Michael M. Knott, M.D.
355 Pine Rose Court
Tahoe City, CA 96145

Non-Confidential Summary of Safety and Effectiveness

NOV 19 1997

November 19, 1997

Michael M. Knott, M.D. Tel - 916-583-9371
355 Pine Rose Court
Tahoe City, CA 96145

Official Contact:	Michael M. Knott, M.D.
Proprietary or Trade Name:	Knott nasogastric tube
Common/Usual Name:	Nasogastric tube
Classification Name:	Nasogastric
Predicate Devices:	Sherwood - Salem Sump Tube - K810156

Device Description:

The Knott NG tube is designed to permit withdrawal or introduction of fluids through a tube which is inserted through the nostril and into the stomach.

Indicated Use --	To permit withdrawal or introduction of fluids into the stomach via a tube placed through the nostril.
Environment of Use --	Hospital, Operating Room (OR), nursing homes, ICU and where nasogastric tubes are required.
Patient population --	Adults > 100 lbs.

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Comparison to Predicate Devices:

Attribute	Knott NG Tube	Sherwood Salem Sump Tube K810156
Design		
Provided in various diameters	Yes	Yes
Double lumen tube	Yes	Yes
One lumen for suction or fluids / one for venting	Yes	Yes
Connects to various vacuum sources	Yes	Yes
Tip has various holes leading to each lumen	Yes	Yes
May be packaged with reflux valve	Yes	Yes
Tubing has marking for assisting clinician	Yes	Yes
Pre-formed tip to help with insertion and advancement	Yes	No
Materials		
Made of PVC	Yes	Yes
Packaging		
Provided sterile	Yes	Yes
Performance Standards/Specification		
None applicable under Section 514	Yes	Yes

Differences between Other Legally Marketed Predicate Devices

The only difference in the intended device and the predicate device is the pre-formed curve and appropriate markings on the tube to assist the clinician when to rotate the tube while inserting/advancing the tube. This difference is not viewed to be significant when addressing patient safety and effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1997

Michael M. Knott, M.D.
c/o Paul E. Dryden, President
ProMedic, Inc.
6329 W. Waterview Court
McCordsville, Indiana 46055

Re: K971354
Knott Nasogastric Tube
Dated: August 18, 1997
Received: August 22, 1997
Regulatory class: II
21 CFR §876.5980/Product code: 78 FEG

Dear Dr. Knott:

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 (Premarket 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 requirement, 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 premarket 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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological 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: K971354 (To be assigned)

Device Name: Knott Nasogastric Tube

Intended Use : To permit withdrawal, introduction of fluids into the stomach or removal of stomach gas via a tube inserted through the nostril.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Nathan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971354

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