



Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, IL 60085
847.473.1500

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K970399

SUMMARY OF SAFETY AND EFFECTIVENESS
Appendix F

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

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

Telephone: (847) 785-3322

Date Summary Prepared: November, 1996

Product Trade Name: Allegiance Kwik Kold™ Peri Cold Pack

Common Name: Perineal Cold Pack

Classification: Cold and Hot Disposable Pack

Predicate Device: Allegiance Peri K™ Perineal Cold Pack

Description: The Allegiance Kwik Kold™ Peri Cold Pack is comprised of a multi layer pouch which is secured to a perineal pad and then wrapped in a one ply polyester material. The cold source pouch consist of ammonium nitrate and water. The water "bubble" is housed in a separate plastic pouch surrounded by ammonium nitrate. The perineal pad is made of a non-woven wrapped cellulose wood pulp fiber. Activation of the cold source occurs by folding and shaking the unit, thus resulting in a cooled solution from an endothermic reaction lasting approximately 30 to 35 minutes with a coldest temperature of approximately 33° F.

Intended Use: The Allegiance Kwik Kold™ Peri Cold Pack is an over-the-counter, single-use, non-sterile device. It is a cold therapy pack intended to be used post delivery to absorb postpartum lochea while providing cold therapy relieving edema and inflammation associated with an episiotomy incision.

Substantial Equivalence:

The Allegiance Kwik Kold™ Peri Cold Pack is substantially equivalent to the Allegiance Peri K™ Perineal Cold Pack, Jack Frost Perineal Cold Pack, Florida Medical Perineal Cool Comfort Pack, and Hospital Medical Services Peri + Plus Peri Cold Pack in that the:

- intended use is the same
- performance attributes are equal
- chemical composition is the same
- method of activation is the same
- coldest temperatures achieved are comparable

Summary of Testing:

All materials used in the composition of this cold pack are evaluated and tested as identified in ISO Standard 10993 Part 1. The materials were subjected to skin sensitization (guinea pig maximization), primary skin irritation and cytotoxicity testing. Physical tests performed include: coldest temperature, time at coldest temperature, and temperature at five minutes. The active chemical mixture was subjected to Primary Skin Irritation testing. This mixture was found to be toxicologically acceptable for its intended usage. This product is in compliance with established standards, where applicable, and was deemed acceptable for its intended use.