K032593

FEB - 3 2004

ENCLOSURE L

Premarket Notification (510(k) - Mercury Medical® Negative Inspiratory Force (NIF) Disposable Manometer

Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness

January 29, 2004

Mercury Enterprises, Inc./Mercury Medical
11300 49th St. N.
Clearwater, Fl. 33762
Tel: (800) 237-6418
Fax: (727) 572-4501

Official Contact: **Karen Seltzer**
QA/RA Manager

Proprietary or Trade Name: Mercury Medical® Negative Inspiratory Force (NIF) Disposable Manometer

Common/Usual Name: NIF Manometer

Classification: Class II, BXR, 21 CFR 868.1780

Classification Name: Airway Pressure Meter (Inspiratory Force)

Device: Negative Inspiratory Force (NIF) Disposable Manometer

Predicate Devices: DHD Medical Products Negative Inspiratory Force Monitoring Kit

Device Description:

The Mercury Medical® Negative Inspiratory Force (NIF) Disposable Manometer is designed to connect to an endotracheal tube. To record the maximum inspiratory pressure, the occlusion knob is held down during patient inhalation. The knob is released immediately after measurement. A memory pointer identifies and remains at the maximum inspiratory pressure to –60cm H_2O. Rotating the memory pointer knob counterclockwise resets the memory pointer.

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Indicated Use:

The Mercury Medical® Negative Inspiratory Force (NIF) Disposable Manometer is used to indicate inspiratory force. Federal law (USA) restricts this device to sale by or on the order of a physician.

Technical Characteristics: The device has the same technical characteristics for measuring negative pressure as the DHD Medical Products NIF Monitoring kit predicate device.

Non-Clinical Data: Performance and specifications of the device are consistent with all requirements for this device type specified by ISO 5356-1: 1987 – Anesthetic and Respiratory Equipment-Conical connectors-Part 1: Cones and Sockets. ASTM F1054 – Standard Specification for Conical Fittings of 15mm and 22mm sizes.

Environment of Use: Hospital/Transport

Conclusions: The comparison to the predicate devices demonstrates that the proposed device is safe and effective and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 2004

Mr. Wayne Glover
QA/RA Engineer
Mercury Medical Inc.
11300 49th St. N.
Clearwater, FL 33762

Re: K032593
Trade/Device Name: Mercury Medical Negative Inspiratory Force (NIF) Disposable Manometer
Regulation Number: 21 CFR 868.1780
Regulation Name: Meter, Airway Pressure (Inspiratory Force)
Regulatory Class: Class II
Product Code: 73 BXR
Dated: December 18, 2003
Received: December 19, 2003

Dear Mr. Glover:

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 such 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.

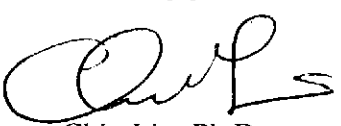
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K032593

Device Name: Negative Inspiratory Force (NIF) Disposable Namometer

Intended Use: The Mercury Medical Negative Inspiratory Force (NIF) Disposable Manometer is used to indicate inspiratory force.

Prescription Use √ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number: K032593