AUG 0 5 2002

K013704
PAGE 1 OF 2

8.0 Premarket Notification [510(k)] Summary

SMDA 510(K) Summary
[as required by Section 80792(c)]

Trade Name:	Mediplus Esophageal Manometery Catheter
Common Name	Esophageal Manometery Catheter
Classification Name:	Gastrointestinal motility monitoring catheter (21 CFR 876.1725)
Applicant:	Mediplus Ltd.
Address:	37-39 Baker Street High Wycombe Buckinghamshire HP11 2RX United Kingdom Telephone: +44 1494 551200 Fax: +44 1494 536333
Submission Correspondent:	Ms. Elizabeth M. Paul 541 Moreno Circle NE St. Petersburg, FL 33703 Telephone: 727.525.1247 Email: epaul@tampabay.rr.com
Date of Preparation:	November 5, 2001
Legally Marketed Devices to which Mediplus claims Equivalence to:	Arndorfer Esophageal Manometry Catheter and Dentsleeve Manometric Multilumen Extrusion

Device Description:

Mediplus GI Motility Manometric Catheters are design for the monitoring of gastrointestinal pressure. They are designed to be used with a manometric infusion pump. The major structure of the Mediplus Manometric Catheter is a multi-lumen PVC tube.

The catheters are designed with variations of the configuration of the channels (depending on the model and application). The catheter facilitates the measurement of pressure at a fixed number of points along the upper gastro-intestinal tract when correctly installed to water perfusion manometry transducer equipment. Measurement is accomplished by perfusion of water through each catheter lumen. Each column of water transmits pressure to a transducer. The equipment terminates in a pressure transducer and 3-way tap.

Intended Use

The Mediplus Single Use GI Manometry Catheter is intended for water-perfused manometry of the GI tract.

Technological Characteristics

The Mediplus GI Monitoring Catheter is technologically equivalent to both predicate devices in design and physical characteristics. Like the Arndorfer catheter, it is made of PVC, which has been used historically for intubations.

Testing and Safety

The Mediplus GI Manometry Catheter has been tested for biocompatibility and meets the requirements of ISO 10993 and USFDA 510(k) Memorandum - # K95-1for the intended use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 5 2002

Mediplus, Ltd.
c/o Ms. Elizabeth M. Paul
Submission Correspondent
RQA Compliance
541 Moreno Circle NE
ST. PETERSBURG FL 33703

Re: K013704
Trade/Device Name: Mediplus Single Use GI Manometry Catheters - Models 2244-1, 2244-8, 2280, 2235 & 2135
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: 78 KLA
Dated: May 1, 2002
Received: May 7, 2002

Dear Ms. Paul:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013704

Device Name: MEDIPLUS SINGLE USE GI MANOMETRY CATHETER

Indications For Use:

The Mediplus Single Use GI Manometry Catheter is indicated for use when measurements of gastrointestinal tract pressures are needed for the diagnosis of suspected gastrointestinal disorders:

- Investigation of gastrointestinal diseases
- Motility disorders
- Swallowing disorders
- Reflux disorders
- Gastric and intestine disorders
- Colonic and anorectal disorders

This product is for use by a trained physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Hegarty

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013704