NOV 30 1998

K983975

Attachment 3

Belmont Instrument Corporation

780 Boston Road, Billerica, MA 01821 Tel (978) 663-0212 Fax (978) 663-0214

Registered In Accordance with ISO-9001 (Certificate # 041007407)

PREMARKET NOTIFICATION
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
[As Required By 21 CFR 807.92(c)]

Date prepared: November 6, 1998

1. Submitter & Manufacturing Site: Belmont Instrument Corporation
780 Boston Road
Billerica, MA 01821

Establishment Registration Number: 1219702

2. Contact Person: Uraiwan P. Labadini, Quality Assurance/Regulatory Affairs Manager

Telephone: (978) 663-0212 Ext. 28 Fax: (978) 663-0214

3. Trade Name: The Belmont Fluid Management System (*FMS2000*)

4. Common name: Infusion Pump with Warmer.

5. Classification name: Infusion Pump (per 21 CFR section 880.5725)

6. Product Code: 80 FRN Infusion Pump
Device Class: Class II

7. Performance Standards:
No performance standards have been officially adopted by the F.D.A.

8. The Modified Belmont Fluid Management Disposable Set System is substantially equivalent to the Belmont Fluid Management Disposable Set System, which was the subject of Premarket Notification #K972284 submitted in June 1997.

9. Brief Description of the Device (Unchanged by the Modification): The Belmont Fluid Management System (*FMS2000*) combines advanced microprocessor technology with an efficient mechanical system to provide a high speed, simple and safe system for rapid infusion of warmed fluid. The Belmont *FMS2000* infuses blood, replacement IV fluids or irrigation fluids warmed to physiologic temperature at user-set rates from 10 to 500 milliliters per minute (ml/min). A low infusion rate at 2.5

ml/min (150 ml/hr) is also available without heating.

The system monitors temperature, line pressure, and air in the fluid path to ensure safe operation and alarms at all unsafe conditions. A hardware override circuit prevents unsafe operation in case of system computer failure. A touch screen displays flow rate, total fluid infused, temperature, line pressure, alarm and status messages and proper procedures to proceed safely after an alarm situation.

A battery backup allows for mobile transport of the patient and system. During battery operation, fluid warming is disabled while pump operation and safety monitoring remain active.

10. Intended Use (Unchanged by the Modification): The Belmont *FMS2000* is for use in high blood loss surgical procedures, trauma and any situation where rapid replacement of warmed blood or replacement fluid at 10 -500 ml/min is required. It can also be used to deliver irrigation fluids at rates up to 500 ml/min.

11. Summary of the technological characteristics of the Modifies Belmont Disposable Set and our current Disposable Set.

The modified Belmont disposable set and our current disposable set are similar in design and concept. The main difference is the modified disposable set has a small piece of Polyester film material added to the flow outlet port of the heat exchanger. This material is added to better mix the fluid which will better control deviation in manufacturing of the heat exchanger resulting in better consistency of the output temperature.

12. Summary of Nonclinical Tests and Results

In order to verify performance of the Belmont *FMS2000* in support of substantial equivalence, the following tests were carried out:

a. The ability of the system to pump fluids accurately over the full range of flow rate and operating conditions including different input fluid temperatures, different back pressure, change in ambient temperature, and change in fluid viscosity.

b. The ability of the system to warm cold fluids to physiological temperature over the full range of flow rate and operating conditions.

c. The ability of the system to detect and alarm at unsafe or ineffective operating conditions including operator errors, the failure of the system sensors, the failure of the system software or computer, and other internal system malfunctions.

The Belmont *FMS2000* performed within specification in all of the above tests.

The system was tested also for hemocompatibility by testing for red cell hemolysis, and red cell fragility. The system was found to have negligible effect on anticoagulated blood and the system is considered "non-hemolytic" according to ASTM F756-93: Standard Practice for Assessment of Hemolytic Properties of Materials.

13. Conclusion: The Modified Belmont Disposable Set is substantially equivalent to our current Disposable Set which received 510(k) approval in November 1997. The Fluid Management System, *FMS2000*, has not changed, and is capable of high infusion flow rates, while maintaining infusate at physiological temperature, and is suitable for use with blood products. The *FMS2000* monitors flow rate, temperature, line pressure, and the presence of air at the input line or within the system, and alarms and stops the system at all unsafe conditions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 30 1998

Ms. Uraiwan P. Labadini
Quality Assurance/Regulatory Affairs Manager
Belmont Instrument Corporation
780 Boston Road
Billerica, Massachusetts 01821

Re: K983975
Trade Name: Belmont Fluid Management System (FMS2000)
Regulatory Class: II
Product Code: FRN
Dated: November 6, 1998
Received: November 9, 1998

Dear Ms. Labadini:

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 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). 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 requirements, 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) 594-4692. 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" (21CFR 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/dsma/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: _____

Device Name: Belmont Fluid Management System (*FMS2000*)

Indications For Use:

A. Infusion of crystalloid, colloid, or blood product, including packed red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery.
B. Infusion of warmed fluid to rewarm patients after surgery or for hypothermia.
C. Infusion of warmed fluid for irrigation in urology procedures.

(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)

(Division Sign-Off) Brenda Dalle
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K983975

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