

510(k) Summary

JUL 3 1997

1. Submitter Information

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

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

2. Establishment Registration Number

For 4349 Corporate Road: 1045510

3. Device Information

Trade Name: SILKAIR™ Low Airloss Therapy
Classification: IOQ (21CFR Part 890.5170)
Class II Device

4. Predicate Device

Trade Name: Flexicair® Low Airloss Therapy Unit
Classification: IOQ (21CFR Part 890.5170)
Class II Device
510(k) Number: K863047

5. General Description

This product provides the therapeutic surface features and the head and leg elevation bed features of the Flexicair® Low Airloss Therapy Unit while eliminating the hospital bed frame. The intent of the design of the SILKAIR™ Low Airloss Therapy is to provide a zoned low airloss surface with the capabilities of head and leg elevation for non articulating bed frames or mattress box springs. SILKAIR attaches the low airloss surface to a positioning base which provides the head and leg articulation features. This positioning base can be attached to any flat surface such as a box spring, converting a regular bed into a hospital bed. The primary care setting for this product will be the home. This product eliminates the need for a hospital bed which often is difficult to bring in the home and may clutter small bedrooms.

6. Indications for Use

The SILKAIR™ Low Airloss Therapy is intended for medical purposes to treat or prevent pressure ulcers, to treat severe or extensive burns, or to aid in circulation. This bed system will be an ideal support for patients who have advanced pressure ulcers, flaps or grafts and require frequent transfers or variable head and leg elevation. SILKAIR will permit easy positioning and egress, thereby enhancing the independence of patients. This intended use is the same as the predicate device, Flexicair® Low Airloss Therapy Unit (K863047) also manufactured by Hill Rom Company.

Low airloss beds have been used for comfort and therapy for individuals who could not move themselves. Low airloss therapy has been demonstrated to reduce the risk of pressure ulcers caused by loss of capillary circulation as well as an aid in the treatment of pressure ulcers. Low airloss therapy maintains patient's peripheral circulation by distributing the patient's weight over cushions filled with air. The even distribution of pressure on the skin limits capillary closure, thereby helping maintain tissue viability around bony prominence such as the sacrum and heels. The fabrics used in the design of the SILKAIR™ cushion and coverlet help to decrease shear and friction against the skin by moving freely of one another.

7. 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 SILKAIR™ Low Airloss Therapy System as compared to the predicate device. There are no performance standards established for this classification.

8. Technological Characteristics

The SILKAIR™ Low Airloss Therapy System is a zoned low airloss surface. The system distributes different pressures in different zones relative to the main air manifold pressure. This system uses basic, simple mechanical and electrical components

One of the most important aspects of equipment designed for home is to have the ability to use two prong electrical outlets found in older homes. In order to achieve this feature the unit is electrically double insulated.

Head and leg articulation required by many patients in the home is achieved through the use of a positioning base. This positioning base consists of plastic support plates and accordion bladders to raise and lower the head and leg sections of the surface.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Edwin L. Bills
Official Correspondent
Hill-ROM®, A Hillenbrand Industry
4349 Corporate Road
Charleston, South Carolina 29405-7445

JUL 3 1997

Re: K964873
Trade Name: Silkair™ Low Airloss Therapy
Regulatory Class: II
Product Code: IOQ
Dated: April 1, 1997
Received: April 3, 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.

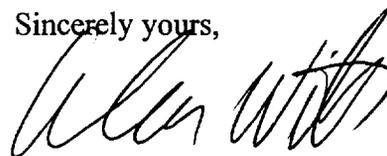
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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

510(k) Number:

SILKAIR™ Low Air Loss Therapy

Indications for Use:

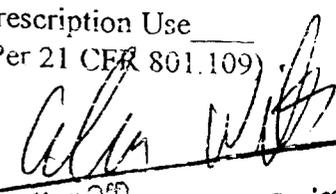
Prevention and treatment of decubitus ulcers, treatment of burns, flaps and grafts and to aid circulation.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use



(Division Sign-off)
Division of General Restorative Devices

510(k) Number

2964873

Prescription Use _____
(Per 21 CFR 801.109)