NOV 1 0 1999

510(k) Notification
Esophageal Manometry System

510(k) SUMMARY

as required per 807.92(c)

1. Submitters Name, Address:

Medtronic Functional Diagnostics A/S
Tonsbakken 16-18
DK-2740 SKOVLUNDE
Tel: (+ 45) 44 57 90 00
Fax: (+ 45) 44 57 90 10
Contact person for this submission: Ann-Christine Jönsson
Date submission was prepared: 6th August, 1999

2. Trade Name, Common Name and Classification Name:

A. Trade Name: Esophageal Manometry System

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Polygraf ID	78 FFX	II	21 CFR 876.1725
Polygram 98, Esophageal Manometry Application	78 KLA, FFX	II	21 CFR 876.1725

3. Predicate Device Identification:

The functionality and intended use of the Esophageal Manometry System is equivalent to Medtronic Synectics Polygraf HR (K872712) with Polygram for Windows, Base Module (K946322) and Esophageal Manometry Analysis Module (K961070).

4. Device Description:

The system is a stationary manometry system for use in evaluating the function of the gastrointestinal tract. The system measures pressure and other parameters online using sensors on and in the patient. The parameters are presented during the capture and are also recorded for later display, analysis and reporting.

In its daily use, a trained technician and/or a physician are the main users of the system.

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The main tasks when performing a manometry procedure with a stationary manometry system are:

- Prepare equipment including calibration
- Enter patient/study demographic information
- Perform procedure and obtain relevant data
- Review, analysis and post procedure activities
- Create and print a report

The Polygram 98 Esophageal Manometry Application software runs on Microsoft Windows® 98

5. Intended Use:

The Esophageal Manometry System is intended to record, store, view and analyze data on line in the gastrointestinal tract to assist in the diagnoses of gastrointestinal disorders.

6. Table of Device Similarities and differences to predicate device

Manufacturer	Medtronic Synectics AB	Medtronic Functional Diagnostics A/S	–
510(k) number	***Predicate devices*** • Polygraf HR – K 872712 • Polygram software, base module – K 946322 • Esophageal Manometry Analysis Module – K 961070	***Modified Device*** Esophageal Manometry System, (EM System) i.e - Polygraf ID & - Polygram 98, Esophageal Manometry Application K number to be decided	–

General:	***Predicate devics:*** - all	***Modified Device*** - EM System	***Explanation of the differences compared to the Predicate devices***
Intended Use / Indication of Use	Record, store, view and analyze data on line in the gastrointestinal tract to assist in the diagnoses of gastrointestinal disorders..	Same	--
Intended Populations	Infant, Pediatric to Adults	Same	--
Sterilization	Accessories are not supplied sterile, manufacturer label the accessories with cleaning instructions.	Same	--
Biocompatibility	The Sensors are the only part that comes into contact with the patients.	Same	--

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Technical Features:	*Predicate devices* - Polygraf HR	*Modified Device* - Polygraf ID	*Explanation of the differences compared to the Predicate devices*
Number of Channels	Up to 16	4-16 channels	Enhanced performance
Sampling rate	1/128 to 128 Hz	105-1674 Hz	Enhanced performance
Power supply	9 –12 V DC	24 V DC	110-230 V Power Supply in one
Measuring range	0-9 pH	-2.5 Vpm, 5 % to 2.5 Vpm 5%	Enhanced performance
Insulation	Burr Brown722 dual isolated DC/DC converter	HCPL-0710. NMV 2405S, and safety power supply: class I	Enhanced performance, isolation provided also within each module of 4 channels (4, 8, 12, 16.)
Current consumption	260 mA nom standard (8bit)	Max 0.8 A	Enhanced performance requires more power
Communication	Optical serial RS 232	USB (Universal Serial Bus)	Enhanced performance (band width)
Resolution	8 bit	22 bit	Enhanced performance
Dimension	11.2" x 2" x 6 "	14" x 8.8" x 2.8"	More channels require more space
Weight	1 050 g	< 3 000 g	Larger box weight more
On-line monitoring	Via PC Screen	Same	---

Features:	*Predicate devices* - Base module & - pH Analysis Module, EsopHogram pH Reflux Analysis	*Modified Device* - Polygram '98, EM Extension	*Explanation of the differences compared to the Predicate devices*
Signals to analyze	Ph, pressure, flow, volume, respiration, oxygen saturation, pulse rate, body position, snoring	Pressure, respiration and swallow	Not all are implemented in this first version.
User commands	Menu selections, keyboard combinations, screen "buttons"	Same	--
Esophageal Analysis	- LES analysis - Esophageal motility analysis - UES analysis	- LES analysis - Esophageal motility analysis	- UES analysis, will be introduced in coming versions of the SW.
Calculated parameters	LES location LES resting pressure LES relaxation LES residual pressure Esophageal motility: - amplitude - duration - velocity UES location UES resting pressure UES residual pressure Quick calculations	LES location LES resting pressure LES relaxation LES residual pressure Esophageal motility: - amplitude - duration - velocity	The following parameters will be introduced in coming versions of the SW: UES location UES resting pressure UES residual pressure Quick calculations
Reports	Signal tracings and reports. Optionally selections only.	Same	--
Patient database	Relational database with logical patient- recording relations	Same	--
Additional data	User definable additional patient/recording parameters	Same	--
User help system	Online help system with descriptions of procedures	Same	--
Signal review method	Time – tracing based	Same	--

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Recording control	Real time monitoring of signals	Same	--
Calibration	Adjustable and fixed gain method. Monitoring of calibration result for range and resolution requirement.	Same	--
Recording configuration	A template is used for each type of recording. User definable. Once used, not possible to change, ensuring recording integrity	Same ('templates' are now called 'protocols')	--
Programming language	'C'	C++, Visual Basic	--
Operating system	Windows 3.11, 95	Windows 98	Enhanced performance

7. Assessment of non-clinical performance data for equivalence:
Verifications results shows that the enhanced system performs as its predicate system.

8. Assessment of clinical performance data for equivalence:
Clinical trials are not performed. This new system doesn't raise any new safety or performance issues.

9. Biocompatability:
Not applicable .

10. Sterilization:
Not applicable

11. Standards and Guidances:

The Esophageal Manometry System complies to the following standards:

- EN 60601-1:1990 and Amendments A1, A11, A12 and A13

- UL 2601-1, Second Edition, 1997

- CAN/CSA C22.2 No.610.1-M90

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1999

Ms. Ann-Christine Jönsson
Regulatory Affairs
Medtronic Functional Diagnostics A/S
Tonsbakken 16-18
Skovlunde DK-2740
DENMARK

Re: K992713
Esophageal Manometry Testing Application
(Polygraf ID, Polygram '98)
Dated: August 6, 1999
Received: August 12, 1999
Regulatory Class: II
21 CFR 876.1725/Procode: 78 FFX

Dear Ms. Jönsson:

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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indication for Use Statement

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510(k) Number (if known): K992713

Device Name: _____

Indications for Use:

The Esophageal Manometry System is intended to record, store, view and analyze data on line in the gastrointestinal tract to assist in the diagnoses of gastrointestinal disorders.

MRI Compatibility Statement:

The Esophageal Manometry System is not compatible for use in a MRI magnetic field.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992713

COMPANY CONFIDENTIAL

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