K981733

510(k) Notification
pH Testing System

FEB 4 1999

510(k) SUMMARY

as required per 807.92(c)

1. Submitters Name, Address:

Medtronic Synectics AB
Renstiernas gata 12
S-116 28 STOCKHOLM
Tel: (45) 44 57 90 00
Fax: (45) 44 57 90 10
Contact person for this submission: Ann-Christine Jönsson
Date submission was prepared: 18th May, 1998

2. Trade Name, Common Name and Classification Name:

A. Trade Name: pH Testing System

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

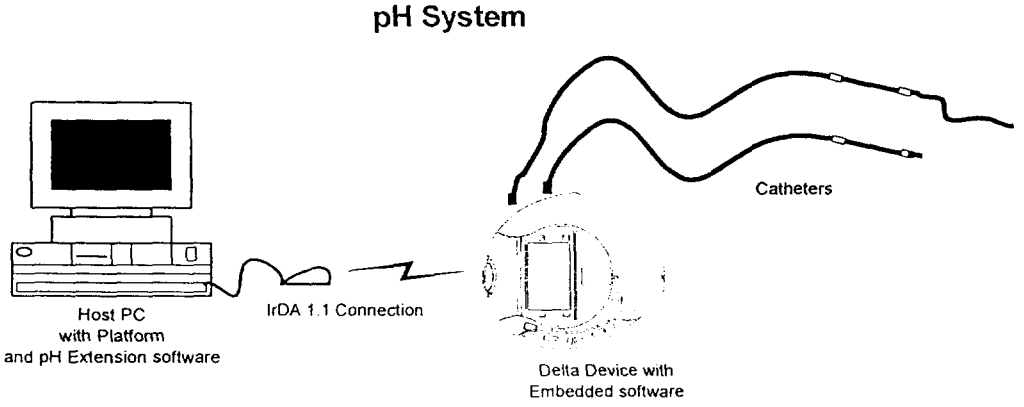
Common Name	Classification Number	Class	Regulation Number
Digitrapper Delta	78 FFX	II	21 CFR 876.1725
Polygram '98, pH Testing Application	78 FFX	II	21 CFR 876.1725
pH catheters	78 FFT	I	21 CFR 876.1400

3. Predicate Device Identification:

The functionality and intended use of the pH Testing System is equivalent to Medtronic Synectics Digitrapper MK III (K913387) with Polygram for Windows, Base Module (K946322) and EsopHogram reflux Analysis (K961346).

4. Device Description:

The pH Testing System consists of a general purpose PC running the pH Application software namned EsopHogram '98, a recording device namned Digitrapper Delta and catheters appropriate for the study to be performed. The illustration below shows the various components.



The general process for use of the system occurs in two parts. In the first part, physiological data is collected by the Delta. This is done by a technician intubating a patient with the appropriate catheter(s), connect the catheter(s) to a Digitrapper Delta, turning on the recording, and allowing the patient to proceed with their normal life. At the prescribed time, the patient returns to the technician who removes the equipment from the patient.

Following that, the technician transfers the recorded data in the Digitrapper Delta to the PC where the pH Extension software is used to analyze it. This analysis includes marking refluxes in the data traces and calculating a variety a measurements such as DeMeester score and the Boix-Ochoa scoring method. Hardcopies can be printed of the raw data as well as tailored reports.

Results of the analysis are then used by a doctor to help make a diagnosis

5. Intended 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 placement of the pH catheter.

6. Table of Device Similarities and differences to predicate device

Manufacturer	Medtronic Synectics AB	Medtronic Synectics AB	–
510(k) number	**Predicate devices** • MK III – K 913387 • Polygram software, base module – K 946322 • pH Analysis Module – K 961346	***Modified Device*** Polyram 98´ pH Testing System, i.e • Digitrapper Delta & • Polygram '98, pH Testing Application - K 981733	–

General:	***Predicate devics:*** - all	***Modified Device*** - pH System	***Explanation of the differences compared to the Predicate devices***
Intended Use / Indication of Use	Esophageal and gastric pH data acquisition and analysis to diagnose reflux disorders.	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 comes into contact with the patients.	Same	--

Technical Features:	***Predicate devices*** - MK III	***Modified Device*** - Digitrapper Delta	***Explanation of the differences compared to the Predicate devices***
Number of Channels	4 pH, 1 p	Same	--
Sampling rate	¼, 1/8, 1/16 Hz	Programmable through 1/16Hz up to 8 Hz	This new range captures all the old range while also allowing the possibility to be flexible enough to cope with possible future demands for higher sampling rates.
Memory Size	96 kB	4Mb Flash Data RAM	Larger memory size to incorporate possible future enhancements.
Event markers	4	3	Customer requirement
Built in memory back up	14 days	Now has Flash ram (no backup required). Clock has 14 days backup.	Flash RAM is non-volatile therefor requires no 'backup'. However the clock will keep the time for convenience sake. (you don't have to reset the time).
Power supply	9 V alkaline battery	2 x 1.5 AA alkaline	More available batteries
Measuring range	0-9 pH	Same	--
Recording time	24, 48 & 96 hours	24 Hours	Customer requirement with only 24 hours.
Current consumption	4 mA	20mA	The new device runs at 3V so the current increases to meet the power demands.
Communication	8 bit parallel Synectics Liberty or Combi Interface, Serial interface to computer or printer	IrDA Communication (Infra Red)	This is a standard device that is present on all Notebooks. The IR Dongle can also be plugged into

			not require a removal of the computer cover to install.
Resolution	0.04 pH	Better than 0.01pH	The MKIII has an 8 bit converter and fixed gain. The new one has 12bit resolution and adjustable gain.
Display	32 character LCD LES identification display	119 by 73 pixel graphic display.	Enhances user interface
Clock	Built-in real time clock	Same	--
Dimension	4.8 x 2.6 x 1.0 in	115 x 140 x 50	--
Weight	10.6 oz (300g)	Approx. the same	--
On-line monitoring	Via own Screen	Same	--

Features:	***Predicate devices*** - Polygram software, base module & - pH Analysis Module, EsopHogram pH Reflux Analysis	***Modified Device*** - Polygram '98, pH Testing Application	***Explanation of the differences compared to the Predicate devices***
Signals to analyze	pH	Same	--
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 Not Available Not Available	-- Excluded in the first version Excluded in the first version
Scoring, Normals	1. DeMeester & Johnson (adult) 2. Boix-Ochoa (pediatric) 3. Infant normals percentile graph (ESPGAN normals)	Same Not Available Not Available	-- Excluded in the first version Excluded in the first version
LES identification	Bar Graph	Displays an actual manometric tracing on screen.	Enhanced LES identification.
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	--
Recording control	Real time monitoring of signals	Same	--
Recording configuration	A template is used for each type of recording. User definable. Once used, not possible to change, ensuring recording integrity	Same	--

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:

Fields tests are on going.

9. Biocompatability:

Not applicable .

10. Sterilization:

Not applicable

11. Standards and Guidances:

The pH System complies to the following standard:

- IEC 60601-1, Second edition, 1988 with Amendment 1, 1991 and Amendment 2, 1995. (EN 60601-1:1990 and Amendments A1, A11, A12 and A13)
- UL 2601-1, 1994
- CAN/CSA-22.2 No 601.1-M90
- JIS T 1001
- AS/NZS 3200-1-0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 1999

Ann-Christine Jönsson
Regulatory Affairs
Medtronic Functional Diagnostics AB
16-18 Tonsbakken
DK-2740 Skovlunde
DENMARK

Re: K981733
Digitrapper Delta, Model 9043G0201 and
Polygram '98 pH Extension
Dated: November 4, 1998
Received: November 9, 1998
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

K 981733.

510(k) Notification
pH System

Indication for Use Statement

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510(k) Number (if known):_____

Device Name:_____

Indications for 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 placement of the pH catheter.

MRI Compatibility Statement:

The 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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981733/S001