

Innovative Design Associates

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10. 510(k) SUMMARY

Submitter: *Innovative Design Associates*

Address: 561 East Saddle River Road, Upper Saddle River, NJ 07458; tel/fax (201) 760-9550

Contact Person: Jerry D. Vloka, M.D., Ph.D.

Date of preparation: February 8, 1999.

Proprietary Name	AnesFlow™ Dual Drip Intravenous Infusion Set
Common Name	Intravenous infusion set with two drip chambers
Classification Name	Intravascular Administration Set
Description of the device	AnesFlow™ Dual Drip Intravenous Infusion Set is an intravenous infusion set incorporating two drip chambers of different flow characteristics (micro and macro drip chambers), intended to provide the operator with a greater flexibility of controlling the intravenous fluids infusion rate (i.g., slow rate through the micro-drip and/or fast rate through the macro-drip).
Intended use of the device	AnesFlow™ Dual Drip Intravenous Infusion Set is a disposable device, intended for administration of intravenous (IV) fluids.
Substantially equivalent legally marketed devices	<p>#1 Additiv®; Primary IV Set (60 drops/ml) with 3 Injection Sites; Manufactured by McGaw, Inc. Irvine, Ca USA 92714-5895</p> <p>#2 Additiv®; Primary IV Set (15 drops/ml) with Check Valve and 2 Injection Sites; Manufactured by McGaw, Inc. Irvine, Ca USA 92714-5895</p> <p>#3 Anesthesia I.V. Set (15 drops/ml) vented set with in-line backcheck valve, three Y-injection sites, two four-way stopcocks, and male luer slip adapter; Product code AD-153Y-2DS; manufactured by B/Braun Medical Inc., Bethlehem, PA 18018.</p>
Explanation: Although the physical characteristics differ among the devices, the devices are substantially functionally equivalent in their intended use for administering IV fluids. The means for controlling the IV fluid infusion rate are also identical. The main significant physical difference is that AnesFlow™ Dual Drip Intravenous Infusion Set incorporates <i>two</i> drip chambers (60 drop as in #1, and 15 drops/ml as in #2 and #3). The principles in their use are however, also identical to those in #1-3.	



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL -1 1999

Jerry D. Vloka, M.D., Ph.D.
President
Innovative Design Associates
561 East Saddle River Road
Upper Saddle River, New Jersey 07458

Re: K990496
Trade Name: AnesFlow™ Dual Drip Intravenous Infusion
Set
Regulatory Class: II
Product Code: FPA
Dated: May 21, 1999
Received: May 24, 1999

Dear Dr. Vloka:

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.

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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,



for Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K990496

Indications For Use

510(k) Number (if known): K990496

Device Name: "AnesFlow" Dual Drip IV Infusion Set

Indications for use:

An intravascular administration set intended to administer fluids from a fluid container (IV bag) to a patient's vascular system through a needle or catheter inserted into a vein.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Ciccanti

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

510(k) Number K990496

Prescription Use or Over-The-Counter

(Optimal Format 1-2-96)

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