ATTACHMENT 6

K970636

510(k) Summary
Totalcare™ Modular Therapy System (MTS)

1. APPLICANT:

Hill-Rom, Inc.
1069 St. Route 46 East
Batesville, IN 47006
Reg. No: 1824206

AUG 26 1997

CONTACT PERSON:

James G. Carpenter
Manager, Regulatory Affairs
Ph: (812)934-1671
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2. DEVICE TRADE/PROPRIETARY NAME:

Totalcare™ Modular Therapy System (MTS)

DEVICE COMMON/USUAL/CLASSIFICATION NAME:

Alternating Pressure Air Flotation Mattress

CLASSIFICATION:

General Hospital and Personal Use Devices
21 CFR 880.5550
80FNM
Class II

3. PREDICATE (CURRENT) DEVICE:

Hill-Rom " Flexicair® Eclipse™ ", K951001
Hill-Rom "Zoneaire™", K945729

The FLEXICAIR® ECLIPSE™ is a five-zone low airloss mattress replacement that can go on existing bed frames. All controls are connected to a microprocessor control board. The microprocessor controls the blower motor, the five proportional valves that maintain the proper pressure in each of the five zones, and monitors the intake manifold temperature and the control panel. It is intended to

be used on a general Medsurg or specialty bed frame in areas thoughout the patient care environment. It is used in the prevention and treatment of bed sores as well as general use.

The ZONEAIRE™ is a six zone powered flotation mattress. It is managed with a microprocessor which controls the solenoid valves that maintain the proper pressure in each of the zones. The air system consists of a compressor, switching valve, low voltage transformer, power supply and microprocessor based electronic control board. It is intended for use with patients requiring pressure management sleep surfaces including the prevention and treatment of bed sores as well as general use.

4. DEVICE DESCRIPTION

The TotalCare™ Modular Therapy System (MTS) is a patient Air Flotation Bed surface operated by a microprocessor controlled air system and proportional air valves. The mattress surface is of a modular design This allows the healthcare facility to add treatment and/or prevention options as the patient condition requires.

The Surface Control Modules contain the software and proportional air valves and dock with the TotalCare™ Patient Support System (PSS) Bed.

The MTS surface maintains peripheral circulation by even distribution of the patient's weight over bladders filled with air. The even distribution of pressure on the skin reduces capillary closure, thereby helping maintain tissue viability around bony prominences, such as the buttocks and heels, both areas prone to ulceration and bed sores.

The surface cover is non-permeable and will not allow the accumulation of perspiration and other bacteria producing body fluids within the cover or bladder of the bed. By wiping of the cover to remove any accumulation of fluids, followed by wiping of the surface of the cover with an antiseptic agent, contamination of the patient is reduced or eliminated.

Design and construction:

The MTS consists of:

Air System - The PSS provides the pressurized air to the MTS control modules. The air system also provides means to attach and mount the control modules. It is constructed of steel or aluminum and polymer materials.

Control Modules - The control modules consist of software and proportional valves required to direct and control the flow of air from the air source to the patient surfaces as required for specified functions. These are constructed of steel or aluminum and polymer materials.

Patient Surfaces - The patient surfaces consist of modules and components required to provide continuous patient support and specified therapies. Patient surface components generally rest upon the articulating deck/weigh frame of the PSS. These are constructed of multi-density foam, polyurethane sealed air cells, tubing and non-permeable covers.

Power and Communication System - The power and communication system consists of electronic modules and cable assemblies required to exchange information between the user and the control modules. The power and communication system also provides power to the air system and control modules. Components of the power and communication system are in the MTS control modules and distributed throughout the PSS.

5. INTENDED USE:

The product is a device intended for medical purposes that consists of a mattress and a control unit which provides automatic changes in distribution and control of body pressure. It is used to prevent and treat conditions where pressure maintenance is beneficial. The device is intended to provide a patient surface suitable for use with the general patient population in a variety of health care environments as determined appropriate by health care professionals.

6. SUMMARY OF SIMILARITIES AND DIFFERENCES

Differences in design between the subject device and the predicates are as follows.

Air Supply

The air supply for the subject device is integrated into the Totalcare™ Patient Support System bed . The distribution is managed by the air control modules. The Eclipse predicate incorporates the blower, controller and valves in an air supply unit that hangs on the footboard of the bed or can sit on the floor. The Zoneaire predicate is available as an incorporated system or as a footboard mounted system.

Mattress

The primary differences between the subject and predicate devices are the modular construction of the MTS as opposed to the fixed construction of the predicates. The MTS also is exclusive to the Totalcare™ Patient Support System bed, whereas the Eclipse and Zoneaire may be mounted on a variety of different manufacturers beds.

Valves

The Zoneaire employs valves that are controlled directly by voltage to the valve with no feedback loop. The Flexicair Eclipse and the MTS utilize proportional valves which are self controlling to a set pressure and will match the output pressure with the signal from the controller.

The subject device and the predicate devices in this submission are substantially equivalent. The subject device has the same or similar materials, technology and performance characteristics as the predicate devices. The intended use for the subject device is the same as the predicates. Any differences between the subject and predicate devices are insignificant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James G. Carpenter
Manager of Regulatory Affairs
Hill-Rom, Inc.
1069 State Route 46 East
Batesville, Indiana 47006-9167

AUG 26 1997

Re: K970636
Totalcare™ Modular Therapy System (MTS)
Regulatory Class: II
Product Code: IOQ
Dated: May 23, 1997
Received: May 28, 1997

Dear Ms. Carpenter:

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

Indications for Use

510(k) Number: Unknown

Device Name: TotalCare™ MTS

Indications for Use:

The product is a device intended for medical purposes that consists of a mattress and a control unit which provides automatic changes in distribution and control of interface pressure. It is used to prevent and treat conditions where reduction of interface pressure is beneficial. The device is intended to provide a patient surface suitable for use with the general patient population in a variety of health care environments as determined appropriate by health care professionals.

The TotalCare™ Modular Therapy System (MTS) is intended to be used in conjunction with the TotalCare™ Patient Support System (PSS). The MTS is not intended for use with patients with unstable cervical fractures.

Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970636

Prescription Use _____ or Over-The-Counter Use X
(Per 21 CFR 801.109)