

Allegiance Healthcare Corporation
510(k) Notification Allegiance Kwik Heat™ Perineal Warm Pack
Thermal Business Unit

NOV 13 1997

K973770

ATTACHMENT F

**SUMMARY OF SAFETY &
EFFECTIVENESS**



Allegiance Healthcare Corporation

1500 Waukegan Road
McGaw Park, IL 60085
847.473.1500
FAX: 847.785.2461

K973770

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SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturer:	Allegiance Healthcare Corporation Thermal Business Unit 808 Highway 24 West Moberly, Missouri 65270
Regulatory Affairs Contact	Patricia Sharpe-Gregg 1500 Waukegan Road McGaw Park, Illinois 60085
Telephone:	(847) 578-3636
Date Summary Prepared:	September 26, 1997
Product Trade Name:	Allegiance Kwik Heat™ Perineal Warm Pack
Common Name:	Perineal Hot Pack
Classification:	Cold and Hot Disposable Pack
Predicate Device: (K970399) Preamendment	Allegiance Kwik Kold™ Peri Cold Pack Large Adult Hot Pack
Description:	The Allegiance Kwik Heat™ Perineal Warm Pack is comprised of an outer pouch which is secured to a perineal pad and then wrapped in a polyester material. The heat source pouch consists of a supercooled solution of sodium thiosulfate, dextrose and water. The sodium thiosulfate, dextrose and water "bubble" is housed in a separate plastic pouch inside the outer pouch. The perineal pad is made of a non-woven wrapped cellulose wood pulp fiber. Activation of the heat source occurs by folding the unit to open the inner bubble which releases the liquid, and kneading the unit, thus creating a physical exothermic reaction.



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Intended Use:

The Allegiance Kwik Heat™ Perineal Warm Pack is an Over-The-Counter, single-use, non-sterile device. It is a heat therapy pack intended to provide heat therapy for body surfaces. Additionally, this pack can be used post delivery to absorb postpartum lochia and provide therapeutic heat to relieve pain associated with an episiotomy incision.

Substantial Equivalence:

The Allegiance Kwik Heat™ Perineal Warm Pack is substantially equivalent to the Allegiance Kwik Kold™ Peri Cold Pack, the Jack Frost Perineal Pad (Warm), and the H.M.S.™ Peri Warm™ Perineal Pack in that the:

- intended use is the same
- performance attributes are the same
- method of activation is the same

The Allegiance Kwik Heat™ Perineal Warm Pack is substantially equivalent to the Allegiance Preamendment Small Hot Pack in that the:

- chemical composition is the same
- performance attributes of active chemical ingredients are the same.

Summary of Testing:

All materials used in the composition of this hot pack were identified, evaluated and tested as required in ISO Standard 10993 Part 1. The materials were subjected to skin sensitization, intracutaneous reactivity and cytotoxicity testing. Physical tests completed include: temperature performance testing. The active chemical mixture was subjected to primary skin irritation testing. This mixture was found to be toxicologically acceptable for its intended usage. The active chemical ingredient was tested as identified in the specifications of the Food Chemicals Codex, 3rd Ed. (1981), p. 304, which is incorporated by reference in the Code of Federal Regulations, 21 CFR 184.1807. Sodium Thiosulfate meets all food grade requirements. This product is in compliance with established standards, where applicable, and was deemed acceptable for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia Sharpe-Gregg
Manager, Regulatory Affairs
Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085

NOV 13 1997

Re: K973770
Allegiance Kwik Heat™ Perineal Warm Pack
Regulatory Class: I
Product Code: IMD
Dated: October 1, 1997
Received: October 2, 1997

Dear Ms. Sharpe-Gregg:

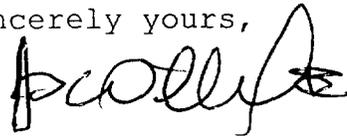
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 pre-market 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) 594-4659. 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,



f Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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510(k) Notification Kwik Heat™ Warm Perineal Pack
Thermal Business Unit
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510(k) Number (if known): Unknown

Device Name: Allegiance Kwik Heat™ Warm Perineal Pack

Indications For Use: Hot disposable pack intended for medical purposes that consists of a sealed plastic bag incorporating chemicals that, upon activation, provides hot therapy for body surfaces. Also used as a heat therapy pack with an absorbent perineal pad; for use post delivery to absorb lochea while relieving edema and inflammation associated with an episiotomy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
 (Per 21 CFR 801.109)

 Over-The Counter Use
 (Division **Sign-Off**)
 Division of General Restorations
 510(k) Number 12973770