DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Terance Grisso
Director, Regulatory Affairs & Quality
Retractable technologies, Incorporated
511 Lobo Lane
P.O. Box 9
Little Elm, Texas 75068

AUG 26 1997

Re: K971763
Trade Name: Blood Collection Tube Holder Vanishpoint™ Tube Holder and Vanishpoint™ Small Tube Adapter
Regulatory Class: II
Product Code: FMI
Dated: August 4, 1997
Received: August 5, 1997

Dear Mr. Grisso:

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 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. 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 (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 requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K971763

Indications For Use

510(K) Number (if known): K971763

Device Name: VanishPoint® Tube Holder and VanishPoint®Small Tube Adapter

Indications for Use:

The function of the VanishPoint® Tube Holder is to provide a safe and reliable method for facilitating blood withdrawal from a patient into evacuated blood collection tubes without exposing the phlebotomist to an accidental needlestick injury. The VanishPoint® Tube Holder works like a conventional tube holder except for its ability to retract the contaminated needle inside of the tube holder immediately after blood collection. Regular size collection tubes are inserted into the tube holder to collect blood through the blood collection needle. Regular size collection tubes are 13mm and 16mm diameter. After the last evacuated tube is filled, the tube is removed and the tube holder endcap is pressed onto the back-end of the tube holder. The needle retraction mechanism is automatically activated and the contaminated needle is withdrawn from the patient's vein and carried into the tube holder. The tube holder cannot be reused. This automatic needle retraction protects the phlebotomist from an accidental needlestick. Accidental needlesticks typically occur between removing the needle from the patient, removing the needle from a reusable tube holder and disposing of the needle into a sharps disposal container.

The function of the VanishPoint®Small Tube Adapter is to permit the phlebotomist to use the VanishPoint® Tube Holder with small volume blood collection tubes. Small volume collection tubes are 10.25mm in diameter. The tube adapter is inserted into the tube holder and the small collection tube is inserted into the tube adapter. After the evacuated tube is filled with blood, the tube adapter is removed from the tube holder and the tube is removed from the tube adapter. The tube adapter can be reused.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Rebecca Cincotta
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971763

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)