DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1999

Ms. Patricia E. Passy
Passy-Muir, Inc.
4521 Campus Drive, Suite 273
Irvine, CA 92612

Re: K990905
Passy-Muir Low-Profile Tracheostomy Speaking Valve PMV 2020 JIT
Regulatory Class: II (two)
Product Code: JOH
Dated: March 18, 1999
Received: March 18, 1999

Dear Ms. Passy:

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,

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

STATEMENT OF INTENDED USE

510(k) Number (if known): K990905

Device Name: **Passy-Muir Low-Profile Tracheostomy Speaking Valve PMV 2020 (Clear) JIT to be used in conjunction with the Passy-Muir Adapter PMA 2020-S JIT 4-6 for use on Pilling Weck metal Jackson Improved tracheostomy tubes sizes #4, #5 and #6 or equivalent, and also for use without an adapter on the Bivona (Non-Foam Filled Cuffed) tracheostomy tubes currently on the market.**

Intended for Use:

The PMV 2020 (Clear) JIT is designed to be used in conjunction with the Passy-Muir Adapter PMA-S JIT 4-6 for use on the Pilling Weck metal Jackson Improved tracheostomy tubes sizes #4, #5 and #6 or equivalent in providing vocalization without finger occlusion for both short-term and long-term tracheostomized patients. It is appropriate for neonatal, pediatric and adult patients and is ideal for use in decannulation as an assessment device for physicians, as well as providing the patient comfort and confidence in upper airway usage. The PMV 2020 (Clear) JIT Valve is also designed to be used without an adapter on the Bivona (Non-Foam Filled Cuffed) tracheostomy tubes currently on the market.

Indications for Use - Including but not limited to the following:

- For Sleep Apnea patients who are tracheostomized as an alternative to plugging when awake
- Bilateral Vocal Cord Paralysis without significant airway obstruction
- Tracheomalacia
- Mild Tracheal and Laryngeal Stenosis
- Non-Obstructive Laryngeal Tumors (can include patients who have intact vocal cords following surgical resection of the tumor)
- Neuromuscular Disease
- Chronic Obstructive Pulmonary Disease
- Brain Injury
- Non-Ventilator Dependent Quadriplegics
- Patients who emotionally or physically are unable to tolerate plugging

Mark A. Gill

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990905

prescriptions use ✓ OTC ____