



DEC 15 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Al Boedeker
Director, Regulatory Affairs Quality Assurance
Nexus Medical, LLC
11315 Strang Line Road
Lenexa, Kansas 66215

Re: K041844
Trade/Device Name: All Safe Huber Safety Infusion Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: August 27, 2004
Received: August 31, 2004

Dear Mr. Boedeker:

This letter corrects our substantially equivalent letter of September 3, 2004 regarding the incorrect Indications for Use statement that was sent to you.

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 (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 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.

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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 continue 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/dsma/dsmamain.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



11315 Strang Line Road, Lenexa, KS

510(k) Number: K041844

Description: All Safe Huber Safety Infusion Sets, K041844
Responses to Reviewers Fax of 7/30/04
8/27/04 Response

Indications for Use Statement

Applicant: Nexus Medical LLC

510(k) Number (if known): K041844

Device Name: All Safe Huber Safety Infusion Sets

Indications For Use:

The AllSafe™ Huber Safety Infusion Sets are used to access surgically implanted vascular ports for the administration of fluids and withdrawal of blood. The AllSafe™ Huber Safety Infusion Sets facilitate the safe removal of the needle and may aid in the prevention of needle stick injuries.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The -Counter Use _____
(21 CFR 801 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 K041844