AUG - 2 2004

K041485

B215905

MARPAC

TRADITIONAL 510(k) SUMMARY
MARPAC MESSENGER™

Marpac
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Contact: Evelyn Trujillo
mfg@marpac.biz

Establishment Registration Number: 1722095

Date of Summary: May 20, 2004

Device Trade Name: Marpac Messenger™
Common Name: Speaking Valve
Classification: Tracheostomy tube and tube cuff. 21 CFR 868.5800

Predicate Device: Passy-Muir Tracheostomy Speaking Valve PMV 2001 by Passy & Passy, Inc. (K903699), 9-4-1990.

Description of Device: The Marpac Messenger™ consists of a plastic outer body with an inner flexible diaphragm made of medical grade silicone. The Marpac Messenger™ attaches to the hub of a standard 15mm tracheostomy tube. The one-way valve design of the Marpac Messenger™ allows airflow into the valve when the tracheostomy patient inhales and maintains a closed position during expiration thereby directing airflow up through the larynx, mouth, and nose enabling speech.

Intended Use: The Marpac Messenger™ attaches to standard 15mm tracheostomy tubes and assists tracheostomy patients with speech by managing airflow. The Marpac Messenger™ has the same intended use as the previously cleared Passy-Muir PMV 2001 Tracheostomy Speaking Valve.

Substantial Equivalence: The Marpac Messenger™ has the same indicated use, uses the same operating principle, and incorporates the same basic speaking valve design as the Passy-Muir PMV 2001 Tracheostomy Speaking Valve which previously received a 510(k) concurrence. Non-clinical test data can be found in Attachment B (Inhalation Flow Resistance Chart). The chart demonstrates substantial equivalence to the predicate device with respect to inhalation flow resistance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 2 2004

Ms. Evelyn Trujillo
Manufacturing Manager
Marpac, Incorporated
8436 Washington Place, N.E.
Albuquerque, New Mexico 87113-1671

Re: K041485
Trade/Device Name: Marpac Messenger™
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: May 20, 2004
Received: June 7, 2004

Dear Ms. Trujillo:

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

Indications for Use

510(k) Number (if known): K041485

Device Name: Marpac Messenger™

Indications for Use: The Marpac Messenger™ attaches to standard 15mm tracheostomy tubes and assists tracheostomy patients with speech by managing airflow.

Prescription Use X AND / OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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: K041485