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 807.87.

1. **NAME OF SUBMITTER, CONTACT PERSON AND DATE SUMMARY PREPARED:**

Name:	Gaymar Industries, Inc.
Address:	10 Centre Drive Orchard Park, NY 14127
Telephone:	800-828-7341
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Official Contact:	Pradeep Gupta Corporate Manager, QA/RA
Date Prepared:	August 11, 2006

2. **DEVICE TRADE NAME AND COMMON NAME:**

Trade Name:	Medi-Temp III, Model FW600
Common/Usual Name:	Sterile Fluid Path, in-line Blood Fluid Warmer
Classification Name:	Warmer, Thermal, Infusion Fluid

3. **PRODUCT CODE:** 80 KZL, Class II
Prior Code: LGZ, unclassified

4. **LEGALLY MARKETED EQUIVALENT DEVICE:**

The predicate device is manufactured by the Submitting manufacturer, Gaymar Industries, Inc. and is the Medi-Temp II, Model FW300 (formerly the Dupaco Counterflo 300), cleared under BK950038.

5. **PERFORMANCE STANDARDS:**

None

6. **DESCRIPTION OF THE DEVICE:**

The Medi-Temp III, FW600 is intended to warm blood or plasma, prior to administration to maintain normothermic temperatures. This warming is accomplished with dry heat applied inside the warmer to Gaymar's disposable blood/fluid warming sets connected to the fluid infusion circuit.

7. **INTENDED USE OF THE DEVICE:**

The Medi-Temp III is intended to aid in the prevention of inadvertent hypothermia during administration of blood, blood products, and other fluids.

8. **COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE:**

CHARACTERISTIC	Predicate, FW300	Proposed, FW600
MODEL	FW300	FW600
INTENDED USE	Same	Same
POWER SWITCH	On/Off	On/Standby
TEMPERATURE DISPLAY	LED	LED
HEAT PLATES	Two aluminum, 500 watts	Two aluminum, 500 watts
MICROCONTROLLER	Outsourced	In-house
TEMPERATURE CONTROL	RTD	NTC Thermistor
BACK UP SENSOR	Yes	Same
ALARMS	Audio/Visual	Audio/Visual
SETPOINTS	38.5°C	38.0-43.0°C

The Medi-Temp III FW600 has the same intended use and very similar technological characteristics, performance features, and as the Model FW300. The minor technological differences between these devices do not raise any new safety or effectiveness issues.

9. **DISCUSSION OF NON-CLINICAL STUDIES:**

Testing was performed in align with requisite design controls. The performance testing of the FW600 included verifying the ability of the system to warm cold fluids and room temperature fluids to normothermic temperature, and verifying the ability of the system to detect and alarm at unsafe or ineffective operating conditions.

10. **CONCLUSION:**

Design changes were verified and validated, change rationale was documented, and substantial equivalency was demonstrated in align with the predicate device.
The modifications to FW600 do not raise any new safety or effectiveness issues.