

MAR - 3 2000



K994429

December 27, 1999

To whom it may concern:

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Trade Name - Venusa Ltd., Extension Set with Filter  
Common Name - Extension Set with .2 micron Air Eliminating Filter  
Classification Name - Intravascular Administration Set

The Venusa, Ltd. Extension Set with filter is intended to be used with an indwelling catheter for the purpose of delivering drugs and solutions. The filter assures that particulate matter greater than .2 micron is removed from the solution and insures that air is not infused. The device consists of female Luer lock, TOTM (non-DEHP) plasticised PVC tubing, a Millipore 0.22 micron air eliminating filter, an on/off clamp, and a male Luer lock adapter. The components and the processes used to manufacture these solution sets with filter are substantially equivalent to like products currently legally marketed by Abbott Laboratories, under K960466 and Baxter Healthcare under K964850. The Venusa, Ltd. Extension Set with Filter will be packaged in tyvek\mylar pouches and sterilized per AAMI guidelines.

The Venusa, Ltd. Extension Set with Filter is similar to the above named predicate devices in following ways:

1. It has the same intended use.
2. It uses the same components..
3. The device configuration is the same, with the exception the Venusa, Ltd. device will not utilize a y-injection site.
4. The composition of the raw materials is similar if not identical.
5. The processes used to manufacture the devices are similar if not identical.

Venusa will purchase the 0.22 micron filter from Millipore and will incorporate it into an extension set. Venusa is making no

changes to the design, components or materials of the Millipore filter. Millipore generated data regarding the functional performance of the 0.22 micron filter. Testing included Reverse Pressure Filter Integrity, Unit Venting, Gravity Flow, Inlet Axial Stress, Forward Pressure Filter Integrity, Downstream Particle Count, Accelerated Endurance, Bioburden Evaluation, In-line Filter Wettability, Burst Strength, and MVI Resistance. The data indicates that the filter meets or exceeds all functional requirements for the devices intended use.

Based on the fact that the Venusa, Ltd. Extension Set with Filter utilizes similar and equivalent designs, components, manufacturing processes as currently legally marketed products, the Venusa, Ltd. Extension Set with Filter is safe and effective when used as intended.

Sincerely,

A handwritten signature in black ink, appearing to be "S. J. Gandy", written in a cursive style.

**31C BUTTERFIELD TRAIL, EL PASO, TX 79906**

**(915) 771 9112 FAX: (915) 771 9107**



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAR - 3 2000**

Mr. Ross Magladry  
Venusa, Ltd.  
31C Butterfield Trail  
El Paso, Texas 79906

Re: K994429  
Trade Name: Venusa, Ltd. Extension Set with Filter  
Regulatory Class: II  
Product Code: FPA  
Dated: December 27, 1999  
Received: December 30, 2000

Dear Mr. Magladry:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

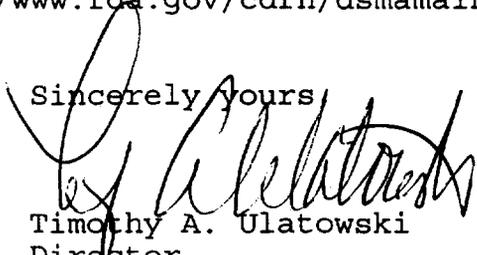
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4690. 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

K994429

510 (k) number: K994429  
Device name: Extension Set with Filter

**Indications for Use:**

The Venusa, Ltd. Extension Set with Filter is used for IV fluid administration where removal of particulate greater than 0.22 micron is desired. Use of the device helps assure the delivery of a bacteria-free product. The device is used in conjunction with an IV administration set and in-dwelling IV catheter.

  
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(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K994429