FEB 28 2000

K992715
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510(k) Notification
Neuro Urodynamic Suite for Duet / Duet MultiP version 8.1

510(k) SUMMARY

as required per 807.92(c)

1. Submitters Name, Address:

Medtronic Functional Diagnostics A/S
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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: Neuro Urodynamic Suite for Duet 8.1

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

Common Name	Classification Number	Class	Regulation Number
Neuro Urodynamic Suite	84 GWF 84 GWP	II	21 CFR 882.1550 21 CFR 882.1870

3. Predicate Device Identification:

The functionality and intended use of the Neuro Urodynamic Suite for Duet/Duet MultiP version 8.1 is equivalent to the two software test programs Motor Nerve conduction (MCV) and Electromyography (EMG) in Medtronic Dantecs Keypoint (K 944547).

4. Device Description:

The Duet version 8.1 is enhanced with a new suite of test programs for EMG and Motor Nerve conduction measurements. The suite is called Neuro Urodynamics Suite and consists of the following predefined testprogram:

- Neuro - Free Run EMG
- Neuro - Motor Nerve Conduction
- Neuro - Sacral Reflex

The Neuro Urodynamic Suite is together with Duet/Duet MultiP intended to record a patients urodynamic functions and examination of the motor innervation of the spincters and the pelvic floor and the sensory innervation of pelvic structures.

The whole system includes transducers, devices, tubing, catheters and electrodes. The tests are operated just like the urodynamic and anorectal tests. A license number is required to enable the software for the Neuro Urodynamic Suite.

5. Intended Use:

The Neuro-Urodynamics Suite for Duet / Duet MultiP is indicated for electrophysiological testing of the pelvic organs including motor nerve conduction, sacral reflex, and free-run EMG tests.

6. Table of Device Similarities and differences to predicate device

Manufacturer	Dantec Medical A/S	Medtronic Functional Diagnostics A/S	–
510(k) number	*Predicate devices* • Keypoint (only software modules EMG, MCV) – K 844547	*Modified Device* - Duet /Duet MultiP with Neuro Urodynamic Suite K number to be decided	–

General:	*Predicate devics:* - Keypoint	*Modified Device* - Duet with Neuro Urodynamic Suite	***Explanation of the differences compared to the Predicate devices***
Intended Use / Indication of Use	Electrophysiological testing.	Electrophysiological testing of the pelvic floor field.	This suite will be used with the other usages for Duet (i.e urodynamics and anorectal manometry).
Intended Populations	Pediatric to Adults	Same	--
Sterilization	Accessories are supplied both sterile and non sterile, OEM manufacturer label the accessories with cleaning instructions.	Same	--
Biocompatibility	The Sensors are the only part that comes into contact with the patients.	Same	--

Technical Features:	*Predicate devices*	*Modified Device*	***Explanation of the differences compared to the Predicate devices***
Signals to analyze	Electrophysiological signals	Same	---
User commands	Menu selections, keyboard combinations, screen "buttons"	Same	Modified Device is running under Windows

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Test programs	- MCV Motor nerve conduction velocity a conventional method to diagnose generalized polyneurophathy or local entrapment. - EMG Studies muscle function. The test is made at muscle rest, during slight activity and during strong volentarily activity.	-Nerve Conduction - Sacral Reflex Same - Free Run EMG Same	New names, same content in test program.
Calculated parameters	Impulse, velocity, response amplitude and area, decay and duration.	Latency, velocity, response, amplitude and duration	Modified Device offers a subset of Predicate Device.
Reports	Signal tracings and reports. Optionally selections only.	Same, reports in Word format	Modified Device is running under Windows.
Patient database	Relational database with logical patient- recording relations	Same, database in Word format	Modified Device is running under Windows
Additional data	User definable additional patient/recording parameters	Same	—
User help system	Online help system with descriptions of procedures	No	Printed Instructions for Use
Signal review method	Time – tracing based	Same	---
Recording control	Real time monitoring of signals	Same	---
Calibration	Adjustable and fixed gain method. Monitoring of calibration result for range and resulotion 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	---

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. This new software version does not raise any new issues regarding performance or safety that can not be tested in-house.

9. Biocompatability:

This new Neuro Urodynamic Suite is an extension of the software and there is no contact with the patient. The only parts 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 Neuro Urodynamic suite is a pure software enabling and doesn't affect the hardware.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2000

Ms. Tove Kjaer
Regulatory Affairs Specialist
Medtronic Functional Diagnostics A/S
Tonsbakken 16-18
DK-2740 Skovlunde
DENMARK

Re: K992715
Medtronic Duet/Duet MultiP Version 8.1
with Neuro-Urodynamics Suite
Dated: November 25, 1999
Received: November 30, 1999
Regulatory Class: II
21 CFR §876.1620/Procode: 78 FEN
21 CFR §882.1870/Procode: 84 GWF
21 CFR §882.1550/Procode: 84 JXE

Dear Ms. Kjaer:

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) 594-4591. 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 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Indication for Use Statement

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510(k) Number (if known): K992715

Device Name: **Neuro Urodynamic Suite**

Indications for Use:

The Neuro-Urodynamics Suite for Duet / Duet MultiP is indicated for electrophysiological testing of the pelvic organs including motor nerve conduction, sacral reflex, and free-run EMG tests.

MRI Compatibility Statement:

The Duet with Neuro Urodynamic 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)

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 K992715 | S001