

K972111

FEB - 2 1998

**Hill-Rom**  
A HILLERBRAND INDUSTRY

**Tab 11**

**510(k) Summary  
RUMORS Dynamic Air Therapy® Unit**

**Date Prepared:** 5-12-97

**1. SUBMITTER NAMES:**

**Submitter:** Hill-Rom®  
4349 Corporate Road  
Charleston SC 29405

**Contact:** Edwin Bills  
Manager Quality Services & Regulatory Affairs  
4349 Corporate Road  
Charleston SC 29405  
(803)740-8380

**FAX:** (803)740-8059

**2. DEVICE NAMES:**

**Common or Usual or  
Classification Name:** Powered Patient Rotation Mattress  
**Proprietary Name:** RUMORS Dynamic Air Therapy® Unit

**3. PREDICATE DEVICES:**

EFICA CC® Dynamic Air Therapy® Unit manufactured by Hill-Rom®  
PULMONEX™ Dynamic Air Therapy® Unit manufactured by Hill-Rom®  
SYNERGY F.A.S.T. manufactured by Cardio Systems  
TriADyne™ Critical Care Healing System manufactured by KCI Therapeutic  
Services

**4. SUBJECT DEVICE:**

**a) Air Supply Unit**

The blower and controller are located in an air supply unit which hangs on the foot board of the bed. The controller can be programmed to accommodate patients of different heights (up to 84 inches) and weights (up to 400 lbs.) respectively. The controller, which utilizes touchscreen technology, controls the functions of the RUMORS Dynamic Air Therapy® Unit. These are low airloss; rotation; percussion; vibration; and combinations of rotation, vibration, and percussion.

**b) Mattress**

The mattress of the RUMORS Dynamic Air Therapy® Unit is designed to be used on different Med-Surg or ICU beds. The mattress is 8 inches high, 80 inches long and width can be set at 32 inches or 35 inches depending upon whether it is being used on a Med-Surg or ICU bed. There are two layers of cushions in the mattress. The top layer is the sleep surface. It has five independently controlled cushions set at customized pressure based upon the patient's height and weight. The bottom layer is the working surface, or substrate, in which the proportional valves and the percussion/vibration valve are installed. The air cushions of the sleep surface are connected to each other by snaps. The working surface is secured to the hospital bed frame by the means of six double polyurethane coated nylon straps.

**c) Valves**

The RUMORS Unit utilizes twelve (12) proportional valves. The proportional valve is a stand alone valve that controls itself to a set pressure and will match the output pressure with the signal from the controller. The Unit also utilizes a percussion/vibration valve capable of producing a percussion range from 1Hz to 5Hz and a vibration range from 6Hz to 25Hz.

5. **INDICATIONS FOR USE:**

The RUMORS Dynamic Air Therapy® Unit is intended to be used on existing bed frames in areas throughout the patient care environment to treat or prevent pulmonary complications and pressure ulcers.

The Unit can operate in rotation mode to reduce pressure shear, friction and maceration while gently rotating the patient from side to side; it can operate in percussion and vibration mode by delivering percussion and vibration to the patient's chest to loosen secretions from the lung wall; and it can also be programmed to operate in a sequential mode of percussion and vibration therapies with and without rotation with patients up to 400 lbs. in weight. The RUMORS Unit also provides low airloss therapy. Low airloss therapy has been demonstrated to reduce the risk of pressure ulcers caused by loss of capillary circulation as well as be a valuable aid in the treatment of bed sores.

6. **COMPARISON TO PREDICATES:**

Differences in design between the subject device and the predicates (none of which have significant effect on safety and efficacy) are as follows:

a) **Adjustable Width Mattress**

The mattress width can be set at 32 inches to accommodate the ICU bed frame and at 35 inches for the Med-Surg bed frame.

b) **Touchscreen Control Panel**

Touchscreen technology instead of membrane switches is used to control the functions on this produce.

(See Tab 9: Comparison Chart for further complications.)

7. **SUMMARY:**

The functions of the RUMORS Dynamic Air Therapy® Unit and the predicate devices are designed for:

- a) the prevention and treatment of pressure ulcers through low airloss;
- b) the reduction of pressure shear, friction and maceration through rotation;
- c) the prevention and treatment of pulmonary complications related to immobility;
- d) any other use where benefits may be derived from rotation therapy.

The RUMORS Unit is able to accomplish these functions through the operation of proportional and percussion/vibration valves in selected combinations which are configured and controlled through resident software in the controller.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB - 2 1998

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

Re: K972111  
RUMORS Dynamic Air Therapy® Unit  
Regulatory Class: II  
Product Codes: IKZ and IOQ  
Dated: November 17, 1997  
Received: November 19, 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.

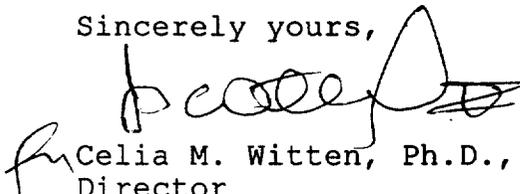
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A ~~substantially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

Page 2 - Mr. Edwin L. Bills

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:

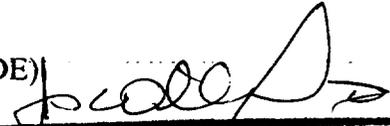
RUMORS Dynamic Air Therapy®

Indications for Use:

The RUMORS Dynamic Air Therapy® Unit is intended to be used to treat or prevent pulmonary complications associated with immobility; to treat or prevent pressure ulcers; or for any other use where medical benefits may be derived from Continuous Lateral Rotation Therapy.

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of **General Restorative Devices**  
510(k) Number 2972111

Prescription Use \_\_\_\_\_ OR  
(Per 21 CFR 801.109)

Over-The-Counter-Use