Summary of Safety and Effectiveness Information (BK990018)

The following information is furnished in accordance with 21 CFR 807.92(a):

1. Submitter's name and address:

   Infra-Med Technologies, Inc.
   5580 Peterson Lane, Suite 200
   Dallas, Texas 75240

2. Submitter's telephone number: (972) 980-9300

3. Contact person: Mr. Bertram J. Hudson

4. Date this 510(k) summary prepared: September 21, 1999

5. Trade/proprietary name of the device: Hot Shot™ Fluid Warmer

6. Classification name of the device:

   Non-electromagnetic blood and plasma warming device: For the intended use labeling claim of, *"warm blood and blood products"*.

7. Legally marketed predicate device to which substantial equivalence is claimed: Baxter Healthcare Corporation ThermaCyl™ Blood/Fluid Warmer

8. Description of the device that is the subject of this premarket notification:

   The device incorporates a heated sterile/non-pyrogenic fluid path to warm the indicated fluids. Fluid temperature, visual alarms, audible alarms, and device performance is controlled electronically. The device is lightweight, portable, and operates from 110 VAC, 240 VAC, vehicle electrical service of 12/24 VDC, or battery pack.

9. Indications for use:

   "Warm blood and blood products"

10. Technological characteristics: The device is electrically powered from 120 VAC 60HZ, 240 VAC 50 HZ, 12/24 VDC (emergency and other vehicles), or portable battery pack.

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The temperature of the infused fluids, visual and audible alarms, and other performance characteristics of the device are controlled electronically. The composition of the fluid path is a latex free proprietary material that is compatible with the method of sterilization, and is non-pyrogenic.

510(k) Summaries for those submissions in which a determination of substantial equivalence is also based on performance data shall also contain the following information in accordance with 21 CFR 807.92(b):

11. Non-clinical: Brief discussion of the non-clinical tests submitted, referenced, or relied upon in this submission:

The relationship between the temperature of the indicated fluid(s) versus the time required to warm the fluid(s) was determined as a function of the initial starting temperature of the indicated fluid(s). These non-clinical test results indicate the candidate device is capable of warming the temperature of the infusion fluid by 30°F (15 °C) within two (2) minutes at a flow rate of 1000 milliliters per hour. The device also complies with the relevant requirements of:

- ISO 11135-1994, Medical Devices, Validation and Routine Control of Ethylene Oxide Sterilization; SAL 10^{-6}
- ISO 11137-1994, Sterilization of Health Care Products, Requirements for Validation and Routine Control, Radiation Sterilization; SAL 10^{-6}
- ISO 10993, Biological Evaluation of Medical Devices
- 47 CFR 15, Radio Frequency Devices
- UL 2601-1, Underwriter Laboratories, Medical Electrical Equipment, Part 1, General Requirements for Safety
- IEC 60101-1, Medical Electrical Equipment, Part 1, General Requirements for Safety
- American Association of Blood Bank Standards for Blood Banks and Transfusion Services

12. Published literature: Studies indicate the clinical utility of warming fluids for infusion in humans is, among others:

- Minimize redistribution of heat from central core to periphery

tissues during general anesthesia: Matsukawa T., Sessler DI, Sessler AM, et al. Heat Flow and Distribution During Induction of General Anesthesia. Anesthesiology 82:662-73, 1995.

- Reducing the incidence of surgical wound infection and decreasing duration of hospitalization: Kurz A, Sessler DI, et al: Mild Perioperative Hypothermia Increases the Incidence of Surgical Wound Infections and the Duration of Hospitalization in Patients Undergoing Colon Resection. N. Engl Med 334: 1209-1215, 1996.

- Reducing the susceptibility to infectious diseases from exposure to cold environments: Rodbard D: The Role of Regional Body Temperature in the Pathogenesis of Disease. N Engl J Med 305: 808-814, 1981.

- Reduction in allogenic blood requirements during total hip arthoplasty: Schmied H, Kurz A, et al: Mild Hypothermia Increases Blood Loss and Transfusion Requirements During Total Hip Arthoplasty. Lancet 347 (8997): 289-292, 1995.

.....END OF SUMMARY.....