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NOW MEDICAL DISTRIBUTION
HUBER CLEAR™ SAFETY INFUSION SET
510(k) PREMARKET NOTIFICATION

510(k) SUMMARY

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

Submitted by: NOW Medical Distribution, Inc.
PO Box 936
Chadds Ford, PA 19317

Contact Person:
Christine Emanuel
Regulatory Consultant
(805) 963-4312 (tel)
(805) 564-8642 (fax)

Date Prepared: April 15, 2005

Device Name:

Proprietary Name:	NOW Huber Clear™ 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

- NOW Huber Plus Safety Infusion Set, NOW Medical Distribution, Chadds Ford, PA K993848

Device Description:

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

The NOW Huber Clear™ 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 NOW Huber Clear™ Safety Infusion Set is supplied sterile and nonpyrogenic, for single use only.

Indication for Use:

The NOW Huber Clear™ 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 Clear™ 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 Now Huber Clear™ Safety Infusion Set is a modification of the Huber Plus Safety Infusion Set, and encompasses no new technology.

Performance Data

Equivalency performance testing has been performed on the Now Huber Clear™ Safety Infusion Set components that have been modified from the predicate Huber Plus. In addition, 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

JUL 12 2005

Now Medical Distribution, Incorporated
C/O Ms. Christine Emanuel
Tecsa Technical Services
1205 De La Vina Street
Santa Barbara, California 93101

Re: K051009
Trade/Device Name: NOW Huber Clear™ Safety Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: April 20, 2005
Received: April 26, 2005

Dear Ms. Emanuel:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K051009

Indications For Use

510(k) Number (if known): K051009

Device Name: NOW Huber Clear™ Safety Infusion Set

Indications For Use:
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Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051009