K082027

510(k) Summary

FEB 13 2009

Applicant: Genesis BPS, LLC
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Submission Correspondent: Carolyn Amditis, BSMT (ASCP)
Telephone: (201) 708-1400
Fax: (201) 708-1104
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Device Information:

Trade Name: These devices will be marketed under the trade name FLU-ADMIN I.V. SETS

Common/Usual Name: Intravascular Administration Set

Classification Name: Set, Intravascular Administration (21 CFR 880.5440)

Establishment Registration Number: 2248588

Class: II

Product code: FPA

Predicate Device: FLU VEN I.V. SETS (K11914)
FLU VEN I.V. SET 0153-C (K843692)

Device Description: The tubing assembly consists of spike and drip chamber connected to tubing with a "Y" injection site and a male luer slip. Between the tubing with a "Y" injection site and a male luer slip is a roller clamp. These sets deliver 20 drops/ml, with the exception of set model 0151C which delivers 60 drops/ml. All models ending with a "C" have a check valve. All sets are vented with the exception of model 0160, which is non-vented.

Intended Use: Intended to be used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2009

Genesis BPS, LLC
Ms. Carolyn Amditis, BSMT (ASCP)
Manager, Technical Services & Quality Control
65 Commerce Way
Hackensack, New Jersey 07601

Re: K082027
Trade/Device Name: FLU-ADMIN I.V. Sets
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: January 28, 2009
Received: February 2, 2009

Dear Ms. Amditis:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Antony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Genesis BPS, LLC
510(k) Notification
FLU-ADMIN I.V. SETS
AMENDMENT

January 28, 2009

Indications for Use Statement

510(k): **K082027**

Device Name: FLU-ADMIN I.V. Sets

Indications of Use: Genesis BPS FLU–ADMIN I.V. Sets are intended to be used to administer fluids from a container to a patient's vascular system through a needle or catheter into a vein.

Prescription Use **XX** 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 AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off) K082027
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082027