Non-Confidential Summary of Safety and Effectiveness
Page 1 of 2
16-Apr-07

Polar Wrap LLC
6047 Executive Center Drive # 8 Tel – 901-767-4171
Memphis, TN 38134 Fax – 901-767-8594

APR 17 2007

Official Contact: Bruce McCormick, President

Proprietary or Trade Name: Health Mask

Common/Usual Name: Respiratory humidifier mask (direct patient interface)

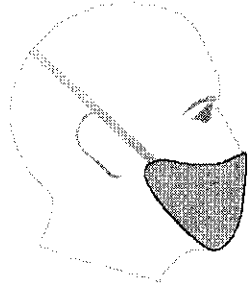
Classification Name: Respiratory humidifier mask (direct patient interface)

Device: Health Mask

Predicate Devices: Pegasus – PMH500 Heated humidifier – K020700
RESPeRate – K020399

Device Description:

The Health mask is a device worn by an individual outdoors when the air is cold. It is designed to retain the heat and moisture exhaled by the wearer and warm and humidify the inhaled cold air.



The wearer breathes through a thermal medium which retains and returns the heat and moisture in the breathed air.

The Thermal medium is placed inside a fabric mask which the wearer places over their mouth and nose. The mask is held in place with an elastic band.

Indications for Use:

Indicated Use -- The Health Mask is intended to moderate the expected physiological response to cold (i.e., increase in blood pressure).

Patient Population -- Diagnosed hypertensives 18 years or older

Environment of Use -- Outdoors

Contraindications -- None

Non-Confidential Summary of Safety and Effectiveness
Page 2 of 2
16-Apr-07

Device Attributes:

	Health Mask
Attributes	
Intended use General	To act as a respiratory gas humidifier to add moisture to, and sometimes to warm, the breathing gases for administration to the patient.
Intended use Specific	To moderate the expected physiological response to cold (i.e., increase in blood pressure).
Environments of use	Outdoors
Patient Population	18+ years old, diagnosed hypertensives
Contraindications	None
Prescription	Prescription
Design	
External device covering patient to reduce heat loss	Placed over the mouth and worn like a mask
Retains heat to be returned to patient	Yes
Materials	
Thermal medium	Wire (copper) mesh
Housing / HME Mask Shell	Wrap – polypropylene and polyester with elastic band to hold the device around the head
Air Chamber Shell	Polypropylene
Performance	
Low resistance to work of breathing or flow	1.6 cm H_2O at 60 Lpm, less than typical resistance to flow (< 5 cm H_2O) guidelines for devices in the breathing system

Differences Between Other Legally Marketed Predicate Devices

The Health Mask is viewed as substantially equivalent to the following predicate devices – Pegasus – PMH500 Heated humidifier – K020700 for technology under CFR 868.5450 and RESPeRATE – K020399 for indications for use under CFR 882.5050, a non-invasive biofeedback device intended to lower blood pressure by guiding and monitoring patients breathing.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2007

Polar Wrap LLC
c/o Bruce McCormick, President
6047 Executive Center Drive #8
Memphis, TN 38134

Re: K070467
Trade/Device Name: Health Mask
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: OBN
Dated: February 15, 2007
Received: February 16, 2007

Dear Mr. McCormick:

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: **K070467**

Device Name: **Health Mask**

Indications for Use:

The Health Mask is intended to moderate the expected physiological response to cold (i.e., increase in blood pressure). For diagnosed hypertensives 18 years or older.

Prescription Use XX **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 Cardiovascular Devices
510(k) Number K070467