

SEP 3 0 2002

K023062

Special 510(k): Device Modification  
Abbott GemStar® Infusion Pump System  
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**510(k) SUMMARY**  
**Abbott GemStar® Infusion Pump System**

**Submitted by:**

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Abbott Park, IL 60064

**Date Prepared:**

September 13, 2002

**Name/Classification of Device:**

Infusion Pump, Class II  
80 FRN – 21 CFR Part 880.5725

Intravascular Administration Set  
80 FPA – 21 CFR Part 880.5440

**Proposed Device:**

Abbott GemStar® Infusion Pump System

**Predicate Device:**

Abbott GemStar™ I.V. Infusion Pump

**Proposed Device Description:**

The Abbott GemStar® Infusion Pump can function as both a pole-mounted and an ambulatory infusion pump and it is intended for use in hospital, ambulatory and home care environments. All GemStar® pumps are single channel pumps and they are offered for sale in the following configurations:

<b>Overview of GemStar Infusion Pump Therapies and Configurations</b>		
<b>7 Therapy Pump</b>	<b>6 Therapy Pump</b>	<b>Pain Management Pump</b>
List #: 13000-04-05	List #: 13100-04-05	List #: 13150-04-05
TPN (Total Parenteral Nutrition)	TPN (Total Parenteral Nutrition)	Pain Management Only
Pain Management	Intermittent	
Intermittent	Continuous	
Continuous	Weight Dosed	
Weight Dosed	mL/hr Only	
Variable Time	Variable Time	
mL/hr Only		

The Abbott GemStar® Infusion Pump is an electromechanical infusion pump that functions on a volumetric, piston driven, fluid displacement principle. The pump delivers I.V. fluids through an intravenous administration set that is also manufactured and distributed by Abbott Laboratories. The sets are described as “GemStar Pump Sets” because they are dedicated for use in this system.

The user interface of the infusion pump allows the healthcare practitioner to program fluid delivery through a variety of weight and medication based units including grams, micrograms, milliliters and other units per specified time interval.

The display on the pump provides visible indication of multiple functions including active pump operations, alarm and program status and the parameters of fluid flow. The pump can also be used for standard or piggyback fluid delivery.

The administration set incorporates integral, set-based free flow protection through a flow stop cassette and other free flow protection measures such as a roller or slide clamp, and an anti-siphon valve. The pump includes a check cassette software function in all modes. Lastly, the labeling for both the sets and the user manual has been revised to highlight these features.

#### **Statement of Intended Use:**

The Abbott GemStar<sup>®</sup> Infusion Pump is intended for use in intravenous, arterial, short-term epidural, and parenteral administration of general I.V. fluids, medications, nutritional fluids, and blood/blood products to patients in hospital and home care environments.

This is the same intended use as the predicate device.

The pump must be used with sterile, dedicated, intravenous GemStar<sup>®</sup> administration sets.

#### **Summary of Technological Characteristics of the New Pump and Sets Compared to Predicate Devices**

The proposed pump and sets have similar designs, materials of construction, components, labeling and manufacturing processes as the currently marketed Abbott GemStar<sup>™</sup> Infusion Pump and New Wave sets.

Abbott proposes to modify the predicate device through minor changes to the mechanical parts, modifying and enhancing the software to incorporate changes requested by users, adapting the existing sets for use with an anti-siphon valve and revising the labeling to reflect the proposed changes.

These differences do not raise new issues of safety and effectiveness nor do they alter the fundamental technology of the predicate device.

**Discussion and Conclusions from Nonclinical Tests:**

Data regarding the functional performance of the proposed Abbott GemStar<sup>®</sup> Infusion Pump and sets has been generated and reviewed.

The results of testing conducted to validate and verify the design modifications demonstrate acceptable performance of the device.



SEP 30 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Frank Pokrop  
Associate Director, Regulatory Affairs  
Abbott Laboratories  
Hospital Products Division  
200 Abbott Park Road  
Dept. 0389, Building J-45  
Abbott Park, Illinois 60064-6133

Re: K023062

Trade/Device Name: Abbott GemStar® Infusion Pump System

Regulation Number: 880.5725

Regulation Name: Infusion Pump

Regulatory Class: II

Product Code: FRN

Dated: September 13, 2002

Received: September 16, 2002

Dear Mr. Pokrop:

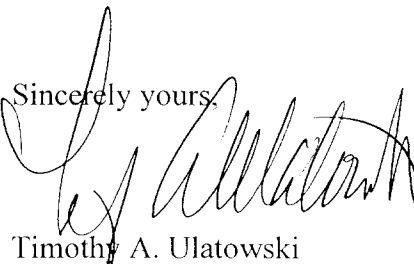
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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 Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

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510(k)  
Number  
(if known)

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Device Name: Abbott GemStar® Infusion Pump System

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Indications For Use: The Abbott GemStar® Infusion Pump System has the following indications for use:

The Abbott GemStar® Infusion Pump is intended for use in intravenous arterial, short-term epidural, and parenteral administration of general I.V. fluids, medications, nutritional fluids, and blood/blood products to patients in hospital and home care environments.

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)

Prescription Use    
(per 21 CFR 801.109)

OR Over-The-Counter Use

*Nick Hubbard for Pat Cicchetti*  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

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