K961703

JUL - 8 1996

APPENDIX I.1

SUMMARY OF SAFETY AND EFFECTIVENESS

BAXTER VOLUMETRIC INFUSION PUMPS

SUMMARY OF SAFETY AND EFFECTIVENESS

BAXTER VOLUMETRIC INFUSION PUMPS

Submitted by:

Tamima Itani, Ph.D.
Manager, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:
April 30, 1996

Proposed Device:
Colleague™ 2 Volumetric Infusion Pump
Colleague™ 3 Volumetric Infusion Pump

Predicate Devices:
- The Colleague™ Volumetric Infusion Pump, by Baxter, cleared under K953098 on December 22, 1995
- The Flo-Gard® 6301 Volumetric Infusion Pump, by Baxter, cleared under K915522 on February 28, 1995.

Device Description and Statement of Intended Use:

The Baxter Colleague™ 2 and 3 Volumetric Infusion Pumps are designed to meet the fluid delivery needs of today's evolving health care environment. The pump can be utilized for continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural or irrigation of fluid spaces applications.

Fluid delivery applications include:

* parenteral fluids, drugs and electrolytes (e.g. cardiovascular drugs, antibiotics, anesthetics, analgesics, chemotherapy agents, total parenteral nutrition products, lipids, solutions for irrigation procedures, etc.); and
* whole blood and blood products.

The Baxter Volumetric Infusion Pumps are designed to travel the continuum of care, following the patient into a variety of care areas, including, but not limited to:

- Hospital:
  - General Floor
  - Medical/Surgical
  - Critical/Intensive Care Areas
  - Pediatrics/Neonatal
  - Labor/Delivery/Post Partum
  - OR/Anesthesia
  - Post Anesthesia/Recovery
  - Cardiac Catheter Lab
  - Emergency Room
  - Burn/ Trauma Units
  - Oncology
- Mobile Intensive Care
- Blood Centers
- Nuclear Medicine
- Hospice
- Subacute Facilities
- Outpatient/Surgical Centers
- Long Term Care
- Nursing Homes

The Baxter Colleague™ 2 and 3 Volumetric Infusion Pumps are designed to accept a wide range of Baxter "s" suffix standard sets equipped with a keyed on/off slide clamp. The uni-directional on/off slide clamp on the sets facilitates appropriate set loading. The pump will accept a variety of currently marketed drug reservoirs, including glass bottles, plastic containers and syringes.

The Baxter Colleague™ 2 and 3 Volumetric Infusion Pump will operate on 90 - 260 VAC, 50/60 Hz. The device can also operate on an optional 12 VDC power adapter for an external power source. Alternatively, power may be supplied from a rechargeable battery integral to the device.

None of the pump components or materials come in contact with the fluid path. All materials used to build the Baxter pump meet the requirements of standards applicable to infusion pumps and electronic devices.

The Baxter Colleague™ 2 and 3 Volumetric Infusion Pump will operate from 0.1 to 1200 mL/hr. Flow rates will be less than or equal to +/- 10% error at rates less than 1.0 mL/hr, and less than or equal to +/- 5% error at rates greater than or equal to 1.0 mL/hr, over any hour, or a collection volume of 0.5 mL increment, whichever is the greater volume.

Flow and rate accuracy will not degrade outside of the specified accuracy over a period of 72-hours using the same set and catheter at 100 mL/hr. The devices will operate at all programmable flow rates with a head height ranging from -36 inches to +48 inches.

As with any electronic infusion device, flow profile is dependent on flow rate. Fluid will not stop flowing for a period greater than 40 seconds at a rate of 0.1 mL/hr; 20 seconds at a rate of 0.2 mL/hr; and 10 seconds at a rate of 0.4 mL/hr. For each subsequent doubling of rate, up to 99.9 mL/hr, the no flow period halves - i.e., 5 seconds at a rate of 0.8 mL/hr. The no flow period will be less than or equal to 0.038 seconds for rates above 100 mL/hr.

The device will operate within the specified accuracy when subjected to static back pressures of 5.8 psi (+300 mm Hg) to -1.9 psi (-100 mm Hg). The device will deliver with a maximum

drop-off of less than or equal to 1% incremental change per psi with up to the maximum operating back pressure of 15 psi (775 mm Hg).

Environmental criteria for the operation of the Baxter pump are 59°F to 100°F; 20% to 95% relative humidity, non-condensing; 700 hPa to 1060 hPa air pressure.

The marketed product will meet the requirements of the following standards:

- UL 2601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 601-2-24, Biological Evaluation of Medical Devices
- IEC 601-1-2, Medical Electrical Equipment, Part 1.
- NFPA 99. Standard for Health Care Facilities, National Fire Protection Association, dated 02/12/93, ANSI/NFPA

It will also meet the requirements of applicable portions of the following standards:

- Electromagnetic Compatibility Standard for Medical Devices, MDS-201-0004
- Electromagnetic Emissions and Susceptibility Requirements for the Control of Electromagnetic Interference, MIL-STD-461C
- Limits and Methods of Measurement of Radio Interference Characteristics of Industrial, Scientific and Medical (ISM) Radio-Frequency equipment (excluding surgical diathermy apparatus), CISPR 11
- Electromagnetic Compatibility for Industrial Process Measurement and Control Equipment, IEC 801-1
- Electrostatic Discharge Requirements, IEC 801-2
- Radiated Electromagnetic Field Requirements, IEC 801-3
- Electrical Fast Transient/Burst Requirements, IEC 801-4
- Radio Interference Suppression of Radio Frequency for Equipment for Industrial, Scientific, and Medical and Similar Purposes, VDE 0871

Summary of Technological Characteristics of New Device to Predicate Devices

A table, comparing the Baxter Volumetric Infusion Pump to predicate devices is attached.

APR 3 0 1996

787

Discussion of Non Clinical Tests; Conclusions Drawn from Nonclinical Tests

Blood hemolysis testing was performed on aged packed red blood cells using an infusion pump with a shuttle mechanism similar to the one used for the proposed volumetric infusion pump. Aged packed red blood cells were tested because our previous experience with infusion pump indicates that they represent the worst case scenario relative to possible hemolysis. The results range from a low of 0.0000% to a high of 0.114% hemolysis.

Accuracy data was generated in accordance with the testing methodology defined by the IEC 601-2-24 standard.

Comparison of the Baxter Multichannel Volumetric Infusion Pumps to Other Large Volume Infusion Pumps

Feature	BAXTER Colleague™ 2	BAXTER Colleague™ 3	BAXTER Colleague™	BAXTER Flo-Gard® 6301
Pump Mechanism	Shuttle	Shuttle	Shuttle	Linear Peristaltic
Number of Channels	2	3	1	2
Set Used	Standard Baxter "s" Sets	Standard Baxter "s" Sets	Standard Baxter "s" Sets	Standard Baxter "s" Sets
Rate Range (mL/hr)	0.1 - 99.9 1.0 - 1,200	0.1 - 99.9 1.0 - 1,200	0.1 - 99.9 1.0 - 1,200	1.0 - 99.9 1.0 - 1,999
VTBI (mL)	0.1 - 9,999	0.1 - 9,999	0.1 - 9,999	1 - 9,999
Adjustable Maximum Rate Limit	●	●	●	●
Adjustable Maximum VTBI	●	●	●	●
Source Containers				
Bags	●	●	●	●
Bottles	●	●	●	●
Syringes	●	●	●	○
Stated Accuracy	≤ 10% at rates less than 1.0 mL/hr; ≤ ± 5% otherwise	≤ 10% at rates less than 1.0 mL/hr; ≤ ± 5% otherwise	≤ 10% at rates less than 1.0 mL/hr; ≤ ± 5% otherwise	≤ ± 10%
Motor Resolution	3414 parts per cc	3414 parts per cc	3414 parts per cc	4000 parts per cc
Air-in-line Detection	● 4 Settings	● 4 Settings	● 4 Settings	● 2 Settings
Upstream Occlusion	●	●	●	●
Occlusion Pressure	Minimum, Moderate, Maximum, Rate Dependent 2 PSI - 15 PSI	Minimum Moderate Maximum, Rate Dependen: 2 PSI - 15 PSI	Minimum, Moderate, Maximum, Rate Dependent 2 PSI - 15 PSI	7 - 17 PSI Adjustable to 7, 12, 17 PSI

● Available
○ Not Available
- Unknown

APR 3 0 1996

789

Feature	BAXTER Colleague™ 2	BAXTER Colleague™ 3	BAXTER Colleague™	BAXTER Flo-Gard® 6301
Auto Restart	●	●	●	●
Free Flow Protection	●	●	●	●
RS232	●	●	●	●
Computer Monitoring	●	●	●	●
Computer Control	○	○	○	●
Pump Configuration Utility	●	●	●	●
Panel Lockout	●	●	●	●
Set Removal Lockout	●	●	●	○
Automatic Piggybacking	●	●	●	●
Flow Check	●	●	●	●
Adjustable Alarm/Alert Intervals	●	●	●	●
Secondary Complete Alert	●	●	●	●
Blood Infusion	●	●	●	●
Epidural Infusion	●	●	●	●
Event Recorder	●	●	●	○
Change Rate while running	●	●	●	●
Power Sources	Internal Rechargeable	Internal Rechargeable	Internal Rechargeable	Internal Rechargeable
Back Light	●	●	●	●
Battery Life Indicator	●	●	●	○
Battery Capacity	5 hr at 100 mL/hr	4 hr at 100 mL/hr	5 hr at 100 mL/hr	6 hr at 1400 mL/hr
Multdirectional Pole Clamp	○	○	●	○
Automatic Tube Loading	●	●	●	○
Tube Misload Detection	●	●	●	●

● Available
○ Not Available
- Unknown

APR 3 0 1996

Feature	BAXTER Colleague™ 2	BAXTER Colleague™ 3	BAXTER Colleague™	BAXTER Flo-Gard® 6301
Infusion Modes				
mL/hr	●	●	●	●
mg/hr	●	●	●	○
mg/kg/hr	●	●	●	○
mcg/hr	●	●	●	○
mcg/kg/hr	●	●	●	○
units/hr	●	●	●	○
units/kg/hr	●	●	●	○
mcg/m^2 /hr	●	●	●	○
mg/min	●	●	●	○
mg/kg/min	●	●	●	○
mcg/min	●	●	●	○
mcg/kg/min	●	●	●	○
units/min	●	●	●	○
units/min	●	●	●	○
mcg/m^2 /hr	●	●	●	○
units/m^2 /hr	●	●	●	○
Volume - Time	●	●	●	●
Ramping	●	●	●	●
KVO (mL/hr)	0.1 - 5	0.1 - 5	0.1 - 5	1.0 - 5.0
Device Diagnostics	●	●	●	●
Label Library	●	●	●	○
Drop Sensor	● Optional	● Optional	● Optional	○
Volume History	●	●	●	●
Nurse call Via External Adapter	●	●	●	●
12 VDC External Cable Connector (accessory)	●	●	●	○
Pump Personality	●	●	●	○

● Available
○ Not Available
- Unknown

s:\510k\...\SMDA

APR 3 0 1996

791