Velocimed™

11400 73rd Ave North, Suite 134
Minneapolis, MN 55369

763-463-4742 • Phone
763-488-9780 • Fax

JAN - 7 2005

K042117

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: Jan 4, 2005

3.1.2 Device Name

Trade Name	Proxis System
Common Name	Percutaneous Catheter
Classification Name	Catheter, Percutaneous
Classification	Class II, DQY

3.2 SUBSTANTIAL EQUIVALENCE

The Proxis System with hydrophilic coating, the subject of this submission, is substantially equivalent to the Proxis System without hydrophilic coating (predicate device) which had been found to be substantially equivalent through the 510(k) notification process (K023548).

The Proxis System with hydrophilic coating is the same as the predicate device except for the addition of the hydrophilic coating.

The addition of the hydrophilic coating does not alter the intended use the Proxis System.

3.3 INDICATION FOR USE

The Proxis System controls the flow of fluids in the coronary and periphery vasculature. This is achieved by the temporary occlusion of vessels and holding the column of fluid in the vessel stagnant. The stagnant column can be used to aid in the visualization of the lesion or be used as a means of local and temporary delivery of therapeutic solution(s). The safety and efficacy of this device as an embolic protection system has not been established. The Proxis Flow Control device is not indicated for use for embolic protection.

3.4 DEVICE DESCRIPTION

The Proxis System has four major components: The Evacuation Sheath Catheter, the Inflation System, Infusion Catheter, and an Evacuation syringe.

The Evacuation Sheath Catheter has two low-pressure compliant sealing balloons that are inflated simultaneously. The proximal balloon stays within the guide catheter while the distal balloon resides in the arterial vessel. Radiopaque markers at the two balloon sites facilitate visualization and intravascular placement of the catheter prior to inflation. The Evacuation Sheath has sufficiently large inner diameter to accommodate standard therapeutic devices within its size range. The balloons are inflated using the Inflation System.

Devices can be deployed through the Evacuation sheath to the target site before, during or after the sealing balloons are inflated to occlude the vessel. Infusing ~0.5cc of contrast dye through the guide catheter will produce a continuous "roadmap" of the lesion as an aid for the physician in guiding the therapeutic device to the lesion site.

Alternatively, while the vessel is occluded, therapeutic solutions like anticoagulant, cardioplegia and thrombolytics may be infused through the guide catheter and stagnated in the target vessel/lesion during the delivery of the therapeutic device or after the deployment of the therapeutic device.

The Evacuation syringe is provided for the removal of the fluid and the emboli/thrombi during aspiration. The infusion catheter may be used to infuse saline to augment the retrograde flow of fluid and the removal the emboli/thrombi.

3.5 PERFORMANCE DATA

The Proxis System has been shown to meet the performance requirements of the product specification. Additionally, the Proxis System complies with the applicable section of the following product standards:

- ISO 10555 (Sterile, single-use intravascular catheter - Part 1: General requirements and Part 4: balloon dilation catheter)
- ISO 10993 (Biological evaluation of medical devices)
- 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, balloon compliance and integrity, catheter tensile strength, torque strength, flexibility and trackability. 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

JAN - 7 2005

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

Re: K042117
Proxis System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 21, 2004
Received: December 28, 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 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,

Donna R. Volkmer

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

Enclosure

Attachment A. Indications for use

510(k) Number: K042117

Device Name: Proxis System

Indication for Use:

The Proxis System controls the flow of fluids in the coronary and periphery vasculature. This is achieved by the temporary occlusion of vessels and holding the column of fluid in the vessel stagnant. The stagnant column can be used to aid in the visualization of the lesion or be used as a means of local and temporary delivery of therapeutic solution(s). The safety and efficacy of this device as an embolic protection system has not been established. The Proxis Flow Control device is not indicated for use for embolic protection.

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)

Donna R. Vochmel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042117