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 95 02
Fax: + 45 44 57 90 10
Contact person for this submission: Tove Kjaer
Date submission was prepared: May 10, 2001

2. Trade Name, Common Name and Classification Name:

A. Trade Name: Polygram 98 pH Testing System (incl. bile)

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

Common Name	Classification Number	Class	Regulation Number
Bilitec 2000	78 FFX	II	21 CFR 876.1725
Optical Fiber Probe	78 FFX	II	21 CFR 876.1725
Polygram 98 pH Testing Application	78 FFX	II	21 CFR 876.1725

3. Predicate Device Identification:

The functionality and intended use of the Polygram 98 pH Testing System (incl. bile) is equivalent to Medtronic Functional Diagnostics A/S's Polygram 98 pH Testing System (K 981733).

510(k) Notification
43S11 Polygram 98 pH Testing System (incl. bile)

4. Device Description:

The system is an ambulatory system for use in evaluating reflux disorders in the gastrointestinal tract. The system measures bile online using sensors in the patient. The data is captured and recorded. The data is uploaded from the Bilitec 2000 by use of the Polygram 98 pH Testing Application software for later display, analysis and reporting. In its daily use, a trained technician and/or physician are the main user of the system.

The Main tasks when performing a reflux testing procedure:

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

5. Intended Use:

The Polygram 98 pH Testing System is intended to record, store, view and analyze esophageal and gastric refluxate data to diagnose reflux disorders. The Polygram 98 pH Testing System can also be used to locate the position of the proximal Lower Esophageal Sphincter (LES) manometrically, to assist in the accurate placement of the pH catheter.

6. Table of Device Similarities and differences to predicate device

Manufacturer	Medtronic Synectics AB	Medtronic Functional Diagnostics A/S	
510(k) number	***Predicate Device*** Polygram 98´ pH Testing System, i.e • Digitrapper pH • Polygram ´98, pH Testing Application **- K 981733**	***Modified Device*** Polygram 98 pH Testing System v2.2 (incl. Bile) , i.e • Bilitec 2000 • Polygram 98, pH Testing Application v2.2 (including Bile)	Polygram 98 software has been updated in order to facilitate upload and analysis of data recorded by the Bilitec 2000 device

510(k) Notification
43S11 Polygram 98 pH Testing System (incl. bile)

General:	***Predicate devics:*** - all	***Modified Device*** - pH System	***Explanation of the differences compared to the Predicate devices***
Intended Use / Indication of Use	The pH System is intended to record, store, view and analyze esophageal and gastric pH data to diagnose reflux disorders. The pH System can also be used to locate the position of the proximal Lower Esophageal Sphincter (LES) manometrically, to assist in the accurate positioning of the pH catheter	The pH System is intended to record, store, view and analyze esophageal and gastric refluxate to diagnose reflux disorders. The pH System can also be used to locate the position of the proximal Lower Esophageal Sphincter (LES) manometrically, to assist in the accurate positioning of the pH catheter	Same
Intended Populations	Pediatric to Adults	Same	
Sterilization	Accessories are not supplied sterile, manufacturer label the accessories with cleaning instructions.	Same	
Biocompatibility	Catheters are the only part that come into contact with the patients.	Same	

Technical Features:	***Predicate devices*** - Digitrapper pH	***Modified Device*** - Bilitec 2000	***Explanation of the differences compared To the Predicate devices***
Number of Channels	4 channels pH, 1 pressure	2 channels Bile	
Sampling rate	¼ Hz	1 Hz with 4, 8 or 16sec averaging time	
Memory Size	2Mb Flash Data RAM	128 Kbytes flash memory	
Event markers	3	1 event marker	
Built in memory back up	Now has Flash ram (no backup required). Clock has 14 days backup.	Has Flash ram.	Flash RAM is non-volatile therefor requires no 'backup'. The Bilitec has no clock and no back-up of date/time information is then required
Power supply	2 x 1.5V AA alkaline	4 x 1,5V AA size alkaline batteries	
Measuring range	0-9 pH	Absorbance from 0 to 1 unit	The spectrophotometric measurement of the absorbance of Bile (bilirubin) is measured in the range of 0 to 1 (0-100%)
Recording time	24 Hours	24 Hours	
Current consumption	20mA	30 mA in normal mode and 16 mA on average in Sampling/idle mode	The set-up mode and the spectrophotometric measurement requires different levels of current consumption
Communication	IrDA Communication (Infra Red)	Serial communication 9600 baud	This is a standard serial port as on all PC's.
Resolution	Better than 0.01pH	<= 0,004 absorbance unit	
Display	119 by 73 pixel graphic display.	LCD consists of 4 rows with 16 characters	
Dimension	115 x 140 x 50 mm	200mm x 100mm x 35mm	
Weight	300 gr.	450 gr.	
On-line monitoring	Via own Screen	Same	

Features:	***Predicate Device*** - Polygram '98, pH Testing Application	***Modified Device*** - Polygram '98, pH Testing Application v2.2 (including Bile)	***Explanation of the differences compared to the Predicate devices***
Signals to analyze	pH	PH and Bile	
User commands	Menu selections, keyboard combinations, screen "buttons"	Same	
Calculated parameters	1. Maximum, Minimum 2. Duration of period 3. Number of acid refluxes 4. Number of long acid refluxes 5. Longest acid reflux 6. Total time pH below 4 7. Fraction time pH below 4 8. Symptom index 9. Symptom Association Probability 10. Number of alkaline shifts 11. Number of long alkaline shifts 12. Longest alkaline shift 13. Total tome pH above 8 14. Fraction time pH above 8	Same for pH, plus for Bile analysis: 1. Maximum, Minimum 2. Duration of period 3. Number of bile refluxes 4. Number of long bile refluxes 5. Longest bile reflux 6. Total time bile above 0,14 7. Fraction time bile above 0,14 8. Symptom index 9. Symptom Association Probability	Calculated parameters for bile are similar to the pH analysis
Scoring, Normals	15. DeMeester & Johnson (adult) 16. Boix-Ochoa (pediatric) 17. Infant normals percentile graph (ESPGAN normals)	Same for pH. NA for the Bile analysis	No scoring system exists for Bile analysis
Reports	Signal tracings and reports. Optional 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	
Recording control	Real time monitoring of signals	Same	
Recording configuration	A template is used for each type of recording. User definable.	Same	

510(k) Notification
43S11 Polygram 98 pH Testing System (incl. bile)

7. Assessment of non-clinical performance data for equivalence:

Verifications results show that the enhanced system performs as its predicate system.

8. Assessment of clinical performance data for equivalence:

Clinical trials have not been performed. This new system does not raise any new safety or performance issues.

9. Biocompatability:

The Optical Fiber probe has been tested for biocompatibility.

10. Sterilization:

Not applicable

11. Standards and Guidances:

The Polygram 98 pH testing System (incl bile) conforms to the following voluntary and mandatory standards:

- EN 60601-1, Medical equipment

The following guidances were followed:

- DRAERD Premarket Notification 510(k) Screening checklist, RRG Rev. 3/14/95
- ODE Guidance for the Content of Premarket Submission for Medical Device Containing Software Draft Document

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 8 2002

Mr. Toni Kennet Jørgensen
Regulatory Affairs Specialist
Medtronic
Functional Diagnostics A/S
Tonsbakken 16-18
DK-2740 Skovlunde
DENMARK

Re: K011471
Trade/Device Name: Polygram '98 pH Testing System (incl Bile), Bilitec™ 2000 and Optical Fiber Probe
Regulation Number: 21 CFR §876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: 78 FFX
Dated: August 9, 2002
Received: August 12, 2002

Dear Mr. Jørgensen:

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

Indication for Use Statement

510(k) Number (if known): K011471

Device Name: **Polygram 98 pH Testing System (incl. bile)**

Indications for Use:

The Polygram 98 pH Testing System is intended to record, store, view and analyze esophageal and gastric refluxate data to diagnose reflux disorders. The Polygram 98 pH Testing System can also be used to locate the position of the proximal Lower Esophageal Sphincter (LES) manometrically, to assist in the accurate placement of the pH catheter.

MRI Compatibility Statement:

The Ambulatory pH 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)

David A. Ayres

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011471