

NOV 22 2004

## SECTION 3. 510(K) SUMMARY

### 3.1 ADMINISTRATIVE INFORMATION

#### 3.1.1 Name and address

Submitted by: Velocimed Inc  
11400 73rd Avenue North, Suite 134  
Minneapolis, MN 55369

Contact Person: John Carline  
Telephone No.: 763-463-4742  
Facsimile No.: 763-488-9780

Date Prepared: Oct 19, 2004

#### 3.1.2 Device Name

Trade Name	Venture Wire Control Catheter
Common Name	Catheter Steerable
Classification Name	Catheter, Intravascular
Classification	Class II DRA, DQY
Model	WCC

#### 3.1.3 Applicant

Applicant's Name: Velocimed Inc  
11400 73rd Avenue North, Suite 134  
Minneapolis, MN 55369

### 3.2 INDICATION FOR USE

The Venture™ Wire Control Catheter is indicated for directing, steering, controlling, and supporting a guide wire to access discreet regions of the coronary and peripheral vasculature. It may also be used for manual delivery of saline solution or diagnostic contrast agents.

### 3.3 DEVICE DESCRIPTION

The Venture Wire Control Catheter is a single use, over-the-wire support catheter with a radiopaque deflectable tip. A rotating knob at the handle controls the tip deflection angle. The tip can be deflected continuously up to about 90° from the catheter axis.

The device is compatible with all 0.014" guidewires. It is torqueable and can be used to instantaneously shape, and control the curvature of the guidewire while in use as well as provide

support to the guidewire when needed. A luer attachment is also provided to allow for the manual injection of dye through the guidewire lumen of the catheter

### **3.4 SUBSTANTIAL EQUIVALENCE**

The Venture™ Wire Control Catheter device covered by this submission is substantially equivalent to previous Venture Wire Control Catheter (K040922).

The Venture™ in this submission has the same indication for use, principles of operation, and technological characteristics as the previously cleared predicate devices. The differences between this device and its predicate devices do not raise new questions of safety or efficacy.

### **3.5 PERFORMANCE DATA**

The summary of the performance test data is provided in the 510(k) submission. The performance data demonstrates that the device complies with the applicable sections of:  
ISO 10555 (Part 1 and Part 4),  
ISO 10993-1,  
Product specification  
ASTM D-4169 (Packaging Integrity Testing)  
ISO 11607 (Packaging for terminally sterilized medical devices)  
ISO 11135: 1994(E) (Validation and routine control of ETO sterilization)

Test results demonstrate that the device meets or exceeds the requirements of these standards and performs substantially equivalent to the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 22 2004

Velocimed, Inc.  
c/o Mr. John Carline  
RA Specialist  
11400 73<sup>rd</sup> Avenue North, Suite 134  
Minneapolis, MN 55369

Re: K042910  
Trade/Device Name: Venture Wire Control Catheter, Model WCC  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: DQY  
Dated: October 19, 2004  
Received: October 25, 2004

Dear Mr. Carline:

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

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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 (240) 276-0120. 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 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,

*Danna R. Lockner*

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

Enclosure

**SECTION 2. INDICATION FOR USE**

510(k) Number: K042910

Device Name: Venture Wire Control Catheter

**Indication for Use**

The Venture™ Wire Control Catheter is indicated for directing, steering, controlling, and supporting a guide wire to access discreet regions of the coronary and peripheral vasculature. It may also be used for manual delivery of saline solution or diagnostic contrast agents.

Prescription Use: X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use: \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dana R. Wilmer  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K042910