I·FLOW®
I-FLOW
CORPORATION

2532 White Road
Irvine, Calif. 92714
Phone (714) 553-0888
(800) 448-3569
Fax (714) 553-8056

K 972173

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

AUG 15 1997

July 2, 1997

Trade Name: Medi-SIS Syringe Infusion System

Common Name: Infusion pump

Classification Name: Infusion pump

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq., R.A.C.
Vice President Regulatory and Legal Affairs

I-Flow Corporation
2532 White Road
Irvine, CA 92614

Telephone: 714.553.0888
Fax: 714.553.8056

1.0 GENERAL INFORMATION

The following Summary of Safety and Effectiveness data has been prepared in support of the I-Flow Medi-SIS Syringe Infusion System.

The information has been prepared in conformance with 21 CFR §807.92 (a) and (b).

1.1 **History**: The Medi-SIS Syringe Infusion System was previously submitted as the Titan Syringe Driver System under premarket notifications K953028 and K954059. The Medi-SIS Syringe Infusion System consists of a plastic, spring driven infusion pump and various administration sets. Two models of the Medi-SIS pump have been developed to accommodate 20 and 60 ml syringes.

I-Flow, as the manufacturer of the Medi-SIS system, does not manufacture (including any form of sterilization or providing primary product packaging) or modify the syringe that is intended to be used in the Medi-SIS pump and/or Medi-SIS administration sets.

In the original submission, the Medi-SIS labeling limited the spring driven syringe pump to use with Becton-Dickinson® brand syringes (20 and 60 ml). Test information specific to the B-D® syringes and the Medi-SIS System is provided here in limited form and only as is necessary for this submission.

1.2 **Purpose of Submission**: This submission is intended to notify Federal Food and Drug Administration that a change is being made to the labeling of the I-Flow Medi-SIS Syringe Infusion System, a device currently marketed.

I-Flow Corporation believes non B-D brand syringes are being used with the system although product labeling specifically identifies Becton-Dickinson syringes as the appropriate accessory device. The information included in the proposed labeling will provide users of non B-D brand syringes, specifically Sherwood Monoject Syringes, guidance for safer use of the system.

1.3 **Statement of Equivalence:** The 20 ml Medi-SIS Pump under review has one minor proposed change to the plunger where the top of the syringe plunger comes into contact with it. The vertical ribs and circumferential base rib surrounding the inner diameter of the 20 ml Medi-SIS pump plunger have been removed to more easily accommodate the slightly wider top of the 20 ml Sherwood Monoject Syringe plunger.

Two changes were made to the 60 ml Medi-SIS Pump. The inner diameter of the opening of the 60 ml Medi-SIS Pump inner sleeve has been increased to accommodate the slightly wider top of the 60 ml Sherwood Monoject Syringe plunger. The other change to the 60 ml Medi-SIS Pump was a slight increase to the inner diameter of the pump plunger.

No other changes to the Medi-SIS System are necessary other than the proposed labeling changes. Thus, it is I-Flow's belief that the Medi-SIS System remains substantially equivalent to the device(s) submitted in K954059 and K954059.

The following sections provide performance information specific to the use of the Medi-SIS Syringe Infusion System with 20 ml and 60 ml Sherwood Monoject Syringes.

2.0 INTENDED USE

2.1 The labeling changes proposed do not change the intended use for the predicate device(s).

2.2 The Medi-SIS Syringe Infusion System was designed and developed by I-Flow Corporation for infusions. The Medi-SIS Syringe Infusion System was designed for general drug and solution infusion uses; limitations of use are based on the volume of drug to be infused.

The acceptable routes of administration include those for similar size syringes, (i.e. intravenous infusions and subcutaneous infusions).

2.3 The administration set is intended for single patient use only.

2.4 The Medi-SIS driver can be reused up to 5,000 times.

2.5 The Medi-SIS system is intended for general infusion use. The Medi-SIS Syringe Infusion System is not limited to any specific type of therapy.

2.5.1 The health care professional should use the Medi-SIS system with drugs that do not require a level or non-decreasing flow rate.

2.5.2 No testing has been conducted to determine the efficacy of the Medi-SIS Syringe Infusion System for the delivery of blood, blood products or TPN. The Medi-SIS Syringe Infusion System is not intended for the delivery of blood, blood products or TPN.

3.0 SAFETY MECHANISMS

3.1 The Medi-SIS Syringe Infusion System is a fixed rate continuous flow device and as such is not subject to fluid runaway conditions similar to that of standard infusion pumps or controller administration sets.

3.2 Under standard operating conditions, tests results for the Medi-SIS Syringe Infusion System when used with 20 ml Sherwood Monoject Syringes produced a maximum average delivery time approximately 31% greater than the labeled delivery time. The slower delivery rate has no effect on safety or efficacy of the device when reviewed against its intended use. The types of drugs that are commonly used with this device are generally given by IV push which doesn't have a specified flow rate.

Test results for the Medi-SIS System when used with the 60 ml Sherwood Monoject Syringe produced an average delivery time approximately 6% less than the labeled delivery time. This performance is well within the labeled specification of ±15%.

4.0 BIOLOGICAL SPECIFICATIONS

4.1 Based on the labeling changes proposed, there are no changes in biological specifications.

4.2 The fluid path components of the administration sets have been subjected to both the USP Plastics Compatibility Tests and the testing required under ISO 10993-1.

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Based on the labeling changes proposed, there are no changes in chemical or drug specifications.

6.0 PERFORMANCE TEST DATA

Note: The Medi-SIS Syringe Infusion System is calibrated to run nominally at 72°F (22°C) using B-D Syringes with normal saline.

6.1 **Delivery Time:** The Medi-SIS Syringe Infusion System is designed to deliver a specific volume of fluid within a minimum specified length of time. The tables below show data for the delivery time for the Medi-SIS System when used with Sherwood Monoject Syringes.

	20 ml B-D Syringe	20 ml Sherwood Monoject Syringe	
		Lot # 724040	Lot # 723462
Administration Set	20ml/15min	20ml/15min	20ml/15min
Average Delivery Time (min)	14.21	19.07	19.60
Std. Dev.	0.24	1.04	1.36
n	20	30	30

The 20 ml Sherwood Monoject Syringe produced an average increase delivery time of 27% for Lot # 724040 and 31% for Lot #723462 from the labeled delivery time of 15 minutes for the 20ml/15min administration sets.

	20 ml B-D Syringe	20 ml Sherwood Monoject Syringe	
		Lot # 724040	Lot # 723462
Administration Set	20ml/30min	20ml/30min	20ml/30min
Average Delivery Time (min)	30.61	37.14	38.60
Std. Dev.	0.97	1.88	2.79
n	20	30	30

The 20 ml Sherwood Monoject Syringe produced an average increase delivery time of 24% for Lot # 724040 and 29% for Lot #723462 from the labeled delivery time of 30 minutes for the 20ml/30min administration sets.

	60 ml B-D Syringe	60 ml Sherwood Monoject Syringe
Administration Set	60ml/30min	60ml/30min
Average Delivery Time (min)	28.32	28.09
Std. Dev.	0.83	1.14
n	30	30

The 60 ml Sherwood Monoject Syringe produced an average decrease in delivery time of 6% from the labeled delivery time of 30 minutes for the 60ml/30min administration sets. This performance is well within the labeled specification of ±15%.

	60 ml B-D Syringe	60 ml Sherwood Monoject Syringe
Administration Set	60ml/60min	60ml/60min
Average Delivery Time (min)	58.11	56.57
Std. Dev.	2.27	0.48
n	30	30

The 60 ml Sherwood Monoject Syringe produced an average decrease in delivery time of 6% from the labeled delivery time of 60 minutes for the 60ml/60min administration sets. This performance is well within the labeled specification of ±15%.

6.2 **Temperature Effect**: The table below shows data for high and low temperature when using 20 ml Sherwood Monoject Syringes. Syringes from lot # 724040 were used for this test.

	20ml/15min Set			20ml/30min Set		
Temperature (°F)	52°F	72 °F	90°F	52°F	72 °F	90°F
Average Delivery Time (min)	25.84	19.07	15.42	51.04	37.14	28.01
Std. Dev.	1.45	1.04	1.79	3.25	1.88	3.11
n	20	30	20	20	30	20

The table below shows data for high and low temperature when using 60ml Sherwood Monoject Syringes.

	60ml/30min Set			60ml/60min Set		
Temperature (°F)	50°F	72 °F	90°F	50°F	72 °F	90°F
Average Delivery Time (min)	36.67	28.09	26.19	72.95	56.57	50.65
Std. Dev.	0.87	1.14	0.45	1.09	0.48	1.31
n	20	30	20	20	30	20

6.3 **Residual Volumes:** The average residual volume is less than 1.3 ml when the Medi-SIS System is used with Sherwood Monoject Syringes as compared to less than 1.0 ml for the B-D syringes.

	20 ml B-D Syringe		20 ml Monoject Syringe	
Administration Set	20ml/15min	20ml/30min	20ml/15min	20ml/30min
Residual Volume (ml)	0.26	0.44	1.19	0.77
Std. Dev.	0.04	0.06	0.07	0.01
n	28	24	5	5

The average residual volume is less than 1.6 ml when the Medi-SIS System is used with 60 ml Sherwood Monoject Syringes. The average residual volume is also less than 1.6 ml when the Medi-SIS System is used with 60ml B-D syringes.

	60 ml B-D Syringe		60 ml Monoject Syringe	
Administration Set	60ml/30min	60ml/60min	60ml/30min	60ml/60min
Average Residual Volume (ml)	1.28	1.58	1.55	1.10
Std. Dev.	0.16	0.35	0.37	0.16
n	30	30	5	5

6.4 **Burst Pressure:** The 20 ml and 60 ml Sherwood Monoject Syringe have been tested up to 60 psi. Test results indicate no effect on structural integrity. The Medi-SIS 20 ml pump applies a load of between 14 and 18.7 lb and the 60 ml pump applies a load of between 18 and 24.75 lb to the fluid in the syringe to achieve the desired initial internal operating pressure of 40 psi. During the infusion, pressure goes from approximately 40 to 25 psi.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert J. Bard, Esq.,R.A.C.
Vice President Regulatory and Legal Affairs
I-Flow Corporation
2532 White Road
Irvine, California 92714

AUG 15 1997

Re: K972173
Trade Name: Medi-Sis Syringe Infusion System
Regulatory Class: Unclassified
Product Code: MEB
Dated: June 6, 1997
Received: June 9, 1997

Dear Mr. Bard:

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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. 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) 594-4618. 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,

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

Enclosure

510(k) Number (if known): K972173

Device Name: Medi-SIS Syringe Infusion System

Indications for Use:

1. Medi-SIS Syringe Infusion System was designed for general drug and solution infusion uses with the limitation being the volume of drug to be infused. The routes of administration include those of the similar size syringes, (i.e. intravenous infusions and subcutaneous infusions).
2. The administration set is intended for single patient use only.
3. The Medi-SIS driver can be reused up to 5,000 times.
4. The Medi-SIS system is intended for general infusion use. The Medi-SIS Syringe Infusion System is not limited to any specific type of therapy.

   4.1 The Medi-SIS Syringe Infusion System is not intended for the delivery of blood, blood products or TPN solutions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Patricia Cucento
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972173

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)