# 5 510(k) SUMMARY

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| **1. Submitted by:** | Hospira, Inc.<br>D-389 Bldg. H2<br>275 N. Field Drive<br>Lake Forest, IL 60045<br>Contact: Yuliya Matlin | Phone :( 224)212-4857<br>Fax: (224) 212-5401 |
| **2. Date Prepared:** | August 11, 2008 | |
| **3. Name/Classification of Device:** | Infusion Pump, Class II<br>80 FRN – 21 CFR Parts 880.5725<br>Administration Sets, Class II<br>80-FPA -21 CFR Parts 880.5725 | |
| **4. Trade Name of Proposed Device:** | GemStar™ SP Infusion System with<br>GemStar™ SP Infusion Suite software | |
| 5. **Predicate Devices:** | Hospira GemStar® Infusion Pump System (K060806)<br>LifeCare PCA ® Infusion System with Hospira MedNet™ Software (K042800) | |

**6. Proposed Device Description:**

GemStar™ SP Infusion System is a family of single channel electromechanical infusion pumps (7-therapy, 6-therapy and Pain Management Pumps). It operates on a volumetric, piston driven, fluid displacement principle. An in-line cassette is used to meter IV fluids through sterile dedicated administration sets designed to be used exclusively with GemStar® infusers. The pumps display provides visible indication of several functions, including active pump operations, alarms, program status and the parameters of fluid flow. The user interface allows the healthcare practitioner to program fluid delivery through a variety of weight and medication based units. Power options include AC main adaptors, a rechargeable battery pack, a docking station, and two disposable AA batteries. The infusers function as both pole mounted and ambulatory infusion pumps.

The subject device is based on modifications of the predicate infusion pumps. The modifications to the Hospira GemStar® Infusion System are made to allow for download of the Infusion Suite to the pump from the PC –based software (GemStar™ SP Infusion Suite) in order to facilitate the programming of the pump and to provide the ability to enforce dosing limits for applicable therapies. GemStar™ SP Infusion Suite software will be distributed separately as an accessory to the pump. No changes are made to the pump performance specifications or to the administration sets used with the pump.

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**7. Statement of Intended Use:**

GemStar™ SP Infusion System with GemStar™ SP Infusion Suite software is intended for use in intravenous, arterial, subcutaneous, short term epidural infusion and parenteral administration of general I.V. fluids, medications, nutritional fluids and blood/blood products.

The indications for use of the subject device are identical to the predicate Hospira GemStar® Infusion Pump System cleared under K060806.

**8. Summary of Technological Characteristics of New Device Compared to Predicate Device**

The subject and predicate devices are similar in design, materials of construction, components, intended use, labeling and manufacturing processes.

**9. Statement of Substantial Equivalence**

GemStar™ SP Infusion System with GemStar™ SP Infusion Suite is substantially equivalent to the predicate devices identified in the submission based on the following similarities:

Infuser similarities to Hospira GemStar® Infusion Pump System:

1. Same Intended Use and Indications for Use
2. Same fundamental scientific technology
3. Same physical operational and performance specifications
4. Same materials of construction for all infuser components

Software application similarities to LifeCare PCA® Infusion System with Hospira MedNet™ software:

1. Similar concept of the protocol download from GemStar™ SP Infusion Suite PC application to the GemStar™ SP Infuser as from the Hospira MedNet™ application to LifeCare PCA® Infuser.

The proposed modifications do not raise new issues of safety and/or effectiveness. GemStar™ SP Infusion System with GemStar™ SP Infusion Suite meets the functional claims and intended use as described in product labeling and is as safe and effective in terms of substantial equivalence as the predicate devices described in the submission.

The claim for substantial equivalence is supported by the information provided in the 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2008

Hospira, Incorporated
C/O Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K083019
Trade/Device Name: GemStar™ SP Infusion System with GemStar™ SP Infusion Suite Software
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: October 9, 2008
Received: October 9, 2008

Dear Mr. Devine:

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division 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

510(k) Number (if known) K983919

**Device Name:** **GemStar™ SP Infusion System with GemStar™ SP Infusion Suite software**

**Indications for Use:**

The GemStar™ SP Infusion System with GemStar™ SP Infusion Suite software is intended for use in intravenous, arterial, subcutaneous, short term epidural infusion and parenteral administration of general I.V. fluids, medications, nutritional fluids and blood/blood products.

The indications for use include hospital, ambulatory and home care environments. The pump must be used with sterile, dedicated, GemStar® administration sets.

**Prescription Use** X **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

**(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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