

OCT 26 1998

K982636

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24 July, 1998

510(k) Summary of Safety and Effectiveness Information

Model No. / Name: **PW810 Patient Warmer**

Classification Name: Infrared Lamp - 89 ILY

Physical Medicine Devices, 21 CFR §890.5500 (Class II)

Predicate Devices: Aragona Medical, Thermal Ceiling OPN XII UL, K871179

Aragona Medical, Mobile Thermal Ceiling MTC XI UL, K871178

Fisher & Paykel Healthcare, IW910 Infant Warmer, K970432

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

(a)(1) - (a)(3) (refer to information above and concluding this summary)

(a)(4) Description of the Device

The PW810 Patient Warmer consists of a heater assembly and controller unit, with mounting pole and base sections.

The heater assembly includes a single rod infrared heating element housed inside a parabolic reflector. An observation lamp is mounted at the back of the heater unit. The heater can be rotated to either side of the warmer, away from the patient. A metal grill on the underside of the heater prevents contact with the element.

The controller unit supports the heater assembly, and contains the device electronics, control panel and labels. The front panel contains the control buttons, temperature displays, main power switch and temperature sensor socket. Controls include operating mode and temperature selection, and lamp operation. LED displays include indicators for operating mode, alarms, lamp, and heater power, with 3-digit temperature displays. The main label is located on the controller rear panel, and the power socket is mounted in the underside.

A single pole mounting system supports the controller unit, with two sections of stainless steel tubing providing a height adjustment option. A height indication scale is etched into the pole sections to enable optimum heater-to-patient distance to be set. The lower pole section is mounted into a stabilizer weight attached to a five-arm base unit, with casters which include foot-operated brake levers.

Accessories for the patient warmer include the skin temperature sensor probe and an accessory hook for IV bags or other small items.

510(k) Summary continued - Fisher & Paykel PW810 Patient Warmer

In Patient mode, the PW810 provides stable control of skin temperature by automatically adjusting the heater power to compensate for varying metabolic and environmental conditions. In Standby mode, power is maintained at a constant level of 25% ready for use.

A double-thermistor sensor probe measures the patient's skin temperature, and audible and visual alarms alert the user to high or low temperature situations, equipment fault, power failure and periodic reminders to reassess the patient's clinical condition. Independent safety features are included to control maximum output and avoid thermal injury to the patient.

(a)(5) Statement of the Intended Use

The Fisher & Paykel Healthcare PW810 is an Infrared Lamp, as per 21 CFR §890.5500. It emits energy at infrared frequencies to provide topical heating, and is used to provide thermal support for patients who have sustained or are susceptible to excessive or undesirable heat loss.

This may include use in pre- and post-operative environments, operating rooms, intensive care units, burns units and emergency departments. Situations requiring frequent intervention or unobstructed access to a patient, and those where injury precludes surface contact, may indicate a radiant warming source should be used.

(a)(6) Technological Characteristics Summary

The technological characteristics of the PW810 Patient Warmer are equivalent to those of the IW910 predicate device. There are no changes to the design, materials, energy source, performance or other aspects of the device which affect substantial equivalence.

(b)(1) Discussion of the Non-Clinical Tests

Testing for the PW810 has been carried out in the areas of mechanical, electrical and thermal safety, environmental conditions and electromagnetic compatibility, functional verification, temperature control, and irradiance distribution patterns. The device meets the requirements of the IEC 60601-1 and IEC 60601-1-2 standards, and the deviations relevant to the USA in UL 2601-1.

The device also meets applicable performance and safety requirements from the standard for Infant Radiant Warmers, IEC 60601-2-21, including temperature distribution and variance, accuracy of temperature control, and maximum irradiance levels for overall IR and near IR spectrum regions.

(b)(2) Discussion of the Clinical Tests

Clinical verification studies demonstrated the ability of the warmers to progressively warm up patients with reduced body temperature, and the ability to control the set temperature accurately for a stable situation.

510(k) Summary continued - Fisher & Paykel PW810 Patient Warmer*(b)(3) Conclusions Demonstrating Safety, Effectiveness and Performance*

The testing carried out for the PW810 Patient Warmer indicates that it meets design and performance functional requirements. Clinical verification studies demonstrate the successful use of the warmer and its ability to provide effective patient warming. The proposed device meets the requirements of international and US medical electrical equipment standards for safety, and key performance and safety requirements from the particular standard for infant radiant warmers which are applicable to general patient warming.

signed: 

Chris Mander
Fisher & Paykel Healthcare Ltd

date: 24 July 1998



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Chris Mander
Regulatory Affairs Engineer
Fisher & Paykel Healthcare Limited
25 Carbine Road, Panmure
P.O. Box 14-348, Panmure
Auckland, New Zealand

Re: K982636
Patient Warmer - Model PW810
Regulatory Class: II
Product Code: ILY
Dated: July 24, 1998
Received: July 29, 1998

Dear Mr. Mander:

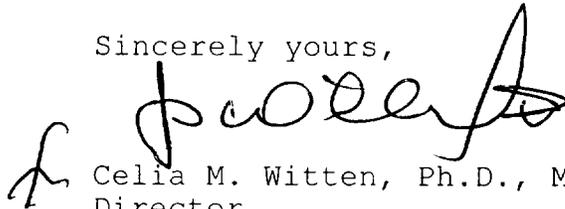
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Premarket 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 premarket 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,



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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Fisher & Paykel PW810 Patient Warmer

**PREMARKET NOTIFICATION 510(k)
INDICATIONS FOR USE STATEMENT**

The Fisher & Paykel Healthcare PW810 Patient Warmer is an Infrared Lamp (as per 89 ILY, 21 CFR §890.5500) containing an infrared heating element to be positioned above an operating table or similar patient bed, in order to maintain a patient's body temperature by means of controlled radiant heat.

The PW810 is intended to provide topical heating to patients in clinical situations where external thermal support is required or desirable. This may include during or following surgical procedures, hypothermia recovery, and severe burns patients.

Situations which necessitate unobstructed access to a patient may indicate the need for a radiant heat source, in preference to thermal regulation systems which rely on extensive surface contact with a patient. Minimal direct contact by a warming system may also be required for particular injuries to patients.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

12902636

Prescription Use
(Per 21 CFR §801.109)