K061115

K-24

5. 510(k) Summary

JUN 30 2006

**Summary Prepared:** 28 Dec 2005
**Common Name:** Speedflow I.V. Set with Easydrop Flow Regulator
**Classification Name:** Intravascular Administration Sets
**Product Code:** FPA
**Panel:** General Hospital and Personal Use
**Device Classification:** II

**Substantially Equivalent to:** B. Braun; Filterflow Filtered Extension Sets
Amsino; I.V. Administration Sets
Leventon; I.V. Extension Sets with I.V. Flow Regulators

**Description:** The GVS Speedflow I.V. Administration Set with Easydrop Flow Regulator consists of a tubing set with a 0.2µm or a 1.2µm filter, various connectors and accessories and an Easydrop flow regulator and is used as a fluid pathway for I.V. administration. A choice can be made on the volume of fluid by easily adjusting the drops/cc setting on the Easydrop Flow Regulator. GVS will offer custom sets to meet customer requirements and specifications.

**Intended Use:** Indicated as a single use, sterile device for use in gravity fed I.V. therapy when an extended fluid path is required for administration.

**Risk Analysis Method-** ISO 14971 was used for the Risk Analysis. The specific risks associated with this device were:

| **Identified Risk** | **Mitigation Measure** |
|---|---|
| Device Malfunction | Bench Testing |
| Adverse Tissue Reaction | Biocompatibility |
| Infection | Sterilization |
| Improper Use | Labeling |

**Device Characteristics:** In order to validate critical parameters of the product required to reduce risk, the following were performed:

**Device Malfunction = Bench tests**
Leak testing on filter and sets,
Joint strength testing,
Flowrate testing (drops/minute),
Filter Integrity testing

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5. 510(k) Summary - continued

**Adverse Tissue Reaction = Biocompatibility**
ISO 10993-10, Sensitization,
ISO 10993-11, Acute Systemic Injection,
ISO 10993-3, Haemocompatibility;
ISO 10993-5, Cytotoxicity MEM Elution;
ISO 10993-10, Intracutaneous Injection

**Infection = Sterilization**
Sterility Testing: According to ISO 11137, the product has been validated to a maximum dose of 40 kGy's, with a sterility assurance level of $10^{-6}$.

Shelf Life Testing: A validation was performed according to EN 868-1 and EN 868-5 resulting in a 5 year shelf life.

Pyrogen Testing: Sets were tested by the LAL test method and were found to be $\leq$ 0.25 EU/ml.

Bacterial Retention Testing: Per industry recommendations,
The 0.2µm was tested and found to remove $\geq$99.9% of the challenged organism, *Brevundimonas diminuta.*
The 1.2 µm was tested and found to remove $\geq$99.9% of the challenged organism, *Candida Albicans.*

**Summary:** The intended use, materials, and test results show that the GVS Speedflow I.V. Set with Easydrop Flow Regulator is substantially equivalent to predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

JUN 30 2006

GVS SPA
C/O Ms. Dawn I. Moore
Consultant
20171 Bowens Road
Manchester, Michigan 48158-9600

Re: K061115
Trade/Device Name: I.V. Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: April 19, 2006
Received: April 21, 2006

Dear Ms. Moore:

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.

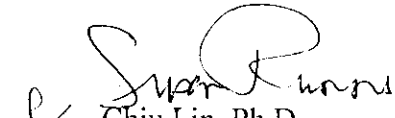
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for 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

## Indications for Use

510(k) Number (if known): K061115

Device Name: I.V. Administration Sets

Indications For Use:

Indicated as a single use, sterile device for use in I.V. therapy when an extended fluid path is required for administration. Environment of use: Hospital, Emergency Medical Services settings, wherever I.V. fluid administration may be indicated.

Prescription Use ___X___ OR Over-The-Counter Use _____

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

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

(Division Sign-Off) Number K061115