

3/9/99

Special 510(k) Notification
13 S Series of Disposable Monopolar Needle

K990375

510(k) SUMMARY
as required per 807.92(c)

1. Submitters Name, Address:

Medtronic Functional Diagnostics A/S
Tonsbakken 16-18
DK - 2740 SKOVLUNDE
DENMARK

Tel: (45) 44 57 95 02
Fax: (45) 44 57 90 10
Contact person for this submission: Ann-Christine Jönsson
Date submission was prepared: 5th February, 1999

2. Trade Name, Common Name and Classification Name:

A. Trade Name: 13 S Series Disposable Monopolar Needle Electrodes

B. Classification Name: Needle Electrode

C. Common name, Class and Regulation Number:

Common Name	Medtronic Code	Class	Regulation Number
Disposable Monopolar Needle Electrode, DMF25	9013S0611	II	21 CFR 882.1350
Disposable Monopolar Needle Electrode, DMN25	9013S0621	II	21 CFR 882.1350
Disposable Monopolar Needle Electrode, DMF37	9013S0631	II	21 CFR 882.1350
Disposable Monopolar Needle Electrode, DMN37	9013S0641	II	21 CFR 882.1350
Disposable Monopolar Needle Electrode, DMN50	9013S0651	II	21 CFR 882.1350
Disposable Monopolar Needle Electrode, DMN75	9013S0661	II	21 CFR 882.1350

3. Predicate Device Identification:

The new 13 S Series Disposable Monopolar Needle electrodes are substantially equivalent to previously marketed 13 R Series Disposable Monopolar Needles electrodes, which were previously determined by FDA to be substantially equivalent the 8th of December, 1992, K915741.

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4. Device Description:

The disposable monopolar needle electrode is designed for single use only. The stainless steel needle electrode is insulated with a special PTFE coating to ensure minimal friction between the needle and the tissue. The tip of the conically sharpened needle is uninsulated and serves as recording area. The sterile electrode is individually sealed and delivered in sets of 48 pcs. In a hygienic and practical package ready for use package.

The electrodes consists of a PTFE coated needle with an exposed area in the tip. The PTFE coating eases insertion into tissue and isolates the needle electrical. There are two diameters of the needles. In the non-invasive end of the device there is attached a connector, which enables the electrical signal to be transferred to the cable.

5. Intended Use:

The Disposable Monopolar Needles Electrodes are used for recording unit potentials in skeletal muscles, spontaneous activity, interference patterns and conduction velocity studies. This process is known as electromyography (EMG).

6. Table of Device Similarities and differences to predicate device:

<i>Manufacturer</i>	Dantec Medical A/S	Medtronic Functional Diagnostics A/S	Comments to differences
<i>510(k) number</i>	Predicate devices 13 R Series Disposable Monopolar Electrodes and 13P82 Disposable Electrode Cable - K 915741	Modified Device 13 S Series Disposable Monopolar Electrode - K number to be decided K 990375	-

Intended Use / Indication of Use	Records unit potentials in skeletal muscles, spontaneous activity, interference patterns and conduction velocity studies.	Same	--
Intended Populations	Pediatric to Adults	Same	--
Sterilization	Gamma irradiation (originally) but it was changed to Ethylene Oxid via our change control system and this was filed internally.	Ethylene Oxid	Today it is the same, a verification report of the sterilization is enclosed under flap PQ.

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SAL level	10 ⁻⁶	Same	--
Packaging	48 pieces individually blister packed electrodes in each box.	Same	--
Uses	Single Use	Same	--
Offered Sizes	0.35 x 20 mm 0.35 x 30 mm 0.45 x 30 mm 0.45 x 40 mm 0.45 x 50 mm 0.45 x 60 mm 0.45 x 80 mm	0.35 x 25 mm 0.45 x 25 mm 0.35 x 37 mm 0.45 x 37 mm 0.45 x 50 mm 0.45 x 75 mm	Enhanced assortment
Shelf-life (Expiring date)	4 years	Same	--
Electrode cable	13P82 Disposable Electrode Cable	9013C0031 shielded 1m with DIN plug 9013C0041 unshielded 80cm with 1,5mm connector.	Class I device, the cable is adjusted to fit the 13 S series needles.
Materials – Needle shaft	Stainless Steel ASTM 304	Same	--
Materials – Needle head (hub)	Polyethylen needle head	Same material, but the hub has been enlarged.	Enhanced ergonomic design on grip
Materials – coating	Teflon coated with Dupont 850.314 Teflon 2 Prog. Primer Green and finished with Dupont 851-214 Teflon Topcoat Green.	Whitford PTFE coat, Xylan 8400/3349	Easier to use and improves work environment when producing the needles.
Protection tube	Mounted on needle head, polyethylene, medical grade	Same	--
Connection	Snap mounted in needle head. Needle and connections are crimped together. Brass	Same	--
Connector	2 mm	0.7 mm	Enhanced changeability
Exposed length	0.8 mm	Same	--
Mechanical pull strength	20 N	Same	--
Recording area	0.3 mm sq	Same	--
Tip Exposure process	The needle point was left uninsulated.	Tip exposure process removes the coat via an abrasive media.	Enhanced tip performance

Medtronic Functional Diagnostics has reviewed its own files and is unaware of any safety or efficacy concerns that have resulted from the use of the predicate device 13 R Series of Disposable Monopolar Needle Electrode.

The changes in the new device doesn't effect any safety or efficacy concerns.

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

Verifications results shows that the enhanced device performs as its predicate device.

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8. Assessment of clinical performance data for equivalence:

Clinical evaluation not performed.

9. Biocompatibility:

The following biocompatibility tests have been performed on the Whitford PTFE coat, Xylan 8400/3349:

- In Vitro Cytotoxicity Test (USP 23/ISO 10993-5 Elution Test)
- Intracutaneous Test performed according to the method described in International Standard ISO 10993-10:1995
- Test for Delayed Contact Hypersensitivity using the Guinea Pig Maximization Test

The results of these tests shows that the material Whitford PTFE coat, xylan 8400/3349 have passed all tests.

10. Sterilization:

The needles are sterilized with ETO at a vendor sterilization plant, Maersk Medical A/S.

It is concluded that the process consistently will comply with predetermined specifications. The specified requirements for sterility (EN 556) are met.

11. Standards and Guidances:

All the performed biocompatibility tests have been performed according to the following standards:

- EN45001
- ISO 10993-1 – Biological evaluation of medical devices – part 1: Guidance on selection of tests.
- ISO 10993-10:1995 - Biological evaluation of medical devices
- USP 23 / ISO 10 993 –5

The needle itself have been developed according to

- EN 46001 – Quality systems- Medical devices- Particular requirements for the application of EN ISO 9001.
- ISO/DIS 14971-1 – Medical Devices – Risk Management

This 510(k) content follow the Guidance document for the preparation of premarket notification 510(k), application for electromyograph needle electrodes.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 1999

Ms. Anne-Christine Jönsson
Regulatory Affairs Specialist
Medtronic Functional Diagnostics A/S
Tonsbakken 16-18
DK-2740 Skovlunde
Denmark

Re: K990375
Trade Name: 13 S Series Disposable Monopolar Needle Electrodes
Regulatory Class: II
Product Code: IKT
Dated: February 5, 1999
Received: February 8, 1999

Dear Ms. Jönsson:

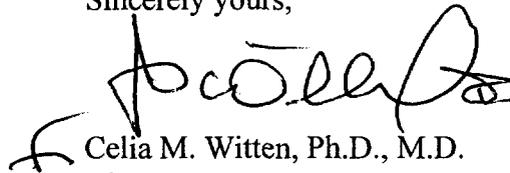
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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) 594-4595. 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/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k) Notification
13 Sx series of Disposable Monopolar Needle

Indication for Use Statement

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510(k) Number (if known): K 990375

Device Name: 13 S Series Disposable Monopolar Needles Electrodes

Indications for Use:

The Disposable Monopolar Needles Electrodes are used for recording unit potentials in skeletal muscles, spontaneous activity, interference patterns and conduction velocity studies.

MRI Compatibility Statement:

Device is not claimed for use in 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
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

[Signature]
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number _____

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