

510(k) Notification
23S20 Anorectal Manometry Suite for Duet / Duet MultiP

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: Ann-Christine Jönsson
Date submission was prepared: 19th April, 1999

2. Trade Name, Common Name and Classification Name:

A. Trade Name: Anorectal Manometry Suite for Duet / Duet MultiP

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

Common Name	Classification Number	Class	Regulation Number
Anorectal Manometry suite	78 FFX	II	21 CFR 876.1725

3. Predicate Device Identification:

The scientific technology and the functionality and intended use of the Anorectal Manometry Suit for Duet is equivalent to Medtronic Synectics Anorectal Manometry Analysis Module (K972439).

510(k) Notification
23S20 Anorectal Manometry Suite for Duet / Duet MultiP

4. Device Description:

The Anorectal Manometry Suit is together with Duet/Duet MultiP intended to record a patients anorectal function comprising EMG and pressure recordings. The whole system includes transducers, devices, tubing, catheters and electrodes.

The Duet / Duet MultiP is an apparatus capable of registration of pressure signals over a long time. The measurements and analysis have originally been developed for urodynamics tests, but since anorectal tests also are measuring pressure signals over a period of time, it is suitable to use the same technique for these types of tests, i.e. anorectal tests.

The device is used in a dedicated clinical setup. The following sets of test types are predefined tests for measuring in the rectum:

- Sphincter Profile,
- Resting Pressure,
- Rectal Balloon test,
- Balloon Expulsion Test,
- Squeeze Test,
- Recto-Anal Inhibitory Test.

The tests are operated just like the urodynamic tests. A license number is required to enable the software for the Anorectal Manometry Suite.

5. Intended Use:

The Duet-with anorectal manometry suite is intended as a diagnostic tool to measure and record the functioning of the patient's urinary tract and anorectal function*. The measurements comprise recording of pressure, volume, flow and EMG.

* expanded indication for use due to the Anorectal Manometry Suit.

510(k) Notification
23S20 Anorectal Manometry Suite for Duet / Duet MultiP

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 evaluation not performed.

9. Biocompatibility:

This new anorectal suit is an extension of the software and there is no contact with the patient. The only part of this system that comes into contact with the body are the accessories and they are already in commercial distribution on the US market.

10. Sterilization:

Not applicable

11. Standards and Guidances:

The Duet / Duet MultiP complies to the following standard:

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

The Anorectal manometry suite is a pure software enabling and doesn't affect the hardware.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 1999

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

Re: K991389
Anorectal Manometry Suite for Duet/Duet MultiP
Dated: April 19, 1999
Received: April 21, 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

Indication for Use Statement

Page 1 of 1

510(k) Number (if known): _____

Device Name: **Anorectal Manometry Suit**

Indications for Use:

The Duet-with Anorectal Manometry Suite is intended to measure and record the functioning of the patient's urinary tract and anorectal function*. The measurements comprise recording of pressure, volume, flow and EMG. The system includes transducers, devices, tubing, catheters and electrodes.

* expanded indication for use due to the Anorectal Manometry Suite.

MRI Compatibility Statement:

The Duet with Anorectal Manometry Suite 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)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K991389

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

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