McGaw, Inc.
2525 McGaw Avenue
P.O. Box 19791
Irvine, California 92623-9791
Telephone: 714.660.2000
Fax: 714.660.2700
510(k) Summary

McGaw

Oct. 7, 1997

510(k) Summary

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92."

"The assigned 510(k) number is: K972678 ."

1. Submitter Information

McGaw, Inc.
2525 McGaw Avenue
P.O. Box 19791
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Contact Person: John G. D'Angelo, M.S., R.Ph.
Director
Regulatory Affairs
Phone: (714) 660-2517
FAX: (714) 660-3292

2. Name of Device

Trade/Proprietary Names:	Millennium CRT™ Infusion Pump and Millennium CRT™ Infusion Pump Administration Sets
Common/Usual Names:	External Infusion Pump I.V. Administration Sets Blood Administration Sets Enteral Administration Sets
Classification Names:	Pump, Infusion Set, Administration, Intravascular Set, Blood Transfusion Set, Enteral Administration

3. Predicate Device

The predicate pump device that McGaw is claiming substantial equivalence to is the Flo-Gard® 6201 Volumetric Infusion Pump marketed by Baxter Healthcare Corporation. The Flo-Gard® 6201 Pump is an electrical, external, single channel, linear peristaltic, volumetric infusion pump. The predicate set devices that McGaw is claiming substantial equivalence to are standard Baxter solution administration sets intended for use with the Flo-Gard® 6201 Pump. McGaw is also using our currently marketed 510(k) cleared standard gravity and pump I.V. administration sets as additional predicate set devices.

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The Flo-Gard® 6201 Volumetric Infusion Pump is marketed by Baxter under their cleared 510(k) K915522. The Flo-Gard® 6201 was introduced by Baxter as an upgrade to their Flo-Gard® 6200 Volumetric Infusion Pump. The following 510(k)s covered the Flo-Gard® 6200 pump: K860162, K870801 and K913895. The standard Baxter solution administration sets are marketed under many Baxter cleared 510(k)s, including K924721 and K921703. The McGaw standard gravity and pump I.V. administration sets are marketed by McGaw under cleared McGaw 510(k)s K941244, K931377, K922637, K921860, K913661, K904518, K896292, K860157, K840248, K840212 and K820133.

4. Description of the Subject Device

The subject devices include an electrical, external, linear peristaltic, volumetric infusion pump called the Millennium CRT™ Infusion Pump and administration sets called the Millennium CRT™ Infusion Pump Administration Sets. The Millennium CRT™ Infusion Pump can only be used with the Millennium CRT™ Infusion Pump Administration Sets. The Millennium CRT™ Infusion Pump Administration Sets do not contain a dedicated cassette. However, these sets do contain a free-flow clip that is a special slide clamp that interfaces with the pump. The Millennium CRT™ pump will not function as intended without the Millennium CRT™ sets. The Millennium CRT™ sets can be used either with the pump for pump infusion or without the pump for gravity infusion.

The system created by using the Millennium CRT™ Infusion Pump Administration Set with the Millennium CRT™ Infusion Pump is intended to provide accurate and continuous flow of parenteral and enteral fluids to the patient. The pump is software controlled and operates using linear peristaltic crushing action against a straight piece of plastic tubing threaded through the pump mechanism. The system detects occlusions in the patient line downstream.

The Millennium CRT™ Infusion Pump Administration Sets are sterile single use devices. The sets are composed of a straight piece of standard tubing, a free-flow clip and various combinations of other standard I.V. set components including filters, check valves, spikes, drip chambers, injection sites (standard needle injection sites and needle free injection sites such as the SafeLine® pre-slit septum injection site and the Clave® Connector luer activated injection site), clamps, measured volume burets, caps or protectors, and luer connectors. All of these standard set components are used in McGaw's currently marketed 510(k) cleared standard gravity and pump I.V. administration sets. The administration set components are welded or bonded and assembled using current McGaw manufacturing procedures to form the completed sets.

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The Millennium CRT™ Infusion Pump Enteral Administration Set is a non-sterile single use device. This enteral administration set is composed of standard administration set components including a straight piece of standard tubing, a free-flow clip, luers, and a drip chamber. The enteral set also includes a pre-attached enteral fluid bag.

The infusion pump contains the following hardware subassemblies: linear peristaltic mechanism assembly, power supply assembly, pole clamp assembly, air-in-line detector assembly, free-flow receptacle assembly, display assembly, and electronics assembly. The linear peristaltic mechanism assembly contains additional subassemblies for downstream occlusion detection. The power supply assembly includes two identical NiMH (Nickel Metal Hydride) batteries. One battery is permanently mounted inside the pump; whereas, the other battery is optional and can be inserted or removed by the user as required to provide additional battery capacity.

5. Intended Use of the Subject Device

The Millennium CRT™ Infusion Pump and Millennium CRT™ Infusion Pump Administration Sets create an infusion system intended for parenteral and enteral administration. This includes, but is not limited to standard I.V. fluids (large volume parenterals and small volume parenterals), blood, blood components, nitroglycerin, Total Parenteral Nutrition (TPN), lipids, enteral fluids, I.V. drugs such as paclitaxel and other chemotherapeutic agents, and epidural administration of anesthetic and analgesic drugs. The pump is capable of drawing fluid from containers or syringes and administering the fluid to a patient through the administration set.

The Millennium CRT™ Infusion Pump Administration Sets can also be used as stand-alone devices without the Millennium CRT™ Infusion Pump. When used without the Millennium CRT™ Infusion Pump, the Millennium CRT™ Infusion Pump Administration Sets are also intended for parenteral and enteral administration. However, administration of these fluids is accomplished through gravity infusion. When used for gravity infusion, these sets may be used for administration of standard I.V. fluids (large volume parenterals and small volume parenterals), blood, blood components, lipids, nitroglycerin, TPN, I.V. drugs including paciltaxel and other chemotherapeutic agents, and enteral fluids.

The Millennium CRT™ pump and associated administration sets are intended for, but are not limited to use in the hospital, home care and/or nursing home (extended care) settings. The Millennium CRT™ Infusion Pump is intended for use by trained healthcare providers in accordance with the instructions provided in the Operation Manual. All data entry and

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validation of the Millennium CRT™ Infusion Pump is performed by the trained healthcare provider per a physician's order.

6. Technological Characteristics of the Subject Device

The subject devices, the Millennium CRT™ Infusion Pump and the Millennium CRT™ Infusion Pump Administration Sets, are substantially equivalent to the predicate devices, Baxter's currently marketed Flo-Gard® 6201 Volumetric Infusion Pump, standard Baxter solution administration sets intended for use with the Flo-Gard® 6201 Pump, and McGaw's currently marketed 510(k) cleared standard gravity and pump I.V. administration sets. The subject and predicate devices are similar in design, material composition, components, manufacturing process, intended use and labeling. There are technological differences between the subject devices and the predicate devices. However, these differences do not raise new issues of safety and effectiveness. The substantial equivalence claim between the subject devices and the predicate devices is supported by the information and data contained in this 510(k) submission. This includes the following items:

- Description of the subject devices and predicate devices.
- Intended use of the subject devices and predicate devices.
- Material composition of the subject devices and predicate devices.
- Labels and labeling for the subject devices and predicate devices.
- Comparison tables of attributes and specifications for the subject devices and predicate devices.
- Subject device customer functional specification.
- Subject device system and software hazard analysis.
- Subject device system and software requirements.
- Subject device system and software test plans.
- Subject device system and software test protocols.
- Subject device system and software test matrix.

7. Signature of Applicant:

McGaw, Inc.
John D'Angelo, M.S., R.Ph.
Director
Regulatory Affairs

Signature

7-14-97

Date

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Rebecca Stolarick
Section Manager Regulatory Affairs
McGaw, Incorporated
2525 McGaw Avenue
Irvine, California 92714-5895

OCT - 7 1997

Re: K972678
Trade Name: Millennium CRT™ Infusion Pump and
Millennium CRT™ Infusion Pump Administration Sets
Regulatory Class: II
Product Code: FRN
Dated: July 14, 1997
Received: July 16, 1997

Dear Ms. Stolarick:

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. 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), promotion, or advertising, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. 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 at (301) 443-6597.

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

Enclosures

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Indications For Use Statement

510(k) Number (if known):

Device Name: Millennium CRT™ Infusion Pump and Millennium CRT™ Infusion Pump Administration Sets

Indications For Use:

The Millennium CRT™ Infusion Pump and Millennium CRT™ Infusion Pump Administration Sets create an infusion system intended for parenteral and enteral administration. This includes, but is not limited to standard I.V. fluids (large volume parenterals and small volume parenterals), blood, blood components, nitroglycerin, Total Parenteral Nutrition (TPN), lipids, enteral fluids, I.V. drugs such as paclitaxel and other chemotherapeutic agents, and epidural administration of anesthetic and analgesic drugs. The pump is capable of drawing fluid from containers or syringes and administering the fluid to a patient through the administration set.

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(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Coverage of CDRH, Office of Device Evaluation (ODE)
510(k) Number K972678

Prescription Use X Over-The-Counter Use 3

(Per 21 CFR 801.109)