

**Section 12 : 510(k) Summary**

SEP 23 1997

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

**Submitter**

Miss Jan L Walters  
Diametrics Medical Limited  
Short Street  
High Wycombe  
Bucks HP11 2QH UK  
Tel: +44 1494 471671  
Fax: +44 1494 474890  
Date of Summary : 10 March 1997

**Device Name**

Proprietary : Paratrend 7 Multiparameter Senior and Satellite Monitor  
System with Paratrend 7 Plus Multiparameter Sensor  
Common : Multiparameter Catheter

**Device Classification**

Panel : Anaesthesiology Devices Panel  
Classification : Class III  
FDA CFR : 868-1150  
Description : Analyser Gas, Carbon Dioxide, Partial Pressure, Blood  
Phase, Indwelling  
Classification No : 73CCC

## Statement of Substantial Equivalence

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

The Paratrend 7 Multiparameter Senior and Satellite Monitor Systems with Paratrend 7 Plus Multiparameter Sensor is a modification of the *Paratrend 7 Intravascular Blood Gas Monitoring System* and *Paratrend 7 Satellite Multi Parameter Blood Gas Monitoring System*. Furthermore, it is also judged to be substantially equivalent to the *Optex Blood Gas Monitoring System* and the *Baxter Swan-Ganz Continuous Cardiac Output Oximetry*.

## Device Description

The Paratrend 7 Plus Sensor (MPS7004P) is a modified version of the currently legally marketed device, the Paratrend 7 sensor (MPS7004). The measurement of pO<sub>2</sub> using an electrochemical sensor (Clark electrode) in the predicate Paratrend 7 sensor has been replaced in the Paratrend 7 Plus device by a sensor based on optical fibre/fluorescence quenching technology. All other measurement parameters are essentially unchanged. The telescopic introduction mechanism in the predicate Paratrend 7 sensor has been replaced by a rotary advancing mechanism. The application has been expanded to include venous access.

## Intended Use

The Paratrend 7 Plus Multiparameter Sensor is intended to be inserted via an intravascular access device into the vascular system (e.g. radial, femoral arteries). It is intended to be used in the management of the critically ill patient by providing continuous blood gas data while permitting the simultaneous monitoring of blood pressure via an external transducer.

The sensor is used in conjunction with the Paratrend 7 Multiparameter Senior and/or Satellite Monitor systems.

## Technological Characteristics

### Measurement Technology

pO <sub>2</sub>	:	fibre optic, fluorescence quenching
Temp	:	thermocouple
pCO <sub>2</sub>	:	fibre optic, photometric absorption
pH	:	fibre optic photometric absorption

### Monitor Technology

Analogue/digital

## **Comparison of Accuracy to the Predicate Paratrend 7 Device**

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

The tonometers were maintained at 37°C and were pre-equilibrated with precision gas mixtures thereby allowing the calculation of “actual” partial pressures. The Henderson-Hasselbalch equation is used to determine the “actual” pH values in the different tonometers.

The measured (displayed) values were recorded after a 20 minute equilibration time. The PDMs were then transferred to Satellite monitors and the measured readings recorded. The PDMs were then returned to the Senior monitor prior to transferring the sensor to the next equilibrated tonometer.

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, as shown in the following table.

The differences obtained on both Senior and Satellite systems were compared.

A linear regression was then performed of the measured Senior readings vs. the measured Satellite readings. The correlation coefficient, line-intercept and line-gradient were recorded.

## **Conclusion**

The data presented above satisfies product accuracy claims and shows comparable results for both Senior and Satellite.

The similarity of the two data sets can be assessed from an analysis of the difference of the Senior and Satellite differences.

A paired sample t-test has been applied to the Senior and Satellite readings. The two data sets showed no significant difference at the 5% level.

A linear regression analysis of the Senior data vs the Satellite data for pO<sub>2</sub>, pH and pCO<sub>2</sub> readings provides further evidence of good correlation between Senior and Satellite readings.

The device under review is considered substantially equivalent.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 23 1997

Ms. Jan L. Walters  
Diametrics Medical Limited  
Short Street  
High Wycombe  
Bucks. HP11 2QH  
ENGLAND

Re: K970906  
Paratrend 7 Multiparameter Senior and Satellite Monitor System  
with Paratrend 7 Plus Multiparameter Sensor  
Regulatory Class: III (three)  
Product Code: 73 CCE  
Dated: June 24, 1997  
Received: June 26, 1997

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 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.

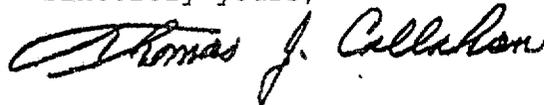
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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" (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,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K970906

Device Name: Paratrend 7+ Intravascular Blood Gas Monitoring System

Indications For Use:

The Paratrend 7+ System is intended to be used in the management of the critically ill patient by providing continuous blood gas data while permitting the simultaneous monitoring of blood pressure via an external transducer. The Paratrend 7+ Multiparameter Sensor is inserted via an intravascular access device into the vascular system (e.g. radial, femoral arteries).

Completion of Monitoring and Sensor Withdrawal

Within the United States market, the use of this device should be limited to 72 hours.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use -----

OR

Over-The-Counter Use-----

(Optional Format 1-2-96)

*A. A. Cirolowsh*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number \_\_\_\_\_