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NOV 26 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
IV/Catheter Extension Set with NAC Plus Needleless Access Connector *and* NAC Plus Needleless Access Connector

Submitted by:
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Date Prepared:
November 15, 2004

Proposed Device:
IV/Catheter Extension Set with NAC Plus Needleless Access Connector *and*
NAC Plus Needleless Access Connector

Comparison Device:
Solution Administration Sets with Luer Access Injection Site *and*
NAC PRN

Device Description:
The IV/Catheter Extension Set with NAC Plus Luer Access Connector constitutes a set for continuous and intermittent fluid delivery into the vascular system. The extension set has luer locks, tubing, slide clamps, tip protectors, and NAC Plus Luer Access Connectors.

The NAC Plus Needleless Access Connector is a Luer activated device cleared under K011193 (Medegen) April 10, 2001. This component is purchased bulk, non-sterile and is packaged by Baxter as both a stand-alone accessory device and as a component integral to IV/Catheter sets. The devices are subsequently packaged, gamma irradiated and distributed to the end user in a cardboard carton.

Statement of Intended Use:
IV/Catheter Extension Set with NAC Plus Needleless Access Connector is intended to administer drugs and solutions into a patient's vascular system. The NAC Plus (integral or stand-alone) allows the user to administer or withdraw solutions. The NAC Plus Needleless Access Connector may aid in the prevention of needle stick injury and is available as a stand-alone accessory or as part of the IV/Catheter Extension set.

Technological Characteristics
The IV/Catheter Extension set with NAC Plus Needleless Access Connector functions with similar characteristics to other legally marketed devices such as the Solution Administration Set with Luer Access Injection Site previously cleared under K984060 July 26, 1999. Both are used for solution administration into the vascular system and both are accessed by a standard male luer adapter for fluid administration or fluid withdrawal.

The function of the NAC Plus Needleless Access Connector is similar to that of other legally marketed devices such as the NAC PRN. Sets containing these in-line luer activated injection sites are accessed by a standard male luer adapter to provide needleless access to the fluid path. These in-line injection sites operate with the same mechanism of action. Connection of a male luer adapter to the female luer end of the luer activated injection site accesses a valve that opens the fluid path. There is a difference in the valve mode of operation between the two devices. The NAC Plus uses a collapsible gland that provides a positive fluid displacement feature where a forward pulse of fluid is directed toward the catheter tip as the male luer is removed from the device. The NAC PRN does not have this feature.

Nonclinical Tests
The biological and chemical reactivity of the materials have been assessed using biological methods specified in ISO Standard 10993-1 and USP physicochemical tests. The material was found to be acceptable for its intended use. Results regarding the functional performance of the proposed NAC Plus have been submitted. The results indicate that the proposed device meets or exceeds all functional requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2004

Ms. Nanette Hedden
Project Manager, Global Regulatory Affairs
Baxter Healthcare Corporation
Route 120 and Wilson Road
Round Lake, Illinois 60073

Re: K042936
Trade/Device Name: IV/Catheter Extension Set with NAC Plus Needleless Access Connector
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 22, 2004
Received: October 25, 2004

Dear Ms. Hedden:

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/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

K042936

Indications for Use

510(k) Number (if known): K042936

Device Name: IV/Catheter Extension Set with NAC Plus Needleless Access Connector

and NAC Plus Needleless Access Connector

Indications For Use:
IV/Catheter Extension Set with NAC Plus Needleless Access Connector is intended to administer drugs and solutions into a patient's vascular system. The NAC Plus (integral or stand-alone) allows the user to administer or withdraw solutions. The NAC Plus Needleless Access Connector, available as a stand-alone accessory or as part of the IV/Catheter Extension set, may aid in the prevention of needlestick injury.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042936

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)