K031383

JUL 0 7 2003

SMDA

510(k) Summary

1.0 Date 6/25/03

2.0 Submitter

Hudson Respiratory Care, Inc.
27711 Diaz Road
Temecula, California 92590

3.0 Contact Person

Charles Mierkiewicz
Senior Regulatory Affairs Specialist

4.0 Telephone

(909) 676-5611 ext.1255

5.0 Proprietary Device Name

5.1 (Circuit) Circuit #780-19, 20, 31, 32, 33, 34, 35, 51, 790-32, 52

6.0 Classification Name

6.1 **(Circuit)** Breathing Circuit

7.0 Common Name

7.1 **(Circuit)** Breathing Circuit

8.0 Predicate Devices

8.1 (Circuit) **Current Hudson RCI Adult Heated Wire Circuit cleared in 510(k) submission K881625**

9.0 Device Description

Breathing circuit that is intended to administer medical gases to a patient. It provides both an inhalation and exhalation route and may include a connector, adaptor, and Y piece. The heated wires are intended to minimize condensation in the ventilator tubing.

10.0 Intended Use

The Hudson Heated Wire Ventilator Circuit is intended as a conduit for respiratory gas between a patient and a ventilator, and includes heated wires for use with a Concha Column Humidifier; the heated wires are intended to minimize condensation in the ventilator tubing.

11.0 Patient Population

Adults

12.0 Comparison of Technological Characteristic.

3.1 Identification of Predicate Device Hudson RCI Heated Wire Ventilator Circuits K 881625	**8.1 Identification of Proposed Device** Hudson RCI Heated Wire Ventilator Circuits K031383
8.2 Product Labeling 8.2.1 Seven (7) general Warnings that apply to all ventilator circuits. 8.2.1.1 Be sure all connections are secure. 8.2.1.2 Test and install the circuit in accordance with the ventilator manufacturer's instructions before use. 8.2.1.3 Verify that all unused ports are capped. 8.2.1.4 Be sure that the temperature probe is properly placed. (Placement of the probe near a radiant warmer or inside an isolette may cause erroneous temperature readings. For accurate reading, verify that the probe is fully inserted into the air stream. 8.2.1.5 Always maintain adequate flow rates through the tubing to prevent overheating of the circuit. 8.2.1.6 If condensation collects within the breathing circuit, drain the circuit frequently to avoid water collection at the patient's airway. 8.2.1.7 If ancillary equipment is placed in line, use appropriate adaptors to insure that all connections are secure. 8.2.2 Four (4) Warnings that apply to heated wire ventilator circuits. 8.2.2.1 When using heated-wire ventilator circuits, be sure that the electrical requirements of the circuit and the heated humidifier are compatible. In compatibility may result in melting of corrugated tubing or heated wire element failure. 8.2.2.2 Do not allow the circuit to rest on the patient's bare skin. 8.2.2.3 Do not cover with sheets, blankets, towels, clothing or other materials. 8.2.2.4 Do not stretch or "milk" the tubing. 8.2.3 One (1) Caution: Federal law (USA)	**8.2 Product Labeling** 8.2.1 Seven (7) general Warnings that apply to all ventilator circuits. 8.2.1.1 Be sure all connections are secure. 8.2.1.2 Test and install the circuit in accordance with the ventilator manufacturer's instructions before use. 8.2.1.3 Verify that all unused ports are capped. 8.2.1.4 Be sure that the temperature probe is properly placed. (Placement of the probe near a radiant warmer or inside an isolette may cause erroneous temperature readings. For accurate reading, verify that the probe is fully inserted into the air stream. 8.2.1.5 Always maintain adequate flow rates through the tubing to prevent overheating of the circuit. 8.2.1.6 If condensation collects within the breathing circuit, drain the circuit frequently to avoid water collection at the patient's airway. 8.2.1.7 If ancillary equipment is placed in line, use appropriate adaptors to insure that all connections are secure. 8.2.2 Four (4) Warnings that apply to heated wire ventilator circuits. 8.2.2.1 When using heated-wire ventilator circuits, be sure that the electrical requirements of the circuit and the heated humidifier are compatible. In compatibility may result in melting of corrugated tubing or heated wire element failure. 8.2.2.2 Do not allow the circuit to rest on the patient's bare skin. 8.2.2.3 Do not cover with sheets, blankets, towels, clothing or other materials. 8.2.2.4 Do not stretch or "milk" the tubing.

restricts this device to sale by or on the order of a physician. 8.2.4 General directions for use. 8.2.5 Circuit specification: Approximately 72 inches (patient connection to machine). 8.2.6 Company name and address	8.2.3 One (1) Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. 8.2.4 General directions for use 8.2.5 Circuit specifications: Approximately 1.52 meters (patient connection to machine) 8.2.6 Company name and address
8.3 Intended Use Act and a conduit for gas delivery to a patient.	**8.3 Intended Use** Act and a conduit for gas delivery to a patient.
8.4 Anatomical Sites Connects to an endotracheal or tracheostomy tube.	**8.4 Anatomical Sites** Connects to an endotracheal or tracheostomy tube.
8.5 Specifications & Performance Test Results 8.5.1 Length: 1.83 meters 8.5.2 Resistance (test method per ISO 5367): 8.5.2.1 Inspiratory: 0.9 cmH_2O (0.09 kPa)/L/sec @ 30 LPM, air 1.5 cmH_2O (0.15 kPa)/L/sec @ 60 LPM, air 2.2 cmH_2O (0.22 kPa)/L/sec @ 90 LPM, air 2.8 cmH_2O (0.28 kPa)/L/sec @ 120 LPM, air 8.5.2.2 Expiratory: 0.7 cmH_2O (0.07 kPa)/L/sec @30 LPM, air 1.3 cmH_2O (0.13 kPa)/L/sec @ 60 LPM, air 1.9 cmH_2O (0.19 kPa)/L/sec @ 90 LPM, air 2.4 cmH_2O (0.24 kPa)/L/sec @ 120 LPM, air 8.5.3 Compliance (test method per ISO 5367): 2.25 ml/ cmH_2O @ 60 cmH_2O (6 kPa) 2.16 ml/ cmH_2O @ 90 cmH_2O (8.8 kPa) 2.22 ml/ cmH_2O @ 110 cmH_2O (11kPa) 8.5.4 Leak Rate: less than 60 ml/min @ 90 cmH_2O	**8.5 Specifications & Performance Test Results** 8.5.1 Length: 1.52 meters 8.5.2 Resistance (test method per ISO 5367): 8.5.2.1 Inspiratory: 0.8 cmH_2O (0.08 kPa)/L/sec @ 30 LPM, air 1.3 cmH_2O (0.13 kPa)/L/sec @ 60 LPM, air 1.9 cmH_2O (0.19 kPa)/L/sec @ 90 LPM, air 2.4 cmH_2O (0.24 kPa)/L/sec @ 120 LPM, air 8.5.2.2 Expiratory: 0.8 cmH_2O (0.08 kPa)/L/sec @ 30 LPM, air 1.3 cmH_2O (0.13 kPa)/L/sec @ 60 LPM, air 1.9 cmH_2O (0.19 kPa)/L/sec @ 90 LPM, air 2.4 cmH_2O (0.24 kPa)/L/sec @ 120 LPM, air 8.5.3 Compliance (test method per ISO 5367): 2.25 ml/ cmH_2O @ 60 cmH_2O (6 kPa) 2.16 ml/ cmH_2O @ 90 cmH_2O (8.8 kPa) 2.22 ml/ cmH_2O @ 110 cmH_2O (11kPa) 8.5.4 Leak Rate: less than 60 ml/min @ 90 cmH_2O
8.6 Size 6.0 foot (1.83 meter) ventilator circuit	**8.6 Size** 5.0 foot (1.52 meter) ventilator circuit
8.7 Materials of Construction 8.7.1 Inspiratory circuit to humidifier adapter: High Density Polypropylene 8.7.2 Corrugated tubing: Polyethylene/EVA blend 8.7.3 Inspiratory circuit to wye connector:	**8.7 Materials of Construction** 8.7.1 Inspiratory circuit to humidifier adapter: High Density Polyethylene 8.7.2 Corrugated tubing: Polyethylene/EVA blend 8.7.3 Inspiratory circuit to wye connector:

	Low Density Polypropylene
8.7.4	Wye connector: Low Density Polypropylene
8.7.5	Patient connector: Low Density Polypropylene
8.7.6	Expiratory circuit to wye connector: Low Density Polypropylene
8.7.7	Expiratory circuit to ventilator adapter: Low Density Polypropylene
8.7.8	Heated Wire entry grommet: Polyvinylchloride
8.7.9	Heated Wire Harness: copper conductor, polyethylene core, polyvinylchloride insulator.
8.7.10	Wire connector: Brass with tin plate.

	Low Density Polypropylene
8.7.4	Wye connector: Low Density Polypropylene
8.7.5	Patient connector: Low Density Polypropylene
8.7.6	Expiratory circuit to wye connector: Low Density Polypropylene
8.7.7	Expiratory circuit to ventilator adapter: Low Density Polyethylene
8.7.8	Heated Wire entry grommet: Polyvinylchloride
8.7.9	Heated Wire Harness: copper / nickel conductor, polyvinylchloride insulator.
8.7.10	Wire connector: Phosphor bronz with tin/lead plate.

8.8 Design: 8.8.1 Inspiratory circuit to humidifier adapter: Single piece, right angle elbow adapter with heated wire entry and temperature monitoring ports. 8.8.2 Corrugated tubing: Seventy-two (72") inch corrugated tubing 8.8.3 Inspiratory circuit to wye connector: 22 mm ID x 22 mm OD connector with "cage" to anchor wire harness and prevent wire migration into wye connector. 8.8.4 Wye connector: Standard 60-degree (60°) entry and exit legs, all legs have a 22 mm OD connections, patient end includes a 15 mm ID connection. 8.8.5 Patient connector: Standard right angle patient connector that allows attachment to 15 mm ID and 22 mm OD connector. 8.8.6 Expiratory circuit to wye connector: 22 mm ID x 22 mm OD connector with "cage" to anchor wire harness and prevent wire migration into wye connector. 8.8.7 Expiratory circuit to ventilator adapter: Single piece, straight adapter with heated wire entry port. 8.8.8 Heated Wire entry grommet. Insert molded around heated wire harness then inserted into inspiratory or expiratory adapter. 8.8.9 Inspiratory Heated Wire Harness: Single strand 8.8.10 Expiratory Heated Wire Harness: Single strand.	**8.8 Design** 8.8.1 Inspiratory circuit to humidifier adapter: Two piece, 60 degree angle adapter with heated wire entry and temperature monitoring ports. 8.8.2 Corrugated tubing: Sixty (60") inch corrugated tubing . 8.8.3 Inspiratory circuit to wye connector: 22 mm ID x 22 mm OD connector with "cage" to anchor wire harness and prevent wire migration into wye connector. 8.8.4 Wye connector: Standard 60-degree (60°) entry and exit legs, all legs have a 22 mm OD connections, patient end includes a15 mm ID connection. 8.8.5 Patient connector: Standard right angle patient connector that allows attachment to 15 mm ID and 22 mm OD connector. 8.8.6 Expiratory circuit to wye connector: 22 mm ID x 22 mm OD connector with "cage" to anchor wire harness and prevent wire migration into wye connector. 8.8.7 Expiratory circuit to ventilator adapter: Two piece, 60 degree angle adapter with heated wire entry port. 8.8.8 Heated Wire entry grommet: Injection molded "clam shell grommet that is placed around wire. 8.8.9 Inspiratory Heated Wire Harness: Seven strand, 8.8.10 Expiratory Heated Wire Harness: Seven strand
8.9 Energy Used / Delivered 21- volt system controlled by Hudson RCI ConchaTherm controller.	**8.9 Energy Used / Delivered** 21-volt system controlled by Hudson RCI ConchaTherm controller.
8.10 Features 8.10.1 22 mm connectors 8.10.2 Transparent corrugated tubing 8.10.3 May be used on all Hudson RCI 21 volt heated wire humidifiers.	**8.10 Features** 8.10.1 22 mm connectors 8.10.2 Transparent corrugated tubing 8.10.3 May be used on all Hudson RCI 21 volt heated wire humidifiers.
8.11 Method of Operation Acts as a gas conduit between ventilator and patient.	**8.11 Method of Operation** Acts as a gas conduit between ventilator and patient.
8.12 Accessories None	**8.12 Accessories** None
8.13 Safety Characteristics No difference identified	**8.13 Safety Characteristics** No difference identified

13.0 Conclusion

Based on the information contained in this special 510(k) submission, Hudson RCI has determined that the current Hudson RCI Cat. no. 780-19, 20, 31, 32, 33, 34, 35, 51, 790-32, 52. and the proposed Hudson RCI cat. No 780-19, 20, 31, 32, 33, 34, 35, 51, 790-32, 52 heated wire circuits are substantially equivalent to their respective predicate devices listed in this submission. These changes to the circuits are truly a modification to the existing Hudson RCI Heated Wire Circuit product line.

These changes are being implemented at this time for cost effectiveness as well as addressing failure modes discovered over time with the current heated wire product offering.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 7 2003

Mr. Charles Mierkiewicz
Senior Regulatory Affairs Specialist
Hudson Respiratory Care, Incorporated
27711 Diaz Road
P.O. Box 9020
Temecula, California 92590

Re: K031383
Trade/Device Name: Hudson RCI Heated Wire Circuit
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: June 26, 2003
Received: June 27, 2003

Dear Mr. Mierkiewicz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031383

Device Name: Hudson RCI Heated Wire Circuit

Indications For Use:

The Hudson Heated Wire Ventilator Circuit is intended as a conduit for respiratory gas between a patient and a ventilator, and includes heated wires for use with a Concha Column Humidifier; the heated wires are intended to minimize condensation in the ventilator tubing.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031383