

K980946

Section 11

510(k) Summary of Safety and Effectiveness

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Date prepared: 02 February 1998

Trade Name: Mark II Manometric Perfusion Pump
 Mark II CO2 Flush Manometric Perfusion Pump
Common Name: Manometric perfusion pump
Classification Name: Monitor, esophageal motility and tube

Substantial equivalence is claimed to the following devices:

Arndorfer Medical Specialties.
 5656 Grove Terrace
 Greendale WI 53129
 U.S.A.

The Pneumo-Hydraulic Capillary Infusion System

Description

The Mark II Manometric Perfusion Pump and the Mark II CO2 Flush Manometric Perfusion Pump are gas powered perfusion pumps designed to facilitate the monitoring and analysis of intra-gastrointestinal pressures. The Mark II Manometric Perfusion Pump and the Mark II CO2 Flush Manometric Perfusion Pump are comprised of a constant gas pressure delivery system and a constant flow constant pressure, multi-channel, perfusate system with the capacity to connect pressure transducers for monitoring intragastric pressures. The Mark II CO2 Flush Manometric Perfusion Pump has an addition CO2 gas circuit for facilitating the removal of air bubbles from the perfusate circuit prior to its clinical use. Both Manometric Perfusion Pump have been designed to be compatible with gastrointestinal motility catheters.

Indications

The Mark II Manometric Perfusion Pump is used to provide a low compliant fluid pathway to enable high fidelity dynamic intragastric pressures to be measured and analyzed in both pediatric and adult populations when used with a gastrointestinal motility catheter. The product is to be used on patients in the hospital environment under supervision of a trained physician.

Technological Characteristics

The Mark II Manometric Perfusion Pump is a medical gas cylinder powered perfusion pump. It has 6 to 24 perfusate channels with attachment squares to connect pressure transducers to each channel.

The Mark II CO2 Flush Manometric Perfusion Pump is a medical gas cylinder powered perfusion pump. It has 6 to 24 perfusate channels with attachment squares to connect pressure transducers to each channel. It also has a CO2 flush circuit to assist the removal of air from the perfusate circuit.

Testing

The Mark II Manometric Perfusion Pump has been tested and shown to enable accurate intergastrointestinal pressure measurements.

Other reports (scientific papers, validation of manometric equipment)

1. **Ronald C Arndorfer**, et al. Improved infusion system for intraluminal esophageal manometry. *Gastroenterology* 73:23-27, 1977
 Depts. of Radiology and Medicine, The Medical College of Wisconsin and dept. of Engineering, Marquette University, Milwaukee, Wisconsin

Abstract

An improved catheter infusion system is needed for esophageal intraluminal manometry. Using conventional syringe pump infusion systems undesirably rapid infusion rates of 6ml/min or more are often needed to achieve accurate recording of esophageal peristaltic pressure. These rapid baseline infusion rates are necessitated by the high compliance of syringe pump systems which causes substantial reduction in the infusion rate during dynamic pressure transients. In this study we tested a hydraulic capillary infusion system designed to have low compliance. This minimally compliant system yields accurate recording of esophageal peristaltic pressure at infusion rates of 0.6 ml/min or less. We believe that the hydraulic capillary infusion system is a useful tool for performing both clinical and investigative studies of esophageal motor function.

2. **J Dent et al.** A pneumatically driven pump for constant perfusion manometry. *The Australian Journal of Experimental Biology and Medical Science*, 55:293-298, 1977
Monash University Dept. of Medicine and dept. of Medical Physics, Austin Hospital Victoria Australia.

Abstract

Syringe pumps are almost universally used for constant perfusion oesophageal manometry, despite important technical limitations. A pneumatically driven perfusion pump has been designed specifically for oesophageal manometry. This pump requires less than one third the flow setting of a syringe pump to achieve a given rate of pressure rise. It is simple to operate and needs infrequent refilling. Nearly two years' practical experience with this pump has confirmed its superiority over the syringe pump for constant perfusion manometry.

3. **Geoffrey S Hebbard et al.** Assessment of gastrointestinal pressure gradients using high resolution perfusion manometry. Abstract, Digestive Diseases Week, Washington US, May 1997

JUN - 8 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. Marcus Tippet
Dentsleeve Pty, Ltd
56 A/B Glen Osmond RD.
Parkside, South Australia
Australia, 5063Re: K980946
Mark II and Mark II CO2 Flush Manometric Perfusion Pump
Dated: February 28, 1998
Received: March 13, 1998
Regulatory Class: II
21 CFR §876.1725/Product code: 78 FFX

Dear Mr. Tippet:

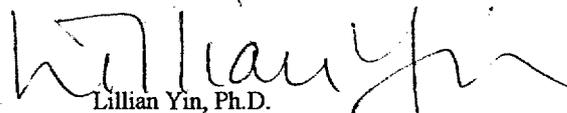
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 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/dsma/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

510(k) number (if known):

K980946

Device Name:

Mark II CO2 Manometric Perfusion Pump & Mark II
Manometric Perfusion Pump
Product code: 78KLA

Indications For Use:

When used in conjunction with a gastrointestinal manometric assembly (catheter), the Mark II CO2 Manometric Perfusion Pump & Mark II Manometric Perfusion Pump, can be used where gastrointestinal manometry is indicated when the following conditions are satisfied;

- 1) When information about patterns of gastrointestinal pressures is judged to be of importance for either determining appropriate patient management or for research studies into gastro-intestinal motility.
- 2) Contra-indications are considered, and the risk-benefit analysis is judged to favour performance of the manometric study, after measures have been taken to minimise all possible risks.

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

Concurrence of CDRII, Office of Device Evaluation (ODE)

Catalyn Y Newland for R. Gething
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K980946

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)