K993848

JAN 2 7 2000

510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SODA and 21CFR § 807.92

Submitted by:

Millennium Medical Distribution
696 Unionville Road, Suite 6
Kennett Square, PA 19348

Contact Person:
Robert Rosato, President
(610) 455-0258 (610) 455-0768 fax

Date Prepared: November 4, 1999

Device Name:

Proprietary Name:	Millennium Huber Plus Safety Infusion Set
Common Name:	Huber Needle and Administration Set
Classification:	Class II: Product Code FPA Regulation Number 21 CFR 880.5440

Identification of Predicate Devices

- ALL-MED Non-Coring Needle Winged Administration Set, Multi-Med Corporation, West Swanzey, NH; K890127, K890340, K891072, K891919.
- Angel Wing Safety Blood Collection and Infusion Set, MBO Laboratories, Inc., Lowell, MA (now owned by Kendall TYCO/Sherwood Davis and Geck), K912563

Device Description:

The Millennium Huber Plus Safety Infusion Set is a standard non-coring right angle Huber needle and administration set with a needlestick prevention feature. The Huber Plus Safety Infusion Set is designed for use with a vascular access infusion system.

The Millennium Huber Plus Safety Infusion Set is fabricated from biocompatible, medical grade materials. The needle is inserted into the vascular access port in a standard manner for fluid infusion or for blood sampling. Removal of the needle is done as with any standard Huber needle, using a one-handed (dominant hand) technique to pull out the needle, and stabilizing the port with the nondominant hand. As the needle is removed, the passive needlestick prevention feature actuates automatically when the users hands are positioned correctly and can be easily seen, felt,

and heard by the user to ensure that the needle cover is secure.

The Millennium Huber Plus Safety Infusion Set is supplied sterile and nonpyrogenic, for single use only.

Indication for Use:

The Millennium Huber Plus Safety Infusion Set is a safety IV administration set with a non-coring, ninety-degree, right-angle Huber needle, used to access surgically implanted vascular ports. The Huber needle is used to administer fluids or to withdraw blood. The Huber Plus system facilitates safe removal of the needle by encapsulating the needle within the attachment wings to help prevent needlestick injuries when using the device for vascular port access.

Technological Characteristics

The Millennium Huber Plus Safety Infusion Set is manufactured from the same materials as the ALL-MED Administration Set and the Angel Wing Blood Collection Set, with the exception of the hinge tube material. The needle, components and safety mechanism are all fabricated out of medical grade material. The Millennium Huber Plus Safety Infusion Set operates as a standard Huber needle with the addition of a safety feature to help prevent needlestick injuries.

Performance Data

Equivalency performance testing has been performed on the Millenium Huber Plus Safety Infusion Set components and its two predicate devices. This testing showed that in all areas tested the devices perform in an equivalent manner. A Simulated Use Study was performed showing that there were no incidences of sharps injuries or incidences where the safety feature failed to be activated during the course of the study.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 7 2000

Ms. Christine Emanuel
RA Consultant, Millennium
Medical Distribution, Incorporated
P.O. Box 936
Chadds Ford, PA 19317

Re: K993848
Trade Name: Millennium Huber Plus Safety Infusion Set
Regulatory Class: II
Product Code: FPA
Dated: January 11, 2000
Received: January 13, 2000

Dear Ms. Emmanuel:

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 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" (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

Include the following "Indications For Use" page that contains the applicant's name, name of the device and the intended use of the device. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the "indications for use" statement.
*For a new submission, do NOT fill in the 510(k) number blank.

INDICATIONS FOR USE

Applicant: Millennium Medical Distribution

510(k) Number (if known): N/A*

Device Name: Millennium Huber Plus Safety Infusion Set

Indications For Use:

The Millennium Huber Plus Safety Infusion Set is a safety IV administration set with a non-coring, ninety-degree, right-angle Huber needle, used to access surgically implanted vascular ports. The Huber needle is used to administer fluids or to withdraw blood. The Huber Plus system facilitates safe removal of the needle by encapsulating the needle within the attachment wings to help prevent needlestick injuries when using the device for vascular port access.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter _____
Per 21 CFR 801.109

Patricia Cucenta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993848