510(k) Summary

K964223

1. Submitter Information

Hill-Rom®, Inc.
4349 Corporate Road
Charleston, SC 29405

MAY 28 1997

Contact: Edwin L. Bills
Manager, Quality Services and Regulatory Affairs
(803)740-8380

2. Establishment Registration Number

For 4349 Corporate Road is: 1045510

3. Device Information

Trade Name: CLINITRON® RITE•HITE™
Air Fluidized Therapy

Classification: INX (21CFR Part 890.5160)
Class II Device

4. Predicate Devices

Trade Name: CLINITRON ELEXIS®
Model Number: C-10
Classification: INX, Class II
510(k) Number: K943385

Trade Name: CLINITRON® AT•HOME™ Air Fluidized Therapy
Model Number: C-6
Classification: INX, Class II
510(k) Number: K942184

5. General Description

The CLINITRON® RITE•HITE™ Air Fluidized Therapy Unit combines the best features of the predicate devices, CLINITRON ELEXIS® (K943385)and the CLINITRON AT•HOME® (K942184), in order to meet the design objectives. The intent of the design is to provide an economical combinational therapeutic support surface on a mobile articulating frame specifically for use in the Long Term Care setting. Another design objective was to provide this type of surface on a frame that would go as low as possible. The CLINITRON® RITE•HITE™ tank edge is at 21.5 inches in its lowest position. This will permit easier positioning and egress.

The combinational support surface includes both low airloss and air fluidized therapies. The upper half delivers low air loss therapy through low-friction support cushions which supports the upper half of the body (above the waist) and the lower half consists of air fluidized therapy which supports the lower half of the body (below the waist). This type of sleep surface is common to both the CLINITRON ELEXIS® and the CLINITRON AT•HOME®.

The CLINITRON® RITE•HITE™ Air Fluidized Therapy is intended for medical purposes to treat or prevent bedsores, to treat severe or extensive burns, or to aid in circulation. This bed will be an ideal support for patients who have advanced pressure ulcers, flaps, grafts, or burns, and require frequent transfers or variable head elevation and any other conditions appropriate for air-fluidized therapy. The bed also can be used for intractable pain, extensive epidermal detachment, Stevens-Johnson Syndrome, purpura fulminans, aid in infection control, induce relaxation which may reduce need for sedative and pain medication, improve patient outcome, and reduce wound healing time. The bed will permit easy positioning and egress, thereby enhancing the independence of residents.

5 Safety and Efficacy

The safety characteristics of this product compare to those of the predicate devices. No significant changes have been made which impact the safety and efficacy of the CLINITRON® RITE•HITE™ Air Fluidized Therapy Unit as compared to the predicate devices. There are no performance standards established for this classification.

6 Technological Characteristics

The air fluidization medium consists of silicon-coated glass microspheres. The microspheres sit on top of a diffuser board and are contained on the sides by an air wall bladder/cushion. An air permeable filter sheet separates the microspheres from the patient.

Pressurized air is delivered to the chamber under the diffuser board. Air enters the chamber, passes through the diffuser board, fluidizes the microspheres, and escapes through the filter sheet. Air to the chamber is heated or cooled as necessary.

A microprocessor controls the user's operations and controls and monitors the main components of the unit.

C. Manufacturer's Statement of Substantial Equivalence

1. Substantially Equivalent Devices

The CLINITRON® RITE• HITE™ Air Fluidized Therapy unit is substantially equivalent to the following device:

The CLINITRON ELEXIS® Air Fluidized Therapy Unit (Model C-10)
manufactured by Hill-Rom, Inc.
Classification number: INX (21 CFR Part 890.5160)
510 (k) #K914351

The CLINITRON® AT• HOME™ Air Fluidized Therapy Unit (Model C-6)
Manufactured by Hill-Rom®, Inc.
Classification number: INX (21CFR Part 890.5160)
510(k) # K942184

2. Device Similarities

The subject device is substantially equivalent to the predicate device in the following aspects:

The CLINITRON® RITE• HITE™, CLINITRON® AT• HOME™ and the CLINITRON ELEXIS® provide a pressure relieving sleep surface for patients who need pressure ulcer treatment. Both devices are also of benefit to patients with other serious wounds such as post-surgical flaps.

The CLINITRON® RITE• HITE™, CLINITRON® AT• HOME™ and the CLINITRON ELEXIS® therapy units provide a pressure relieving sleep surface. Air fluidized therapy is used in the lower section; the vast majority of pressure ulcers occur from the waist to the heels.

Like the CLINITRON ELEXIS®and the CLINITRON® AT• HOME™, the CLINITRON® RITE• HITE™ unit fluidizes microspheres by passing pressurized air through a permeable diffuser board. The same microspheres, filter sheet fabric, and similar closure systems are used in both models.

The CLINITRON® RITE• HITE™ device uses cushions to provide a pressure relieving head section like the CLINITRON ELEXIS® and the CLINITRON® AT• HOME™. The cushion section of all the models allows an articulable head which assists with activities of daily living (feeding, reading, watching

television, etc.). The soft air wall, which is a feature of all three products, facilitates patient egress.

The CLINITRON® RITE• HITE™ , CLINITRON® AT• HOME™ and CLINITRON ELEXIS® products have air cushions organized into zones which are continuously monitored to adjust the pressures when the patient reposition themselves or when the angle of head elevation is changed.

The CLINITRON® RITE• HITE™ , CLINITRON® AT• HOME™ and CLINITRON ELEXIS® Therapy Units use identical cushion material and construction.

The CLINITRON® RITE• HITE™ , CLINITRON® AT• HOME™ and CLINITRON ELEXIS® are operated and controlled by a microprocessor. The microprocessor allows the products to provide the caregiver with easy to operate functions and read-outs. The microprocessor allows constant monitoring and feedback for readjustments and servicing.

3. Device Differences

The predicate device differs in the following aspects:

The CLINITRON® RITE• HITE™ Air Fluidized Therapy unit has been designed for use and servicing in a long term care environment. The CLINITRON RITE HITE has operator controls which are appropriate for long term caregivers and the environment.

The CLINITRON ELEXIS® was designed as an acute care, hospital product with features suitable for use in an intensive care unit (ICU) and operation by trained medical personnel. Acute Care features found on the CLINITRON ELEXIS® but not on the CLINITRON® RITE• HITE™ include: CPR function which automatically deflates the cushions and lowers the head and frame; radiotransluscent plate and film tray for taking X-rays without removing patient from the bed; built-in scale for weighing patient; trendelenburg/reverse trendelenburg; oxygen tank holder.

The CLINITRON® AT• HOME™ unit makes use of new materials to create a light weight frame which can be easily transported and reassembled. The CLINITRON ELEXIS® has a frame constructed of steel and is transported on integral casters. The steel frame construction of the CLINITRON ELEXIS® permits the unit to have a high/low feature which raises the entire bed up and down. The CLINITRON® RITE•HITE™ uses the frame construction of the CLINITRON ELEXIS®, but is modified to provide a lower low position.

The CLINITRON® AT• HOME™ has a base with a wide footprint which distributes the weight of the unit across a large surface area. The combined weight reduction and wide footprint alleviates the concern for the structural integrity of older homes and trailers. The CLINITRON® RITE• HITE™ is not intended for use in homes, rather medical facilities.

The CLINITRON® RITE• HITE™ unit has a remote control with large head up/down buttons compared to the CLINITRON ELEXIS® unit which has smaller head up/down buttons built into the siderails. The large buttons on the CLINITRON® RITE•HITE™ remote control are easy for the elderly or disabled to operate.

The control panel of the CLINITRON® RITE• HITE™ has fewer functions and is much easier to understand than the CLINITRON ELEXIS®. Because the CLINITRON ELEXIS® Therapy Unit has more functions than the CLINITRON® RITE• HITE™, all corresponding hardware and software is more complicated.

In the event of a mechanical or electrical failure, the CLINITRON® AT• HOME™ unit shuts down, an audible alarm sounds, and a message shows on the control panel.

The CLINITRON ELEXIS® and the CLINITRON® RITE• HITE™, in the event of a failure, show a specific error message on the display screen and sounds an alarm. With the, the alarm can be silenced by pushing a button since trained medical personnel are taking responsibility for the patient and notifying Hill-Rom of the need for service.

The CLINITRON® RITE• HITE™ unit has four removable, siderails with a sliding bar locking mechanism. The CLINITRON ELEXIS® has four non-removable, collapsible siderails which lock in place by a spring loaded latch.

The CLINITRON® AT• HOME™ unit has a folding cover under the head assembly (similar to the hood of a baby carriage) to keep the family from misusing the area for storage or allowing pets to sleep on top of the base. The CLINITRON ® RITE• HITE™ being an institutional product, does not require this feature.

Although these differences provide servicing and user benefits, none of the differences adversely affects the safety or efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1997

Mr. Edwin L. Bills
Official Correspondent
Hill-Rom, Inc.
4349 Corporate Road
Charleston, South Carolina 29405-7445

Re: K964223
CLINITRON® RITE•HITE™
Regulatory Class: II
Product Code: INX
Dated: February 25, 1997
Received: February 27, 1997

Dear Mr. Bills:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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,

for 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

510(k) Number:

CLINITRON® RITE•HITE™ Air Fluidized Therapy

Indications for Use:

The CLINITRON® RITE•HITE™ Air Fluidized Therapy is intended for medical purposes to treat or prevent bedsores, to treat severe or extensive burns, or to aid in circulation. This bed will be an ideal support for patients who have advanced pressure ulcers, flaps, grafts, or burns, and require frequent transfers or variable head elevation and any other conditions appropriate for air-fluidized therapy. The bed also can be used for intractable pain, extensive epidermal detachment, Stevens-Johnson Syndrome, purpura fulminans, aid in infection control, induce relaxation which may reduce need for sedative and pain medication, improve patient outcome, and reduce wound healing time. The bed will permit easy positioning and egress, thereby enhancing the independence of residents.

(Division) Sign-Off
Division of General Restorative Devices
510(k) Number K964223

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)