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K090710

Mercury Medical, Inc.
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Clearwater, FL 33762-4800

Tel – (727) 573-0088
Fax – (727) 571-3922

AUG 20 2009

Official Contact: Jeff Ratner – VP Engineering and Quality Assurance

Proprietary or Trade Name: Mercury CPAP

Common/Usual Name: Flow generator / PEEP Valve

Classification Name/Code: BYE – attachment, breathing, positive end expiratory pressure

Device: Mercury CPAP

Predicate Devices: Vygon SA – Boussignac CPAP – K013884

Device Description:
The Mercury CPAP is a respiratory aid device intended for use with a facemask and gas supplying device to elevate pressure in the patient's lungs. Alternatively the device may be used in conjunction with an endotracheal tube to generate and maintain constant positive airway pressure during standard intubation procedures.

Indications for Use:
The Mercury CPAP is intended to provide CPAP to spontaneously breathing patients in the hospital and pre-hospital environment.

Environment of Use: Hospital and pre-hospital

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Summary of substantial equivalence

	Predicate **Vygon Boussignac CPAP** **K013884**	**Proposed Device** **Mercury CPAP**
Indications for Use	Intended to provide CPAP to spontaneously breathing patients in the hospital and pre-hospital environment	The Mercury CPAP is intended to provide CPAP to spontaneously breathing patients in the hospital and pre-hospital environment
Patient Population		
Environment of use	Hospital and pre-hospital	Same as predicate

Physical and Performance Characteristics		
Gas flow provided by	Wall gas or cylinder	Wall gas or cylinder
Requires a flow meter with ~30 Lpm range	Yes	Yes
Typical flow rate range	10-25 lpm	10-25 lpm
CPAP pressure range	Up to 10 cm H_2O	Up to 10 cm H_2O
In-line pressure manometer	Recommended that a manometer be connected	Includes an integral manometer, Mercury K954486
Excessive pressure relief	No excessive pressure relief	Integrated pop-off at 25 cm H_2O
Patient interface	Face mask with head harness Connects to ET tube with adapter Permits a nebulizer to be connected	Face mask with head harness Connects to ET tube without adapter
Single patient use, disposable	Yes	Yes
Environment of use	Hospital and pre-hospital	Hospital and pre-hospital
Contraindications and Warnings		
Contraindications and Warnings	None	None

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The Mercury CPAP is viewed as substantially equivalent to the predicate device because:

Indications –

- Identical to predicate – Vygon Boussignac CPAP – K013844

Technology –

- Similar technology used to generate CPAP pressure – Vygon Boussignac CPAP – K013844

Materials –

- The materials in patient contact are identical to predicate devices

Environment of Use –

- Identical to predicate – Vygon Boussignac CPAP – K013844

Differences –
The differences are:

- Integral pressure manometer in the Mercury CPAP
- Integral excessive pressure pop-off valve set to 25 cm H_2O

Any other differences are not significant between the proposed device and the predicate device and do not introduce any new patient safety issues.

Comparative Performance

- We have performed comparative performance testing, Comparative Flow vs. CPAP Pressure
- Performance of the pressure relief valve

The results demonstrated that the devices were substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mercury Medical
C/o Mr. Paul Dryden
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

AUG 20 2009

Re: K090710
Trade/Device Name: Mercury CPAP
Regulation Number: 21 CFR 868.5965
Regulation Name: Positive End Expiratory Pressure Breathing Attachment
Regulatory Class: II
Product Code: BYE
Dated: July 16, 2009
Received: July 21, 2009

Dear Mr. Dryden:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: Mercury CPAP

Indications for Use:

The Mercury CPAP is intended to provide CPAP to spontaneously breathing patients in the hospital and pre-hospital environment.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use** __ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

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

510(k) Number: K090710