K023579

JAN 2 8 2003

2.1 510(k) Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness

October 23, 2002

ProMedic, Inc.
6329 W. Waterview Ct.
McCordsville, IN 46055-9501

Tel (317) 335-3780
Fax (317) 335-9270

Official Contact: Paul Dryden - President
Proprietary or Trade Name: Gas Sampling Lines
Common/Usual Name: Gas sampling accessories
Classification Name: Analyzer, Gas, Carbon dioxide, gaseous phase – accessory
Predicate Devices: Catheter Research, Inc. – K946044
Disposable gas sampling lines

Device Description:

Small bore tubing of various internal diameters and lengths, commonly referred to as gas-sampling lines. These connect to a port in the breathing circuit. May incorporate standard luer connector fittings and / or in-line filter at monitor end.

Intended Use: The gas sampling lines are intended to connect from a port in the breathing circit to the expired gas monitor.

Disposable, single use.

Environment of Use: Hospital, Sub-acute Institutions

Non-Confidential Summary of Safety and Effectiveness
Page 2 of 2
October 23, 2002

General Technical Characteristics

Attribute	**ProMedic - Proposed device**
Indications for use	The gas sampling lines are intended to connect from a port in the breathing circuit to the expired gas monitor
Intended for single use	Yes
Prescription	Yes
Intended population	Not applicable
Intended Environment of Use	Hospital, Sub-acute Institutions
Design	
Connects to a luer port in the breathing circuit and then sampling the gas, which is then transferred via the small bore tubing to the monitor	Yes
Of various lengths and diameters	Yes
May incorporate an in-line filter intended to prevent water from entering the monitor	Yes
Materials	
Tubing – PVC or PVC / PE	Yes
Luer connectors – PVC, PC	Yes
Sampling line – not in gas path	Yes
Performance Standards	
None under Section 514	Yes
ISO 594-2 – Conical fittings for luer tapers	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

JAN 28 2003

Mr. Paul Dryden
President
ProMedic, Incorporated
6329 W. Waterview Court
McCordsville, Indiana 46055-9501

Re: K023579
Trade/Device Name: Gas Sampling Lines
Regulation Number: 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: November 14, 2002
Received: November 19, 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), 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.3 Indications for Use

510(k) Number: K023579 (To be assigned)

Device Name: Gas Sampling Lines

Intended Use: The gas sampling lines are intended to connect to a port in the breathing circuit to the expired gas monitor.

Disposable, single use.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number: K023579