SEP 1 8 2000

K993282

medical products

Division of:
INHALATION PLASTICS, INC.
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MED/CERT
ISO 9001 EN 46001 CE

Section 5 **Premarket Verification [510 (k)] Summary**

Non-Confidential Summary of Safety and Effectiveness

Official Contact:	Mazh Said, Ph.D., Director Regulatory Affairs/Quality Assurance
Proprietary of Trade Name:	IPI Humidification Chamber for Fisher & Paykel and Marquest Humidifier Bases
Common/Usual Name:	Accessories for Heated Humidifiers
Classification Name:	73 BTT - Respiratory Gas Humidifiers (Direct Patient Interface) Subsection 868.5450
Classification	Class II (Two)
Intended Use:	Humidifier Chambers for use with Marquest SCT 3000 Heated Humidifier and Fisher & Paykel MR 700, MR720, and MR730.
Predicate Devices:	Marquest SCT 3000 - K903138 and K962223 HPD Medical - K864173 Fisher & Paykel - K850647, K862923, K934140
Device Description:	The humidifier chambers offered for use with the Marquest SCT 3000 and Fisher & Paykel MR700, MR720, and MR730

Adult- Hi Flow Humidifier Chamber 1130
Adult - Hi Flow Humidifier Chamber with Autofeed 1131
Pediatric - Low Compressible Volume Humidifier Chamber 1140
Pediatric - Low Compressible Volume Humidifier Chamber with Autofeed 1141

Indicated Use:

The humidifier chambers are indicated for use with the Marquest SCT 3000 unit and Fisher & Paykel MR700, MR720, and MR730 to hold water required to humidify the air being delivered to patients.

Targeted Population:

Any patient utilizing the Marquest SCT 3000 Heated Humidifier or Fisher & Paykel MR700, MR720, and MR730. Adult and Pediatric.

Environment of Use:

Hospital: Anesthesia, ICU, Respiratory Therapy, Homecare

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2000

Mr. David Levine
I.P.I. Medical Products
3217 N. Kilpatrick Avenue
Chicago, IL 60641

Re: K993282
IPI Humidifier Chamber
Regulatory Class: II (two)
Product Code: 73 BTT
Dated: August 30, 2000
Received: September 6, 2000

Dear Mr. Levine:

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,

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

Enclosure

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 K993282 (To be assigned)

Device Name:	Humidifier chambers
Indications for Use:	The humidifier chambers for the SCT 3000 are indicated for use with the SCT 3000 unit and to hold water required to humidify the air being delivered to patients.
Targeted population:	Any patient utilizing the SCT 3000 heated humidifier. Adult and pediatric.
Environment of use:	Hospital, anesthesia, ICU, respiratory therapy
Disposable / reusable:	Disposable - single use

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number: K993282

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___