K970478

Non-Confidential Summary of Safety and Effectiveness
February 5, 1997

JUL 16 1997

Marquest Medical Products, Inc.
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Englewood, CO 80112

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Official Contact:	Thomas W. Dielmann, Vice President, Regulatory Affairs / Quality Assurance
Proprietary or Trade Name:	SCT 3000 Heated Humidifier
Common / Usual Name:	Heated Humidifier
Classification Name:	Respiratory Gas Humidifier Subsection 868.5450
Intended Device:	SCT 3000 uses breathing circuits and humidification chambers to precisely control the delivery of gas temperature and humidity to the patient.
Predicate Devices:	Marquest SCT 3000 - K903138 Fisher & Paykel 730 Respiratory Humidifier - K913368
Device Description / Indicated Use:	Servo-Controlled Tracking SCT 3000 heated humidifier is designed to provide heated, humidified gas to a patient whose own humidification system - the nose and upper airway - is compromised. The unit is used primarily during anesthesia or prolonged respiratory therapy to prevent damage to the upper airway and lungs caused by dry gas while helping to maintain the patient's body temperature stable.

Non-Confidential Summary of Safety and Effectiveness
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Device Description / Indicated Use (continued):	The whole system, including disposable humidification chambers, heated wire breathing circuits and no-wire (vent) circuits, achieves precise control of delivered gas temperature and humidity by a servo controlled mechanism. The SCT 3000 employs a feedback loop where the temperature input from the thermistors controls the heating elements. The SCT 3000 has two thermistors that provide analog input. This information, in turn, is used to control the amount of time that the two heating elements are cycled on/off. The SCT's microprocessor - the Intel P80C32, regulates this servo mechanism. the advanced design allows simple operation, sophisticated diagnostic routines and superior safety features to be built into the instrument, resulting in better performance and safer operation.
Targeted Population:	Adult, neonate, and pediatric
Environment of Use:	Hospital, anesthesia, ICU, respiratory therapy, home healthcare

Comparison to Predicate Devices:

Attribute	**Marquest SCT 3000**	**Fisher & Paykel MR 730**
Use		
Indicated for anesthesia	Yes	Yes
Indicated for respiratory therapy	Yes	Yes
Population - adult, pediatric, neonate	Yes	Yes
Indicated for use only with specific manufacturers heated circuits	Yes	Yes
Use with heated wire circuits	Yes	Yes
Use with no-wire circuits	Yes	Yes
Single patient use applications	Yes	Yes
Reusable circuits application	Yes	Yes
Heated wire operation	Yes	Yes
No-wire operation	Yes	Yes
For use with low flow chambers	Yes	Yes
For use with high flow chambers	Yes	Yes

Comparison to Predicate Devices:

Attribute	**Marquest SCT 3000**	**Fisher & Paykel MR 730**
Use (continued)		
For use with ventilators - with or without exhalation valves	Yes	Yes
For use with anesthesia systems	Yes	Yes
For use with various heated wire circuit configurations	Yes	Yes
For use with various no-wire circuit configurations	Yes	Yes
Design		
Microprocessor controlled	Yes	Yes
High Temperature Alarm	Yes - Distal Temperature > 1 degree C of Set Temp.	Yes - Distal Temperature > 2 degrees C of Set Temp.
Low Temperature Alarm	Yes - Distal Temperature < 4 degrees C of Set Temp.	Yes - Distal Temperature < 4 degrees C of Set Temp.

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Attribute	Marquest SCT 3000	Fisher & Paykel MR 730
Design (continued)		
Maximum Heater Plate Temperature	98 degrees C	110 degrees C
Humidification Method	Pass Over Wick	Pass Over Wick
Alarm Mute	1 Minute	3 Minutes
Other Features	Pause Mode	Standby Mode
Safety Alarms	Yes - Visual Display of All Alarms	Yes - Visual Display or Error Code Display
Performance Testing		
Meets UL 544, Medical and Dental Equipment / Patient Care Equipment	Yes	Yes
Meets CSA C22.2 No. 125-M1984, Electromedical Equipment	Yes	Yes
Meets ANSI Z79.9-1979, Humidifiers and Nebulizers for Medical Use	Yes	Yes

Differences
Any differences that do exist would not have an effect on the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas W. Dielmann
Marquest Medical Products, Inc.
11039 East Lansing Circle
Englewood, Colorado 80112

JUL 16 1997

Re: K970478
SCT 3000 Heated Humidifier
Regulatory Class: II (two)
Product Code: 73 BTT
Dated: May 28, 1997
Received: June 2, 1997

Dear Mr. Dielmann:

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) 594-4648. 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Englewood, Colorado 80112 U.S.A.
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Section # 3 **Labeling (continued)**

C. Indications for Use Statement

Pursuant to the Notice of 2/6/96 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number K970478 (to be assigned)

Device Name:	SCT 3000 Heated Humidifier
Indications for Use:	The SCT 3000 Heated Humidifier is indicated for use with breathing circuits when healthcare professionals require humidified and /or heated gas being delivered to patients.
Targeted Population:	Adult, neonate, and pediatric
Environment of Use:	Hospital, anesthesia, ICU, respiratory therapy, home healthcare
Disposable / Reusable:	Reusable - Supplied Clean Non-Sterile

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970478

Prescription Use ✓ or Over - The - Counter Use ____
(per 21 CFR 801.109)