K040922

AUG 1 8 2004

SECTION 2. 510(K) SUMMARY

2.1 ADMINISTRATIVE INFORMATION

2.1.1 Name and address

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

Contact Person: Sew-Wah Tay, Ph.D.
Telephone No.: 763-463-4707
Cell Phone: 612-801-6782
Facsimile No.: 763-488-9780

Date Prepared: April 5, 2004

2.1.2 Device Name

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

2.1.3 Applicant

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

2.2 INDICATION FOR USE

The Venture™ Guidewire 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.

2.3 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 use 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

2.4 SUBSTANTIAL EQUIVALENCE

The Venture™ Guidewire Control Catheter device covered by this submission is substantially equivalent to other legally marketed devices namely, IntraLuminal Therapeutics Deflectable Catheter (K012749), Catheter Research Inc's Cynosar Catheter (K 904785) and Xtrak TOPS catheter

The Venture™ has the same general indication for use, similar principles of operation, and similar 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.

2.5 PERFORMANCE DATA

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)

Performance testing included dimensional verification; tip integrity, catheter tensile strength, torque strength, flexibility, and trackability. Four chronic animals (total of nine coronary vessels) were treated with the Venture Guidewire Control Catheter to test and validate the performance and safety of the device. Test results demonstrate that the device meets or exceeds the requirements of these standards and performs substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2004

Velocimed Inc.
c/o Sew-Wah Tay, Ph.D.
V.P. Regulatory and Clinical Affairs
11400 73rd Avenue North, Suite 134
Minneapolis, MN 55369

Re: K040922
Trade Name: Venture™ Wire Control Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 9, 2004
Received: August 10, 2004

Dear Dr. Tay:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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. for
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K040922

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)

Neil R. Ogden for SVZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040922