts or was found to meet specification (i.e. the performance was clinically acceptable) in every case. In terms of biocompatibility, the GT1 guide wires were shown to be biocompatible.

A summary of all testing may be found below. More in depth protocols and results may be found in Appendix 2 (bench testing) and in Appendix 1 (biocompatibility testing).



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fred L. Boucher, R.A.C.
QA/RA Manager
AVE Massachusetts, Inc.
129 Concord Road
Billerica, MA 01821-0566

Re: K983927
Trade Name: GT1 Guide Wires
Regulatory Class: II
Product Code: DQT
Dated: March 3, 1999
Received: March 4, 1999

Dear Mr. Boucher:

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 (Pre-market 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 pre-market 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

Device Name: GT1 Guide Wires

Indications for Use:

AVE guide wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. AVE guide wires are not intended for use in the cerebral vasculature. AVE steerable exchange wires are used to facilitate the substitution of one diagnostic or interventional device for another.

Contraindications:

No known contraindications.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-the-Counter Use
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983927