

K970102



Non-Confidential Summary of Safety and Effectiveness

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January 7, 1997

JUN 24 1997

ProMedic, Inc.
6329 W. Waterview Ct.
McCordsville, IN 46055

Tel - (317) 335-3780

Fax - (317) 335-9270

Official Contact: Paul E. Dryden, President

Proprietary or Trade Name: Filter

Common/Usual Name: Breathing circuit filter

Classification Name: Filter, bacterial, breathing circuit

Device: Filter

Predicate Devices: Dryden (Gibeck-Dryden) - K833066
Med-Plastics - K930760
Engstrom - wye filter - K954194

Device Description:

A filter with a translucent housing and filter media which connects to the patient connector and the circuit tubing and manual resuscitators.

Intended Use:

Indicated Use -- To provide filtration of a patient's exhaled air and it may reduce the potential of contamination when it is utilized in anesthesia breathing circuit, ventilator circuits, manual resuscitators and during transport.

Environment of Use -- Hospital, OR, anesthesia, ICU, PACU, manual resuscitators and during transport.

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Comparison to Predicate Devices:

Use

Intended provide filtration in a breathing circuit	Yes	Yes	Yes
Used with anesthesia breathing circuit, ventilator circuits, resuscitators	Yes	Yes	Yes
Environment of use - Hospital, OR, anesthesia, PACU, ICU, transport	Yes	Yes	Yes
Indicated for single patient use	Yes	Yes	Yes

Design

Placed in the breathing circuit	Yes	Yes	Yes
Standard 15 / 22 mm fitting	Yes	Yes	Yes
May have a port for sampling CO ₂ gases	Yes	Yes	Yes
Media hydrophobic	Yes	Yes	Yes
Has a translucent housing	Yes	Yes	Yes
Compact, low deadspace	Yes	Yes	Yes

Performance Standards / Specifications

Filtration efficiency rating of BFE and VFE 99%+	Yes (Nelson)	99.9% Sangtec	Yes (Nelson)
Fittings - ASTM 1054	Yes	Yes	Yes

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Materials

Housing - Polyethylene, polystyrene	Yes	Yes	Yes
Filter media - Electrostatic	Yes	Yes	Yes
Hydrophobic media	Yes	Yes	Yes

Differences between Other Legally Marketed Predicate Devices

There is no significant differences between the intended device and the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1997

Mr. Paul E. Dryden
ProMedic, Inc.
6329 W. Waterview Court
McCordsville, Indiana 46055-9501

Re: K970102
ProMedic Wye Filter
Regulatory Class: II (two)
Product Code: 73 CAH
Dated: April 15, 1997
Received: April 21, 1997

Dear Mr. Dryden:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 3

INDICATIONS FOR USE

Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: K970102 (To be assigned)

Device Name: Filter

Intended Use : To provide filtration for reducing possible contamination between patient and equipment.

Environment of use: Hospital - OR, anesthesia, transport, PACU, manual resuscitators, and ICU

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard T. Phillips

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970102

Prescription Use
(Per CFR 801.109)

or Over-the-counter use