JUL 28 1998

K981683

January 18, 1998

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. Huber Needle Infusion Set
Common Name -Huber Needle Set, Vascular Access Device
Classification Name - Intravascular Administration Set

The Venusa, Ltd. Huber Needle Infusion Set is intended to be used access an implanted port for the purpose of delivering drugs and solutions. The device consists of female Luer lock adapter, Non-DEHP PVC tubing, an on\off clamp, 314 stainless steel Huber point non-coring needle bent to 90 degrees. The device includes a winged hub that surrounds the needle to aid in the insertion, securement, and removal of the device. The components and the processes used to manufacture these Huber needle infusion sets are substantially equivalent to like products currently legally marketed by Pfizer Strato (K921674), Douglas Medical Products (K932638), and Marquette Medical (K884212). Venusa, Ltd. Huber Needle Infusion Sets will be packaged in tyvek\mylar pouches or tyvek and polyethylene form\fill\seal container and sterilized per AAMI guidelines.

Based on the fact that the Venusa, Ltd. Huber Needle Infusion Sets utilize similar and equivalent designs, components, manufacturing processes, and have the same intended use as the currently legally marketed products, the Venusa, Ltd. Huber Needle Infusion Sets are safe and effective when used as intended.

Sincerely,

Neil Kulkarni

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 1998

Mr. Neil Kulkarni
Product Development Engineer
Venusa Ltd.
31 Butterfield Trail, Suite C
El Paso, Texas 79906

Re: K981683
Trade Name: Huber Needle Infusion Set Model Number 20601, Huber Needle Infusion Set w/y-site Model Number 20601y
Regulatory Class: II
Product Code: FPA
Dated: May 8, 1998
Received: May 13, 1998

Dear Mr. Kulkarni:

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 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). 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 requirements, 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) 594-4692. 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 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/dsma/dsmamain.html".

Sincerely yours,

S. Ulatowski for

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

Enclosure

510(k) Number (if known):_____

Device Name: Huber Needle Infusion Set

Indications For Use:

The Venusa, Ltd. Huber Needle Infusion Set is intended to be used to deliver solutions and drugs into vascular implant ports.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981683

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)