K993773 2

SEP 1 3 2000

# SECTION 2. SUMMARY AND CERTIFICATION

## A. 510(K) SUMMARY

### Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Hudson RCI AB summary for the Humid-Heat™.


| | |
|---|---|
| SUBMITTER'S NAME: | Hudson RCI AB (Formerly Louis Gibeck AB) |
| ADDRESS: | Box 711<br>SE-194 27 Upplands Väsby<br>Sweden |
| CONTACT PERSON: | Constance Bundy |
| TELEPHONE NUMBER: | 612-574-1976 |
| FAX NUMBER: | 612-571-2437 |
| DATE OF SUBMISSION: | November 1, 1999 |


1. **Identification of device**
   Proprietary Name: Humid-Heat™
   Common Name: Respiratory gas humidifier
   Classification Status: Class II per regulations 868.5450
   Product Codes: 73 BTT

2. **Equivalent devices**
   Hudson RCI AB believes the Humid-Heat™ is substantially equivalent to Fisher & Paykel Dual Servo Controlled Heated Respiratory Humidifiers, cleared for marketing under 510(k) K913368.

3. **Description of the Device**
   Humid-Heat™ is an active respiratory humidifier that heats and humidifies dry breathing gases supplied from a ventilator via an endotracheal, tracheostomy tube or a face mask to adult patients under intensive care or anesthesia. Patients receive physiologically optimized breathing gases (37°C, 100% relative humidity) instead of the dry and cool breathing gases they would otherwise receive if connected directly to a ventilator. They thus avoid the thickened mucus, decreased cilia activity and secretions trapped in the lower airways that are often caused by exposure to cool, dry gases. By heating and humidifying the supplied breathing gases, Humid-Heat™ overcomes these problems and provides optimal conditions for long-term ventilation.

   Heating and humidification take place close to the patient, thereby eliminating the problem of condensation in ventilator circuits. Humid-Heat™ does not require any water traps or heated wires and water consumption is reduced. Humid-Heat™ is suitable for use with volume and pressure-controlled ventilators.

The Humid-Heat™ consists of five main components: the supply unit, the heater, the temperature probe, the HME and the water feed set. It is controlled with a keypad consisting of four buttons; up/down buttons to set the minute volume of the ventilator, start button, stop button, and the power switch.

4. **Intended use**
The Humid-Heat™ is intended for use as an active respiratory humidifier to heat and humidify dry breathing gases supplied from a ventilator via an endotracheal tube, a tracheostomy tube, or a face mask to adult patients under intensive care or anesthesia.

5. **Technological characteristics, comparison to predicate device.**
Like the predicate devices, the Humid-Heat™ is intended to add moisture to, and to warm, the breathing gases for administration to a patient.

Comparison table

| **Characteristic** | **Predicate device: Fisher & Paykel MR850, K983112** | **Humid-Heat ™** |
|---|---|---|
| Intended Use | To warm and add humidity to gases delivered to patients requiring mechanical ventilation. | Same |
| Airway Temperature output | 30-39° C marked<br>29-40° C actual | 37° C± 2° C |
| Moisture output | At least 30 mg $H_2O$/L if temperature of gas delivered to patient is set to 37° C for a given continuous flow. | 44 mg $H_2O$/L active $V_T$ 800 ml<br>30 mg $H_2O$/L passive $V_T$ 800 ml |
| Technical background | The warmth and moisture are supplied by passing the breathing gas over heated water while the temperature of the gas flowing through the breathing circuit is maintained by a heated wire. | The supply unit pumps external water onto a wick in the HME. The water on the wick is evaporated by an electrical heater. |
| Ventilator systems | Mechanical ventilation or positive pressure breathing assistance | Volume and pressure-controlled ventilators |
| Passive humidification | Maximal 20 mg $H_2O$/L | 30 mg $H_2O$/L passive $V_T$ 800 ml |

6. **Discussion of performance testing.**
An extensive collection of tests have been conducted and successfully completed, including electrical safety (IEC 601-1), performance and environmental testing.

**7. Conclusion**

It is the conclusion of Hudson RCI AB that the Humid-Heat™ is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2000

Hundson RCI AB
c/o Ms. Constance G. Bundy
6470 Riverview Terrace
Fridley, MN 55432

Re: K993773
Hudson RCI AB Humid-Heat™
Regulatory Class: II (two)
Product Code: 73 BTT
Dated: August 17, 2000
Received: August 18, 2000

Dear Ms. Bundy:

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 legally marketed predicate 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) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III MD
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## B. INDICATIONS FOR USE

510(k) Number K993773

**Device Name:** Humid-Heat™

**Indications for Use:**

The Humid-Heat™ is an active respiratory humidifier that heats and humidifies dry breathing gases supplied from a ventilator via an endotracheal tube, a tracheostomy tube, or a face mask to adult patients under intensive care or anesthesia.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993773

Prescription Use √ OR Over the Counter Use_____
(Per 21 CFR 801.109)