K980380

Section 11 : 510(k) Summary

This section satisfies the 510(k) summary as required by 21 CFR 807-92 (C).

1. Submitter

Miss Jan Walters
Diametrics Medical Limited
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Tel: +44 1494 471671
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Date of Summary : 30th January 1998

2. Device Name

Proprietary : Neurotrend Multiparameter Sensor, with Paratrend 7+ Multiparameter Senior & Satellite Monitor System

Common : Multiparameter Catheter

3. Device Classification

Panel	:	Neurology Devices Panel
Classification	:	Class II
FDA CFR	:	21 CFR 882.1620
Description	:	Device, Intracranial Pressure Monitoring
Classification No.	:	84GWM

4. Statement of Substantial Equivalence

Diametrics Medical Ltd claims substantial equivalence to products which have received FDA clearance by the Premarket Notification process.

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5. Device Description

The Neurotrend Sensor (C7004S) is a modified version of the Fluorescent Paratrend 7 sensor which has been cleared for the US Market (K953893). The measurement parameters for Neurotrend are essentially the same as the Fluorescent Paratrend 7. The sensor does not require a heparin treatment, as a consequence of the application – to monitor cerebral tissue and fluid gas parameters.

6. Technological Characteristics

Measurement Technology

pO_2	:	fibre optic, fluorescence quenching
Temp	:	thermocouple
pCO_2	:	fibre optic, photometric absorption
pH	:	fibre optic photometric absorption

Monitor Technology

Analogue/digital

7. Intended Use

The Neurotrend Multiparameter Sensor measures intracranial oxygen, carbon dioxide, pH, and temperature. The Sensor is used in conjunction with the Paratrend 7+ Multiparameter Senior and/or Satellite Monitor Systems.

8. Predicate Devices

K953893	Fluorescent Paratrend 7 Multiparameter Blood Gas Monitoring Sensor
K962928	Neurocare Intracranial Pressure & Temperature Monitoring Kit
K914497	Microsensor Intracranial Pressure Transducer
K896515	Laserflo Blood Perfusion Monitor $8PM_2$

9. Comparison of Accuracy to the Predicate Fluorescent Paratrend 7 Device

The device under review was manufactured under standard process conditions and calibrated on the Senior Monitor.

Sensors were tested *in vitro* to determine whether the absence of the heparin treatment affected the performance of the sensors. Sensors, both heparin treated (n=8) and untreated (n=7), were calibrated as detailed in the Instructions For Use (IFU).

The tonometers were maintained at 37°C and were pre-equilibrated with precision gas mixtures to precise barometric pressure which allowed the calculation of "actual" partial pressures. The Henderson-Hasselbalch equation was used to determine the "actual" pH values in the different tonometers.

The 90% step response times were calculated from the data collected when moving the sensors from one equilibrated tonometer to another. Sensors were then allowed to run for 72 hours and the bias at the end of this time was averaged over the period to give mean drift.

The data were analysed by calculating the bias (the mean of the differences between the measured Paratrend 7 value and that the actual value of the equilibrated solution) and the precision (sample standard deviation of the differences). The data were collected over the relevant range of gases.

The results from the sensors were then collated and used to determine the performance characteristics of both sub-sets of sensors versus the primary standard.

10. Conclusion

The data satisfy product accuracy claims and show comparable results for heparin-treated and non-heparin treated sensors.

The device under review is considered substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1999

Ms. Jan Walters
Diametrics Medical, Ltd.
Short Street
High Wycombe, Bucks
UNITED KINGDOM
HP11 2QH

Re: K980380
Neurotrend Multiparameter Sensor C7004S
Dated: February 23, 1999
Received: February 25, 1999

Dear Ms. Walters:

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.

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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) 594-4648. 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,

Philip J. Phillips
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Attachment 1

510(k) Number : K980380

Device Name: **CODMAN Neurotrend™ Multiparameter Monitoring System**

Indications For Use:

"The CODMAN Neurotrend Cerebral Tissue Monitoring System measures intracranial oxygen, carbon dioxide, pH and temperature, and is intended as an adjunct monitor of trends in these parameters, indicating the perfusion and metabolic acidosis/alkalosis status of cerebral tissue local to sensor placement. Because the Neurotrend values are relative within an individual, the Neurotrend should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice, in cases where hypoxia/ischaemia is a concern."

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Phillip J. Brady, Director, ODE 7/14/99

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)

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