JUN 2 6 2002

K014282

Munktell Filter AB
Box 300
S 790 20, Grycksbo, Sweden

Non-Confidential Summary of Safety and Effectiveness

April 18, 2002

Munktell Filter AB
Box 300
S 790 20 Grycksbo, Sweden

Tel - 011 (46) 23-683-80
Fax - 011 (46) 23-401-15

Official Contact: Gustav Kyrk – Managing Director

Proprietary or Trade Name: Bacstop, Bacstop Mini, Bacstop Humini

Common/Usual Name: Bacterial / Viral Filter and Heat and Moisture Exchanger

Classification Name: Filter, Bacterial, Breathing Circuit

Predicate Devices:
Gibeck – Humid-Vent Filter – K881657
Hudson RCI (Artema) Aqua +FH – K945359
Mallinckrodt – Hygroboy and Hygrobac – K941381
Mallinckrodt – Barrierbac and Barrierbac "S" – K941536

Device Description:

The Munktell Bacstop Filter and Filter / HME are available in multiple sizes and incorporate standard 15 / 22 mm connectors with a gas sampling luer port. The depth filter uses electrostatic media for filtration and a foam media for the HME media.

Intended Use:

Indicated Use -- For use with ventilators, anesthesia machines, and open flow systems where filtration of inspired and / or expired gases is desired and to add and retain moisture in the circuit as required. For pediatric patients with tidal volumes 150–500 ml and adult patients with tidal volumes >250 ml. Duration of use up to 24 hours. Single patient use.

Environment of Use -- Home, Hospital, Sub-acute Institutions, Emergency Services

General Technical Characteristics

Attribute	Munktell – Proposed devices
Indications for use - To filter inspired and / or expired gases and add and retain moisture	Same
Intended for single patient, up to 24 hours	Yes
Prescription	Yes
Intended population	Any patient, including adults and pediatrics
Intended Environment of Use	Home, Hospital, Sub-acute Institutions, Emergency Services
Placement in various locations in circuit	Yes
Design	
Gas sampling port	Yes
Standard 15/22 mm connectors	Yes
Dead Space (ml)	23 to 85 ml
Resistance to flow	$\leq$ 2.1 cm H_2O @ 60 lpm - Adult $\leq$ 0.82 cm H_2O @ 15 lpm - Pediatric
Bacterial filtration – BFE – Nelson Lab.	99.999%
Viral filtration – VFE – Nelson Lab.	99.99+%
Weight (gm)	13 to 40 gm
Humidification output (mg H_2O/l)	31 mg H_2O /L at TV of 1000 ml – adult 32 mg H_2O /L at TV of 250 ml – pediatric
Tidal volume ranges	150 – 500 ml – pediatric > 250 ml - adult
Materials	
Housing polystyrene	Yes
Filter media	Electrostatic polypropylene
HME media	Foam
Performance Standards	
None under Section 514	Yes
ISO 5356-1 Conical 15/22	Yes
ISO 594-2 Luer Fittings	Yes
ISO 9360 – HME moisture output	Yes

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed devices when compared to the predicate devices are safe and effective and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2002

Munktell Filter AB
c/o Mr. Paul Dryden
ProMedic, Inc.
6329 W. Waterview Court
McCordsville, IN 46055-9501

Re: K014282
Munktell Bacstop Filter and Filter/HME, Model # 321 201, 321 202, 321 203, 321 204 Adults, Model # 321 209, 321 210 Pediatric
Regulation Number: 868.5260
Regulation Name: Breathing Circuit Filter
Regulatory Class: II (two)
Product Code: CAH
Dated: April 2, 2002
Received: April 3, 2002

Dear Mr. Dryden:

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.

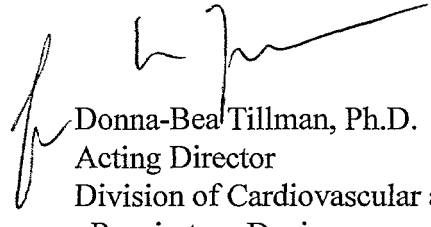
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K014282

Device Name: Bacstop Filter and Filter / HME

Intended Use: For use with ventilators, anesthesia machines, and open flow systems where filtration of inspired and / or expired gases is desired and to add and retain moisture in the circuit as required.

For patients with a tidal volume 150-500 ml (pediatrics) and >250 ml (adults).

Single patient use. Duration of use up to 24 hours.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014282

Prescription Use __ **or** **Over-the-counter use** __
(Per CFR 801.109)