mediplus

K031617

JAN 1 6 2004

Premarket Notification [510(k)] Summary

[as required by Section 80792(c)]

1.1 Trade Name	Mediplus Single Use Anorectal Manometry Catheter
1.2 Common Name	Anorectal GI manometry catheter
1.3 Classification Name	gastrointestinal motility monitoring catheter (21 CFR 876.1725)
1.4 Product Code	78KLA
1.5 Applicant	Mediplus Limited
1.6 Address	Unit 7 The Gateway Centre Coronation Road Cressex Business Park High Wycombe Bucks HP12 3SU United Kingdom Telephone: +44 (0) 1494 551200 Fax: +44 90) 1494 536333
1.7 Submission Correspondent	Dr. Norman Estrin Estrin Consulting Group Inc 9109 Copenhaver Drive Potomac, MD20854 USA Telephone: 301 279 2899 Fax: 301 294 0126
1.8 Date of Preparation	January 9, 2004
1.9 Predicate Device	Medtronic Zinectics anorectal water perfused manometry catheter

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1.10 Device Description

Mediplus Single Use Anorectal GI Manometry Catheters are designed for the monitoring of anorectal canal pressure. They are designed to be used with a manometric infusion pump. The major structure of the Mediplus Anorectal GI Manometry 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 anorectal gastrointestinal 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.

1.11 Intended Use

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

1.12 Indications for Use

The Mediplus Single Use Anorectal GI Manometry catheter is indicated for use when measurements of gastrointestinal tract pressures are needed to assist in the diagnosis of suspected colonic and anorectal disorders. The product is for use by a trained physician.

1.13 Technological Characteristics

The Mediplus Single Use Anorectal GI Manometry is technologically equivalent to the predicate device in design and physical characteristics. Like the Medtronic Zinectics anorectal water perfused manometry catheter, it is made of PVC, which has been used historically for intubations.

1.14 Testing and Safety

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2004

Mediplus Ltd.
c/o Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaven Drive
POTOMAC MD 20854

Re: K031617
Trade/Device Name: MEDIPLUS® Single Use Anorectal GI Manometry Catheter
Regulation Number: 21 CFR §876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: 78 KLA
Dated: October 23, 2003
Received: October 24, 2003

Dear Dr. Estrin:

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 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 one of the following numbers, based on the regulation number at the top of the 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" (21CFR Part 807.97) you may obtain. 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: K031617

Device Name: Mediplus single use anorectal GI manometry catheter

Indications for Use:

The Mediplus single use anorectal GI manometry catheter is intended for use when measurements of gastrointestinal tract pressures are needed to assist in the diagnosis of suspected colonic and anorectal disorders. The 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 X (Per 21 CFR 801.109) OR Over-the-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031617