

Baxter

Surgical Group

Baxter Healthcare Corporation
1500 Waukegan Road, Bldg. K
McGaw Park, Illinois 60085
USA

708.473.1500
FAX: 708.785.2460

14961154

SUMMARY OF SAFETY AND EFFECTIVENESS

Appendix F

JUN - 6 1996

Manufacturer: Baxter Healthcare Corporation
Surgical Group
Thermal Business Unit
808 Highway 24 West
Moberly, Missouri 65270

Regulatory Affairs Contact: Maryalice Smith
Surgical Group
1500 Waukegan Road
McGaw Park, Illinois 60085

Telephone: (847) 785-3322

Date Summary Prepared: February, 1996

Product Trade Name: Baxter Sodium Acetate Infant Heel Warmer™

Common Name: Infant Heel Warmer

Classification: Hot Disposable Pack

Predicate Device: Baxter Infant Heel Warmer™ (K950680)

Description: The Baxter Sodium Acetate Infant Heel Warmer™ is comprised of a polyethylene/BON pouch enclosing the phase change chemical and the activator disk-like trigger. Upon pinching and flexing trigger also located within the pouch, aluminum oxide grit is released into the sodium acetate and water mixture thus initiating a chemical exothermic reaction. The hot pack immediately reaches a maximum temperature of 104 °F +/- 2.9 °F and gradually diminishes over time.

Intended Use:

The Baxter Sodium Acetate Infant Heel Warmer™ is a single-use, non-sterile device. It is a heat therapy pack intended to be used on an infant's heel in order to increase peripheral blood flow and oxygenation prior to blood sampling.

Substantial Equivalence:

The Baxter Sodium Acetate Infant Heel Warmer™ is substantially equivalent to the Baxter Infant Heel Warmer™, PRISM Infant Heel Warmer and the RECOVER® Infant Heel Warmer in that:

- intended use is the same
- performance attributes are the same

Summary of Testing:

All materials used in the composition of this hot pack are evaluated through USP XXII/Sodium Acetate Solution and relevant tests identified in ISO Standard 10993. The outer pouch material was subjected to Skin Sensitization (Guinea pig Maximization), Primary Skin Irritation, and cytotoxicity testing. The materials were subjected to the following physical tests: material tensile strength width/length, side and top seal tensile strength, peak temperature, time at peak temperature, temperature at five minutes. The active chemical mixture was subjected to Primary Skin Irritation testing. This mixture was found to be non-toxic, food grade and toxicologically acceptable for its intended usage. This product is in compliance with established standards, where applicable, and was deemed acceptable for its intended use.