

K973318

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SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

FEB 19 1998

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Ortivus AB summary for the Mobimed™ System.

SUBMITTER'S NAME: Ortivus AB
 ADDRESS: Enhagsslingan 5
 S-183 25 Täby, Sweden
 CONTACT PERSON: Jörgen Eklund, Quality Manager
 TELEPHONE NUMBER: 011-46-8-446 45 10
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 DATE OF SUBMISSION: 2 September 1997

1. Identification of device
 - Proprietary Name: Mobimed™ System, (Pegasus and Polaris)
 - Common Name: Monitor, Cardiac; Radio-frequency physiological signal transmitter and receiver; Oximeter.
 - Classification Status: Class II per regulations 870.2300 and 870.2910 and 870.2700
 - Product Codes: 74DRT, 74DRG, and 74DQA

2. Equivalent devices
 - Ortivus believes the Mobimed™ System is substantially equivalent to the LifePak® Cardiac Monitor/LifeNet RS100 Receiving Station manufactured by Physio-Control Corporation (K912189) The SpO₂ module is the Nellcor MP204P, same as used in the NPB-75 made by Spegas (K964239)

3. Description of the Device
 - The Mobimed™ System consists of one or several stationary units called Polaris (typically hospital located) receiving patient cardiac information from mobile units called Pegasus. A mobile unit can be permanently mounted in an ambulance or operate as a portable unit. The Mobimed™ equipment can telemonitor (using radio-based cellular telecommunications network) a patient where he or she is at the moment. This makes it possible to monitor the patient and acquire data during transportation to the hospital. The system can acquire and transmit the following information:
 - VCG or 12-Lead ECG (automatically and manually acquired reports).
 - One channel ECG or VCG reports
 - Monitoring ECG (not transmitted)
 - Trends (automatically and manually acquired).
 - Patient records/forms

- Alarms (presented on the Pegasus and not transmitted to Polaris)
- Messages

4. Intended use

The Ortivus AB Mobimed™ is a cardiac monitoring system consisting of a portable and stationary unit which communicate with each other using the Mobitex radio-based cellular telecommunications network. The cardiac data includes ECG, SpO₂, NIBP, GCS, and patient information. The system is intended for use by trained personnel in emergency care, specifically emergency ambulance and pre-hospital care.

5. Technological characteristics, comparison to predicate device.

Like the predicate devices, the Mobimed™ System is intended to be used in an emergency care situation to communicate cardiac information from a remote site such as an ambulance to a hospital. Standard ECGs can be transmitted, but in addition, SpO₂, NIBP and GCS information can also be transmitted. The NIBP (Non-invasive blood pressure) values are entered manually into the Pegasus. This means that the values must be obtained by some other equipment, for example a standard blood pressure cuff. There is no automatic NIBP measurement equipment. The GCS (Glasgow Coma Scale) is a scoring system for the patient's status. GCS is an internationally well spread scoring system for estimating the degree of consciousness of the patient. The GCS value is based upon the observation of three fundamental physiological parameters; eye movements, motor response, and verbal response. Each parameter gets a numerical value based on standardized questions, and the sum of the three individual values is the GCS.

Comparison table

Characteristic	Predicate device, Lifepak 11	Mobimed™ System
Single lead ECG	Yes	No
12 lead ECG	Yes	Yes
Frank lead (VCG)ECG	No	Yes
SpO ₂	No	Yes
Interpretive ECG	Yes	No
Digital telecommunications	Yes	Yes
Local ECG display	Paper and Monitor	Monitor only
Receiving station display	Paper only	Monitor and paper
Power sources	Internal rechargeable battery or AC line (charging source)	Internal rechargeable battery or 12 volt automotive system (charging source)or AC line
Labeling	Labels on devices, an operating manual and a physicians guide	Labels on devices, a Pegasus User's Manual, and a Polaris User's Manual

6. Discussion of performance testing.

An extensive collection of tests has been conducted and successfully completed, including electrical safety (to IEC-601-1), ECG performance (using appropriate sections of IEC 601-2.27), SpO₂ performance (Using ISO 9919), power source (battery and charger), environmental (shock, humidity, vibration, temperature), EMC (using CISPR 11 and IEC 61000-4-2,3,4, and 5) and communications to and from the hospital based unit.

7. Conclusion

Based on extensive performance testing and a comparison to the predicate device, it is the conclusion of Ortivus AB that the Mobimed™ System is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness. In fact, the use of cellular digital technology enhances communication capability over previous direct radio frequency communications systems.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

FEB 19 1998

Ms. Constance G. Bundy
Ortivirus, AB
Enhagsslingan 5
SE-183 25 Täby, Sweden

Re: K973318
Trade Name: Ortivirus AB Mobimed™ System
Regulatory Class: II (two)
Product Code: 74 MSX
Dated: January 21, 1998
Received: February 3, 1998

Dear Ms. Bundy:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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

B. INDICATIONS FOR USE

510(k) Number K973318

Device Name: Mobimed™ System

Indications for Use: The Ortivus AB Mobimed™ is a cardiac monitoring system consisting of a portable and stationary unit which communicate with each other using the Mobitex radio-based cellular telecommunications network. The cardiac data includes ECG, SpO₂, NIBP, GCS, and patient information. The system is intended for use by trained personnel in emergency care, specifically emergency ambulance and pre-hospital care.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Pugh
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number _____

✓
Prescription Use _____
(Per 21 CFR 801.109)

OR

Over the Counter Use _____