

4-6-99

K990091

510(k) SUMMARY

1. **Classification Name:** Infusion Pump, Accessory or Piston Syringe
2. **Common Name:** Medication Reservoir
3. **Proprietary Name:** S.P.A.R.TM Sterile Ambulatory Reservoir
4. **Classification:** Class II
5. **Predicate Device:** SIMS Deltec Medication CassetteTM (K843772)
6. **Description of the Device:**

The S.P.A.R.TM Sterile Ambulatory Reservoir is a sterile, disposable, non-pyrogenic, tamper proof (evident), ambulatory, reservoir system designed for use with the SIMS Deltec CADD-PCA[®] Model 5800 and CADD-Prizm[®] Model 6100 infusion pumps.

7. **Intended Use:**

The S.P.A.R.TM Ambulatory Reservoir is intended for use as an accessory to the SIMS Deltec CADD-PCA[®] Model 5800 and CADD-Prizm[®] Model 6100 infusion pumps by replacing the Deltec Medication CassetteTM, Model 2050 - 50 mL and 2100 - 100 mL with S.P.A.R.TM Sterile Ambulatory Reservoir.

The use of the S.P.A.R.TM Ambulatory Reservoir as an accessory to the SIMS Deltec CADD-PCA[®] Model 5800 infusion pump was previously studied and approved for marketing by the FDA on July 18, 1997 (510(k) - K962159). The current 510(k) - 990091, covers studies and information on the SIMS Deltec CADD-Prizm[®] Model 6100 infusion pump.

8. **Technological Characteristics:**

The S.P.A.R.TM Sterile Ambulatory Reservoir uses similar technology to that found in the SIMS Deltec Medication CassetteTM. In both cases, the pump platform and tubing components are in communication with the pump in the same manner.

9. Substantial Equivalence:

The SIMS Deltec CADD-Prizm® Model 6100 infusion pump operates when coupled with either its original SIMS Deltec reservoir, or the S.P.A.R.™ Sterile Ambulatory Reservoir. In both cases the pumping principle is the same, with flow occurring as a series of fixed volume pulses, where pulse frequency determines the nominal flow rate.

Pulse frequency is controlled electronically to a high level of accuracy, whereas, pulse volume, or stroke displacement, as it is more correctly termed, is subject to variation and is the major determinant of flow rate accuracy.

The study carried out, therefore, identified statistically significant factors affecting stroke displacement from both the original Deltec reservoir and the S.P.A.R.™ reservoir when coupled with the Deltec CADD-Prizm® Model 6100 infusion pump. The factors investigated were temperature, back pressure in the delivery line, fluid viscosity, magnitude of flow rate, and reservoir type.

10. Conclusion Based on Non-Clinical Test:

Measured stroke displacement data established the equivalence of the two reservoirs in that both are affected by the same factors in a similar manner. Reducing temperature from 40°C to 2°C reduces the stroke displacement in both S.P.A.R.™ and Deltec reservoirs. Changing fluid viscosity from 0.9% Sodium Chloride Injection USP to 30% Dextrose Injection, USP does not affect stroke displacement in either reservoir. Increasing back pressure from -100 mmHg to 300 mmHg reduces stroke displacement in both reservoirs. Increasing flow rate from 0.1 mL/hr to 30 mL/hr increases stroke displacement in both reservoirs. Thus, the S.P.A.R.™ reservoir can be considered substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 1999

Dr. Heike Maaser
Faulding Pharmaceutical Company
11 Commerce Drive
Cranford, New Jersey 07016

Re: K990091
Trade Name: S.P.A.R Sterile Ambulatory Reservoir
Regulatory Class: II
Product Code: MRZ
Dated: January 8, 1999
Received: January 11, 1999

Dear Dr. Maaser:

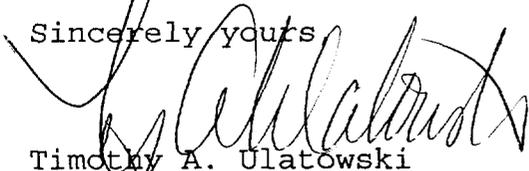
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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 (if known): _____

Device Name: S.P.A.R.™ Sterile Ambulatory Reservoir

Indications For Use:

The S.P.A.R.™ Sterile Ambulatory Reservoir is intended for use with the Sims Deltec CADD-PCA® Model 5800 and CADD-Prizm® Model 6100 Ambulatory Infusion Pumps, manufactured and distributed by Sims Deltec Inc., St. Paul, Minnesota. The S.P.A.R.™ Ambulatory Reservoir is intended for use as an accessory to the Sims Deltec CADD-PCA® Model 5800 and CADD-Prizm® Model 6100 infusion pumps by replacing the Deltec Medication Cassette™, Model 2050 - 50 mL and 2100 - 100 mL with S.P.A.R.™ Sterile Ambulatory Reservoir.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

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

Rafaela Cuente
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K 990091