K972284

NOV 13 1997

Belmont Instrument Corporation

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

Date prepared: June 9, 1997

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: (508) 663-0212 Ext. 28 Fax: (508) 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 Belmont Fluid Management System (*FMS2000*) is substantially equivalent to the Haemonetics Corporation Rapid Infusion System, R.I.S.®, which has been in commercial distribution since 1987, and which was the subject of Premarket Notification #K852645 submitted in June, 1985.

9. Brief Description: 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

    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 Belmont *FMS2000* compared to the Haemonetics R.I.S.®

    The two systems perform the identical function, both contain a high flow pump, a fluid warmer, and a safety/surveillance system to ensure safe operation. Both can operate at high flow rates. The main differences between the two systems are as follows:

    a. Size and Weight: The Belmont *FMS2000* is a 26 pound compact, portable system which can be mounted on an IV pole. The Haemonetics R.I.S.® weighs 260 pounds, and is contained in a free standing console on casters.

    b. Maximum Infusion Rate: The Belmont *FMS2000* unit will infuse up to 500 ml/min, and will empty a one unit of blood in less than a minute. The Haemonetics R.I.S.® unit will infuse up to 1500 ml/minute, and requires a large reservoir in the disposable set.

    c. Disposable Set. The Belmont *FMS2000* and Haemonetics R.I.S.® disposable sets are similar in concept. The main difference is the reservoir

size. In the Belmont *FMS2000* system, the reservoir serves to filter the fluid, to separate air and fluid, and to allow the air to vent via a hydrophobic filter. It serves as a conduit from the fluid bag to the system. In the Haemonetics R.I.S.® system, the reservoir acts as a filter, separates air and fluid, and also contains a large 3 liter volume for fluid storage, necessitated by the possibility of using a very high, 1500 ml/min. flow rate. In our system this volume is not needed.

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.

In order to verify biocompatibility, the system was tested for cytotoxicity, sensitization, irritation, and systemic toxicity, using the per ANSI/AAMI 10993-1: 1994 Biological evaluation of medical devices - Part 1: Guidance on selection of tests. All tests were passed. The system was tested 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 Belmont *FMS2000* is substantially equivalent to the Haemonetics R.I.S® which received 510(k) approval in June 1985. Both systems are capable of high infusion flow rates, while maintaining infusate at physiological temperature, and both systems are suitable for use with blood products. Both systems monitor flow rate, temperature, line pressure, and the presence of air at the input line or within the system, and alarm and stop 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 13 1997

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

Re: K972284
Trade Name: Fluid Management System
Regulatory Class: II
Product Code: FRN
Dated: August 12, 1997
Received: August 15, 1997

Dear Mr. 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 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: K972284

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972284

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