

JUL 27 1999

K984627

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
Address: 129 Concord Road, Billerica, MA 01821
Phone: (978) 739-3116
Fax: (978) 777-0390
Contact Person: Fred Boucher
Regulatory Affairs Manager
Date of Preparation: 6/28/99

B. Device Name

Trade Name: AVE 4F SiteSeer (II) Cardiovascular
Angiographic Catheter
Common Name: Cardiovascular Angiographic Catheter
Classification Name: Diagnostic Intravascular Catheter
/Percutaneous Catheter

- C. Predicate Device Name(s):
1. AVE SiteSeer™ Catheter
 2. AVE Envision™ Catheter
 3. Cordis Infiniti™ Angiographic Catheter
 4. Cordis Vista™ Bright tip Catheter

D. Device Description

The 4F SiteSeer (II) catheter is an intravascular diagnostic catheter for use in the cardiovascular system.

E. Intended Use

Intravascular diagnostic catheters are used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels.

F. Technological Characteristics

The AVE 4F SiteSeer II catheter is similar to the AVE 4F SiteSeer and Cordis Infiniti and Vista Bright Tip catheters regarding materials of construction, packaging, and sterilization.

The indications for use are similar to both the AVE Angiographic catheters and the Cordis catheters. They are all

indicated to deliver media or substances into the vascular system. The actual indications are listed below:

The AVE 4F SiteSeer II is indicated for use in the cardiovascular system. Their primary function is to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels.

The Cordis Infiniti indications are designed to deliver radiopaque contrast media to selected sites in the vascular system. Similar to the AVE and Cordis catheters, the AVE SiteSeer II catheter will be available in various curve styles.

G. Performance Date

AVEM conducted tensile strength, bending stiffness, straight-line torque, high-pressure static leak, flow rate and natural frequency testing. The test results demonstrate that the 4F SiteSeer II catheter is substantially equivalent to the AVE SiteSeer™ catheter, the AVE Envision™ Catheter, or the Cordis Vista™ Bright tip 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 4F SiteSeer II catheter is biocompatible.

Shelf-life testing on the AVE 4F SiteSeer II catheter demonstrates that the device meets all performance specifications within its labeled life expiration date.

Based on the results of the above testing, AVEM concludes that the AVE 4F SiteSeer catheter II 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

JUL 27 1999

Mr. Fred Boucher
Regulatory Affairs Manager
AVE Massachusetts, Inc.
129 Concord Road
Billerica, MA 01821-0566

Re: K984627
4F SiteSeer™ II Cardiovascular Angiographic Catheter
Regulatory Class: II (two)
Product Code: 74 DQO
Dated: June 18, 1999
Received: June 21, 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

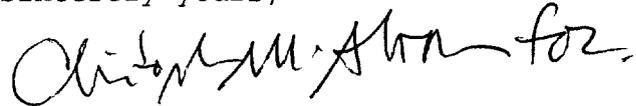
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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, FDA will verify such assumptions. Failure to comply with

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the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the 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,



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: AVE 4F SiteSeer™ Cardiovascular Angiographic Catheter

Indications for Use: An intravascular diagnostic catheter is a device used to record intracardiac pressure, to sample blood, and to introduce substances into the heart and vessels.

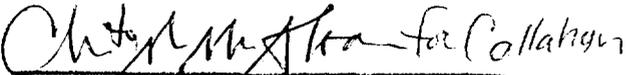
Contraindications: None

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____



(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K984627