K081420

PREMARKET NOTIFICATION
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FOR VANISHPOINT® I.V. CATHETER
(As Required By 21 CFR 807.93)

NOV - 7 2008

Contact Person: Rhonda Wells
Regulatory Affairs Manager

Date of Summary Preparation: May 16, 2008

Trade Name: VanishPoint® I.V. Catheter
Common Name: Intravenous Catheter
Classification Name: Intravascular Catheter

Device Classification: Class II

Legally Marketed Substantially Equivalent Device:
VanishPoint® I.V. Catheter (K051355)

Description of Device: The VanishPoint® I.V. Catheter is a safety device. The retracting introducer places the catheter portion in a vascular vessel in the same way as a conventional catheter, but upon removal of the placement needle, the caregiver activates a safety mechanism which retracts the needle completely into the handle/introducer assembly. In this way, if properly performed, it does not expose the caregiver to an accidental stick from a contaminated needle. The energy to retract the needle and chamber is provided by a spring interacting between the housing and the needle chamber assembly. Once the needle/chamber is retracted, the retracting introducer assembly is no longer required and taken away from the patient.

Intended Use: The intended use of the VanishPoint® I.V. Catheter is to provide safe and reliable access to the vascular system for short term use (less than 30 days). The VanishPoint® I.V. Catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure. The VanishPoint I.V. Catheter aids in the prevention of needlestick injuries.

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Comparison of Technical Characteristics:

The subject VanishPoint I.V. Catheter and the VanishPoint I.V. Catheter predicate device are very similar in design and technological characteristics. The different materials are equivalent and the intended use is identical.

Substantial Equivalence:

The VanishPoint I.V. Catheter is being expanded to offer additional customer preference options. There is no substantive differences between the predicate device and subject device that would raise new issues of safety and effectiveness. The devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2008

Ms. Rhonda Wells
Regulatory Affairs Manager
Retractable Technologies, Incorporated
511 Lobo Lane
Little Elm, Texas 75068

Re: K081420
Trade/Device Name: VanishPoint® I.V. Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: October 10, 2008
Received: October 16, 2008

Dear Ms. Wells:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Annette Y. Michaud MD
FOR DR. CHIU LIN

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: VanishPoint® I.V. Catheter

Indications for Use:

The intended use of the VanishPoint® I.V. Catheter is to provide safe and reliable access to the vascular system for short term use (less than 30 days). t The VanishPoint® I.V. Catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure. The VanishPoint I.V. Catheter aids in the prevention of needlestick injuries.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081430