K061426

2. 510(k) Summary

JUN - 6 2006

Applicant

Porous Media
1350 Hammond Road
St. Paul, MN 55110
Telephone: 651-653-2000
Fax: 651-653-2230

Contact: David Rasch

Date

April 19, 2006

Device Name

Oxygen Concentrator Filters

Please reference the following table for the Proprietary and Common names of the devices included in this submission.

Proprietary Name	Common Name
DBF32	Bacterial Intake filter
DBF24	Bacterial Intake filter
DBF27	Bacterial Intake filter
DBF25	Bacterial Intake filter
DFC06	Compressor filter, HEPA
DDF47	Final bacteria filter

Classification

Breathing Circuit Bacteria Filter, 21 CFR 868.5260

Substantial Equivalence

Porous Media's devices identified in this submission are substantially equivalent to the filters installed and used in the following oxygen concentrators:

- Respironics Millennium (subject to pre-market notification K972614) and Millennium M10 Oxygen Concentrators (subject to pre-market notification K043006).
- DeVilbiss 303 Series Oxygen Concentrators (subject to pre-market notification K953815), DeVilbiss 505 Series Oxygen Concentrators (K991722), and DeVilbiss 515 Series Oxygen Concentrators (K991722).
- Invacare Platinum Series Oxygen Concentrators (K020386).

The original component filters are approved for sale subject to the pre-market notifications outlined above. In each case the original filter is part of the 510(k) submitted for the oxygen. concentrator, such that, the original devices (oxygen concentrators) are indicated for use as oxygen generators and not filter devices. Because the original filters are not classified as separate devices, the Breathing Filter is included in this submission for the sole purpose of establishing the indications for use as a filter device.

Porous Media's devices identified in this submission are substantially equivalent to AG Industries Breathing Filter Bacterial/Viral (K052087), such that both are used as replacement filters in medical devices.

Device Description

Room air is drawn into the compressor through the bacterial intake filter. From the compressor, the air passes through the compressor filter, if one is installed on the machine, and proceeds to the sieve beds. The sieve beds condition the air, by removing nitrogen from the air stream, which results in a higher concentration of oxygen. The air then passes through the final filter before being supplied to the patient.

Intended Use

The devices identified in this submission are intended to help remove air-borne contaminants, including air borne bacteria and other particulate debris, from the air stream of an oxygen concentrator.

Technical Comparison

Technical Comparison, DBF24 Bacterial Intake Filter

Item	DeVilbiss	Porous Media
Part Number	493-0012-002	DBF24
Intended Use	DeVilbiss 303 Series Oxygen Concentrators	Identical
Filtration Efficiency	99.999% BFE	Identical
Filter Material	Glass microfiber	Identical
Housing Material	Polystyrene or approved equivalent	Identical
Air Flow Resistance	4.0 inH_2O @ 100 scfh	Identical
Maximum Flow Rate	100 LPM	Identical
Connection	Male 22mm ISO	Identical

Technical Comparison, DBF27 Bacterial Intake Filter

Item	DeVilbiss	Porous Media
Part Number	493-0012-006	DBF27
Intended Use	DeVilbiss 505 or 515 Series Oxygen Concentrators	Identical
Filtration Efficiency	99.999% BFE	Identical
Filter Material	Glass microfiber	Identical
Housing Material	Polystyrene or approved equivalent	Identical
Air Flow Resistance	4.0 inH_2O @ 100 scfh	Identical
Maximum Flow Rate	100 LPM	Identical
Connection	Male 22mm ISO	Identical

Technical Comparison, DBF25 Bacterial Intake Filter

Item	Invacare	Porous Media
Part Number	1131249	DBF25
Intended Use	Invacare Oxygen Concentrators	Identical
Filtration Efficiency	99.999% BFE	Identical
Filter Material	Glass microfiber	Identical
Housing Material	Polystyrene or approved equivalent	Identical
Air Flow Resistance (@ 4.50 scfm)	35.0 inH_2O (Platinum 5) 18.0 inH_2O (Platinum 10) 7.0 inH_2O (non-Platinum)	Identical
Maximum Flow Rate	100 LPM	Identical
Connection	3/8" FNPT	Identical

Technical Comparison, DBF32 Bacterial Intake Filter

Item	Respironics	Porous Media
Part Number	100-6629-20	DBF32
Intended Use	Respironics Millennium Series Oxygen Concentrators	Identical
Filtration Efficiency	99.999% BFE	Identical
Filter Material	Glass microfiber	Identical
Housing Material	Polystyrene or approved equivalent	Identical
Air Flow Resistance	3.0 cmH2O @ 100 slpm	Identical
Maximum Flow Rate	100 LPM	Identical
Connections	22mm ISO Male/Female	Identical

Technical Comparison, DFC06 Compressor Filters (DeVilbiss)

Item	DeVilbiss	Porous Media
Part Number	493-0019-003	DFC0644M03P
Intended Use	DeVilbiss 303, 505, or 515 Series Oxygen Concentrators	Identical
Filtration Efficiency	99.99% @ 0.3 μm	Identical
Filter Material	Glass microfiber	Identical
Housing Material	Polyester	Identical
Filtration Area	57 in^2	Identical
Connections	¼"-18 FNPT	Identical

Technical Comparison, DFC06 Compressor Filters (Respironics)

Item	Respironics	Porous Media
Part Number	100-0610-00	DFC0676M03N
Intended Use	Respironics Millennium Series Oxygen Concentrators	Identical
Filtration Efficiency	99.99% @ 0.3 μm	Identical
Filter Material	Glass microfiber	Identical
Housing Material	Nylon 6/6	Identical
Filtration Area	57 in^2	Identical
Connections	3/8" Hose Barbs	Identical

Technical Comparison, DDF47 Final Bacteria Filter (DeVilbiss)

Item	DeVilbiss	Porous Media
Part Number	493-0014-003	DDF4711M02Y
Intended Use	DeVilbiss 303, 505, or 515 Series Oxygen Concentrators	Identical
Filtration Efficiency	99.97% @ 0.3 μm	Identical
Filter Material	Glass microfiber	Identical
Housing Material	Polypropylene or approved equivalent	Identical
Connection	1/8" Hose Barbs	Identical

Technical Comparison, DDF47 Final Bacteria Filter (Invacare)

Item	Invacare	Porous Media
Part Number	P0750X030	DDF4700M03Y
Intended Use	Invacare Oxygen Concentrators	Identical
Filtration Efficiency	99.97% @ 0.3 μm	Identical
Filter Material	Glass microfiber	Identical
Housing Material	Polypropylene or approved equivalent	Identical
Connection	1/4" Hose Barbs	Identical

Technical Comparison, DDF47 Final Bacteria Filter (Respironics)

Item	Respironics	Porous Media
Part Number	369-0343-00	DDF4711M03Y
Intended Use	Respironics Millennium Series Oxygen Concentrators	Identical
Filtration Efficiency	99.97% @ 0.3 μm	Identical
Filter Material	Glass microfiber	Identical
Housing Material	Polypropylene or approved equivalent	Identical
Connections	1/8" Hose Barbs	Identical

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2006

Porous Media Corporation
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K061426
Trade/Device Name: Oxygen Concentrator Filters
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: May 22, 2006
Received: May 23, 2006

Dear Mr. Lehtonen:

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.

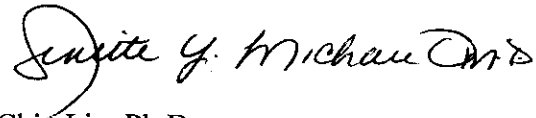
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

1. Statement of Indications for Use

Indications for Use

510(k) Number (if known): _____

Device Name: Oxygen Concentrator Filters

Indications for Use:

Porous Media oxygen concentrator filters are replacement filters intended for use in oxygen concentrator machines to help remove contaminants, including air borne bacteria and other particulate debris from an air stream. When used with oxygen concentrator machines, the replacement filters may be used in the home, nursing home, patient care facility, etc.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Ann Graham

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

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