K970756

OCT 31 1997

SECTION 10
510(k) SUMMARY

Prepared: February 21, 1997

Submitter: Mercury Medical
11300 49th St. No.
Clearwater, Florida 34622-4800
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Contact: Arthur J. Ward
1024404 (Registration Number)

Proprietary Name: Mercury Medical Reusable CPR Bag

Common Name: Manual Resuscitator

Classification Name: Ventilator, Emergency Manual (Resuscitator)

Substantial Equivalence: This device is similar in design to the Mercury Medical single patient use CPR Bag (K911622) except manufactured with reusable materials similar to the Puritan Bennett PMR and Laerdal Bag Mask Resuscitator both of which are pre-amendment devices.

Description: The Mercury Medical Reusable CPR Bag uses the same technology as the Mercury CPR, Puritan Bennett PMR and most other manual resuscitators in the market. The bag is compressed by hand to move air into the patient. When released the bag re-expands with air flowing through the intake valve. Supplemental oxygen tubing may be connected to an oxygen source to allow intake of oxygen enriched air.

Intended Use: The intended use of this device is to provide manual, bag mask/tube pulmonary resuscitation.

Technology Comparison: The Table of Technological Comparison in Section 5 indicates that this device and predicate device are similarly designed with identical materials.

Performance Comparison: The Table of Performance Comparison in Section 5 also demonstrates that this and the predicate devices all have similar performance characteristics exceeding the ASTM standards.

Summary Conclusion: Based upon the review of this information we have submitted this 510(k) request as the information indicates these devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 1997

Mr. Arthur J. Ward
Mercury Medical
11300-49th Street North
Clearwater, Florida 34622-4800

Re: K970756
Mercury Medical Reusable CPR Bag
Regulatory Class: II (two)
Product Code: 73 BTM
Dated: August 18, 1997
Received: August 19, 1997

Dear Mr. Ward:

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

SECTION 2
INTENDED USE

The intended use of this device is to provide manual, bag mask/tube pulmonary resuscitation. This bag is similar in design and function to the Mercury CPR Bag and Puritan Bennett PMR.

Charles C. Hufnagel for RAC

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970956

✓ prescription use

OTC