

JUL 30 1999

K984482



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: AVE Massachusetts, Inc.
Address: 129 Concord Road, Billerica, MA 01821
Phone: (978) 739-3116
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Contact Person: Fred L. Boucher
Regulatory Affairs Manager
Date of Preparation: July 15, 1999

B. Device Name

Trade Name: AVEM GL-1 Guiding Catheter
Common Name: Guiding Catheter
Classification Name: Diagnostic Intravascular Catheter/Percutaneous Catheter

C. Predicate Device Name(s):

1. AVEM Mainstay™ Guiding Catheter
2. ACS Guidant Viking™ Guiding Catheter
3. Cordis Brite™ Tip Guiding Catheter
4. Schneider Guider™ Guiding Catheter

D. Device Description

The GL-1 catheter is a guiding catheter for use in the vascular system.

E. Intended Use

Guide catheters provide a pathway through which dilatation systems and other interventional devices are introduced.

AVE Massachusetts, Inc.

129 Concord Road

Billerica, MA 01821-0566

Phone: 978 667-2511

www.avei.com

F. Technological Characteristics Summary

The AVEM GL-1 Guiding Catheter is similar to the AVEM Mainstay guiding catheter regarding materials, construction, packaging and sterilization.

The indications for use are also similar to the AVEM Mainstay catheter and both the ACS Guidant Viking and the Cordis Brite Tip Guiding catheters.

The proposed GL-1 indications for use are:

AVE guiding catheters are designed for use in the vascular system. Their primary function is to provide a pathway through which dilatation systems and other interventional devices are introduced. AVE guiding catheters also allow pressure monitoring and injection of contrast agents.

Similar to the Mainstay Guiding catheters, the GL-1 Guiding catheter will be available in 6 French - 8 French, and will be offered in various curve styles.

G. Performance Data

AVEM conducted tensile, stiffness, burst, torque, and natural frequency testing. The test results demonstrate that the GL-1 Guiding Catheter is substantially equivalent to the AVEM Mainstay™ Guiding Catheter, the ACS Guidant Viking™ Guiding Catheter, the Cordis Brite™ Tip Guiding Catheter and/or the Schneider Guider™ Guiding Catheter.

AVEM also conducted the following biocompatibility tests in compliance with ISO 10993: acute intracutaneous reactivity, acute systemic toxicity, cytotoxicity, hemolysis, material-mediated pyrogen and sensitization test. All tests demonstrated that the GL-1 Guiding Catheter is biocompatible.

Shelf-life testing on the GL-1 Guiding catheter and its packaging demonstrates that the device and packaging meet all performance specifications within its labeled shelf-life expiration date.

Based on the results of the above testing, AVEM concludes that the AVE GL-1 Guiding Catheter is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Fred L. Boucher
Regulatory Affairs Manager
AVE Massavchusetts, Inc.
129 Concord Road
Billerica, MA 01821

Re: K984482
Trade Name: AVE GL-1 Guiding Catheter
Regulatory Class: II
Product Code: DQY
Dated: July 15, 1999
Received: July 16, 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

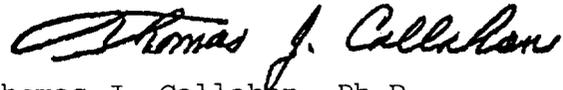
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your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

D. INDICATIONS FOR USE

Device Name: AVEM GL-1 Guiding Catheter

Indications for Use:

AVE guiding catheters are designed for use in the vascular system. Their primary function is to provide a pathway through which dilatation systems and other interventional devices are introduced. AVE Guiding catheters also allow pressure monitoring and injection of contrast agents.

Contraindications:

There are no known contraindications for this product.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christopher M. Allen for Callahan

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

510(k) Number K994482

Prescription Use
(Per 21 CFR 801.109)

OR Over-the-Counter Use