

DEC 28 1999

K993643

Nexan Telemed Ltd. 510(k) Submission

## 14 Safety and Efficacy - Premarket Notification 510(k) Summary

510(k) Summary as required per 807.92.

### 14.1 Submitter Details

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Date of submission: 1<sup>st</sup> September 1999

### 14.2 Device Name and Classification

#### 14.2.1 Device name

Nexsystem

#### 14.2.2 Device Common Name

Ambulatory Patient Monitor

#### 14.2.3 Classification, product code

Class:	II		
Product Codes:	ECG	74DPS	CFR: 870.2340
	Respiration	73BZQ	CFR: 868.2375
	Temperature	80FLL	CFR: 880.2910
	Transmitter	74DRG	CFR: 870.2910

### 14.3 Predicate Device Information

The following predicate devices are considered:

<u>Company</u>	<u>Device</u>	<u>510(k)</u>
Sabratek	Patient Home Monitoring System	K980619
Protocol Systems	Propaq Encore	K951246
Mortara	Ambulatory X-12 Telemetry Module	K974149
Reynolds	Tracker Holter Recorder	K943278
Reynolds	Pathfinder 7000 Holter Analyser	K951902
Instromedix	Poseidon Cardiac Monitoring System	K964408

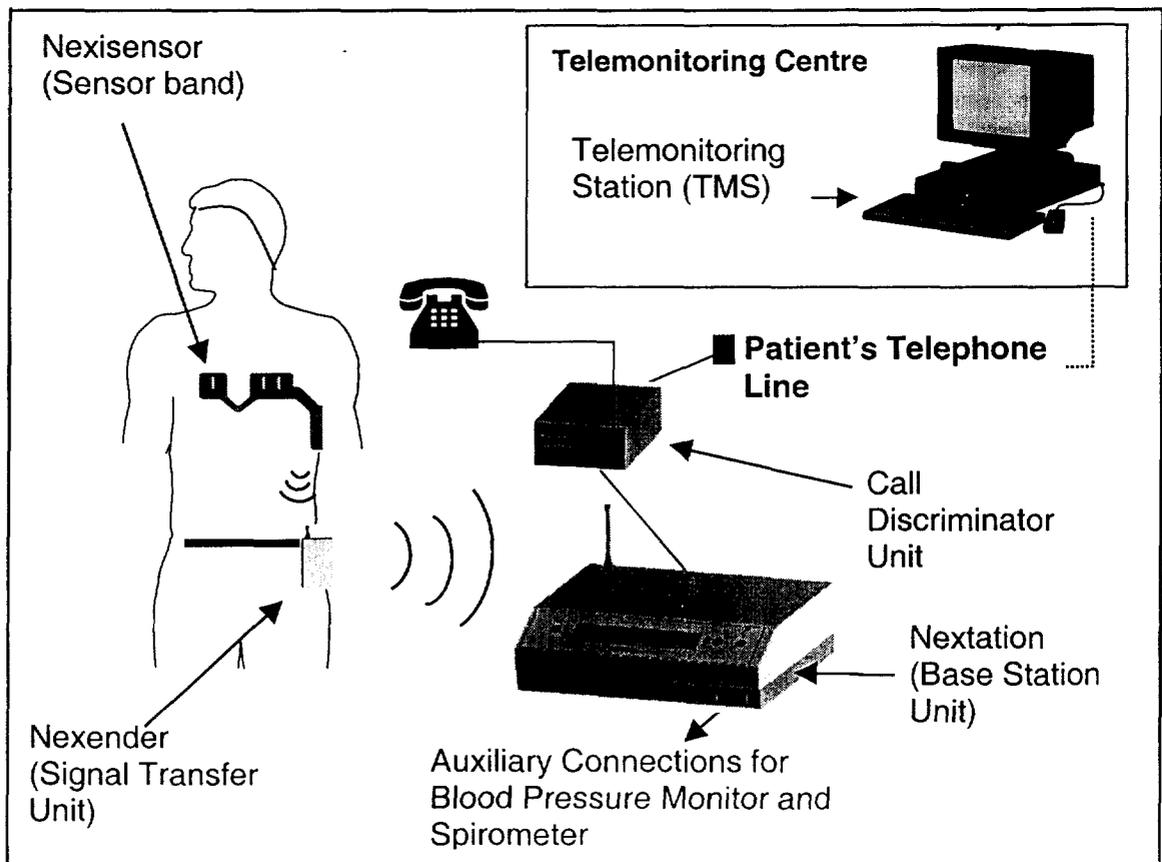
## 14.4 Device Description

### 14.4.1 System Overview

The Nexsystem is a non-invasive ambulatory patient monitoring system for recording multiple physiological parameters from patients who may be located at home or in an alternate care setting. The Nexsystem continuously gathers physiological data from a sensor band attached to the patient and transmits the data wirelessly via a Signal Transfer Unit (Nexender) to a Base Station Unit (Nextation) where the data are recorded and stored. Additionally, the Base Station Unit has interfaces for auxiliary sensors – spirometer and blood pressure monitor – for recording point in time lung function and blood pressure measurements. A Call Discriminator Unit enables incoming telephone calls to be correctly routed to either the Nextation or a telephone handset.

The data are transmitted for display, monitoring and storage on a computer (Telemonitoring Station TMS running the Nexoft application software) at a distant location (Telemonitoring Centre). This data transfer is under the control of the Health Care Professional (HCP) at the TMS. Data may be transferred in real time to enable the HCP to check on the quality of the physiological data being recorded and/or the status of the patient. Normally data is transferred at a scheduled time after the end of a patient data recording session. Once transferred to the TMS the data can subsequently be displayed for analysis by the HCP. The Nexsystem enables the HCP to print reports of raw or summary data.

The Nexsystem comprises a number of system components identified below.



#### **14.4.2 Identification of System Components**

The Nexsystem comprises several distinct components which together form a complete monitoring system. In this section each of these components is separately identified

##### **14.4.2.1 Nexisensor**

The Nexisensor is a disposable, battery powered, adhesive band containing electrodes and sensors, which is attached to a patient's chest. It captures physiological signals, processes and transmits them, via a wireless link, to a Nexender.

##### **14.4.2.2 Nexender**

The Nexender is a portable, battery powered, wireless Signal Transfer Unit either worn by, or in close proximity (within 1.5m) to, the patient. The Nexender receives the physiological data from the Nexisensor and forwards it to the Nextation via a UHF radio link when within operational range (30m).

##### **14.4.2.3 Nextation**

The Nextation is a table-top device, requiring connection to line voltage and direct connection to a hard-wired telephone line. The Nextation acts as a Base Station Unit receiving and recording data from the Nexender. The Nextation has two serial ports for the direct connection of a spirometer and a blood pressure monitor for the recording of point in time measurements.

##### **14.4.2.4 Spirometer**

The spirometer interfaced with the Nexsystem is the Micro Medical MicroPlus Spirometer MS03.

##### **14.4.2.5 Blood Pressure Monitor**

The Blood Pressure Monitor interfaced with the Nexsystem is the OMRON IC fully automatic blood pressure monitor with inflation pre-set.

##### **14.4.2.6 Call Discriminator**

In situations where a dedicated telephone line is not available at the patient location for use of the Nexsystem a telephone call discriminator unit may optionally be utilised to differentiate between incoming voice calls for the patient and data calls from the TMS for the Nextation. The unit utilised is the Viking FAXJ-300 Fax Jack Phone/Fax Switch.

##### **14.4.2.7 Telemonitoring Station (TMS) Computer/Nexoft Software**

The TMS Computer is a standard Windows NT PC located at the HCP's office running the Nexoft application software that is used to download patient data from the Nextation for display, recording and printout of reports for analysis by the Health Care Professional.

#### **14.5 Intended Use**

The Nexsystem is an ambulatory patient monitoring system intended for use in the home or alternate care settings. It consists of a patient worn sensor (Nexisensor), signal transfer unit (Nexender), communications module (Nextation), and a telemonitoring station computer based display and storage system (TMS) located at the health care professional's facility. The device stores and transmits ECG data, respiration data, skin temperature, systolic and diastolic blood pressure (non-invasive), and PEF and FEV1.

## **14.6 Non-clinical performance data for equivalence**

### **14.6.1 ANSI/AAMI EC12**

Compliance testing of the Nexisensor to ANSI/AAMI EC12 Disposable ECG Electrodes has been conducted and the detailed Compliance Test Report 100-TR-080 is located in Appendix R.

The report concludes that the Nexisensor is compliant with ANSI/AAMI EC12. This compliance is subject to the understanding that the Nexisensor electrodes are integral and not wired, and that the Nexisensor is not designed to withstand a defibrillator as it will be removed by paramedics prior to the application of the defibrillator electrodes.

### **14.6.2 ANSI/AAMI EC38**

Compliance testing of the Nexsystem to ANSI/AAMI EC38 Ambulatory Electrocardiographs has been conducted and the detailed Compliance Test Report 100-TR-079 is located in Appendix S.

The report concludes that the Nexsystem is a Type I ambulatory electrocardiograph and is compliant with ANSI/AAMI EC38. This compliance is subject to the understanding that the Nexsystem provides only a single lead of ECG and that as ECG analysis is not provided there is only a partial application of the standard.

## **14.7 Clinical performance data for equivalence**

Not applicable

## **14.8 Predicate Device Comparison**

The comparison of intended use and technological features of the Nexsystem with other legally marketed devices taken together with the validation results, performance tests and other information in this submission indicate the Nexsystem is substantially equivalent to legally marketed devices in safety, effectiveness and intended use.

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**Predicate Devices:**

**Sabratek Patient Home Monitoring System (PHMS)  
Protocol Systems Propaq Encore**

**510(K)#: K980619**

**510(K)#: K951246**

**Parameters being compared:**

**Physiological parameters, auxiliary devices, general equipment specification**

Parameter	Nexsystem	Sabratek PHMS	PROPAQ Encore	Explanation of Differences
<b>Electrocardiogram</b>				
Records and stores extended monitor bandwidth electrocardiogram.	Yes, 0.05 - 85 Hz	No	Yes, 0.05 - 40 Hz	85 Hz gives improved signal fidelity
Single lead (2 active electrodes plus a 'ground' electrode)	Yes	Yes	Yes	
QRS or arrhythmia detection	QRS detection	No	QRS detection	
Heart rate range	30 - 250 BPM	n/a	25-350 BPM	Nexsystem range complies with EC38
Heart rate accuracy	± 3 BPM	n/a	± 3 BPM	
Detects an electrode lead off condition	No	Yes	Yes	Signal quality can be checked via Nexoft at any time
ECG sensing electrodes	Ag / AgCl custom	n/a	Any Ag / AgCl electrode is recommended.	
Alarms on low / high heart rate	No	No	Yes	Events outside pre-set thresholds can be logged for review.
Wireless operation	Yes	No	No	Provides greater operational patient convenience
<b>Respiration</b>				
Measure respiration rate by impedance	Yes	No	Yes	
Range	0 - 72 BPM	n/a	0 (apnoea), 2-150 BPM	Nexsystem is not an apnoea monitor.
Accuracy	±2 BPM	n/a	±2 BPM or 2%	Validation against clinical trial data
Sensor	Ag / AgCl custom	n/a	Any Ag / AgCl electrode is recommended	
<b>Temperature</b>				
Thermistor	Alpha Sensors: medical 400 series for skin surface (disposable)	n/a	Arbo: 400 series for skin surface (disposable)	
Range	25.0 - 45.0 °C	n/a	30.0 - 42.0 °C	Nexsystem has extended range.

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Thermistor Accuracy	± 0.2 °C	n/a	± 0.1 °C	±0.2°C is sufficiently accurate for trend analysis.
Non Invasive Blood Pressure	Omron IC (HEM725C1C)	AND Medical	Unit meets ANSI-AAMI SP10-1992 performance standard	Nexsystem uses a legally marketed device
510K #	K913523	K871720	n/a	
Spirometer	Micromedical MicroPlus	n/a	n/a	Nexsystem uses a legally marketed device
510K#	K963035	n/a	n/a	
<b>Nextation General</b>				
Communications capability	up to 2 external devices at any one time	up to 10 external devices	n/a	2 auxiliary sensors considered adequate for any one patient.
Display	2 line x 20 character LCD	4 line x 20 character LCD	n/a	Adequate for patient messages.
Display back light	Yes	Yes	n/a	
Keypad	3 push buttons	5 row by 5 column custom	n/a	Keeps system operation simple.
Patient alerts / notification	Messages displayed to prompt patient auxiliary measurements and communicate system faults	Audio and visual patient alarm notification	n/a	Nexsystem not an alarm monitor.
Size	approx. 24 x 34 x 9 cm	Approx. 30 x 30 x 10cm	17 x 21 x 13 cm (basic unit)	
Weight	3.6 kg / 7.9 lbs.	4.5 kg / 10 lbs.	2.8 kg / 6.25 lbs (basic unit)	
Operating temperature	0 to 45°C	0 to 60°C	0 - 40 °C	
Storage humidity	5 to 95% non-condensing	0 to 95% non-condensing	15 to 95% non-condensing	
Shipping/storage temperature	-20 to 65°C	-20 to 60°C	-20 to 65°C	
Drip proof	Tested to IEC 60601-1	IEC 529 IPX1	IEC 529 IPX1 (monitor)	IEC 60601-1 test offers similar level of protection as IEC 529 IPX1
<b>Nextation Power</b>				
Operation	110-120V 220-240V 50/60Hz	115 / 230 VAC 50 / 60 Hz	100-120V 220-240 V 50/60 Hz	
Current consumption	250 mA continuous	Not known	250 mA continuous	
Operation from internal battery pack	No	Yes, > 1 hour	Yes, > 2.5 hour	1 hour data buffer in Nexender.
Double insulation	No	Yes	n/a	Nextation is class I device and earthed
Power input	< 100 Watts	< 40 Watts	n/a	
Ambulatory sensor power	3 x 1.4 V675AT Zinc Air cells	n/a	n/a	
Nexender power	4 x 1.5 V Alkaline cells	n/a	n/a	

**Predicate:** Mortara Ambulatory X-12 Telemetry Module  
**Parameters being compared:** Nexender to Nextation radio link parameters

**510(K)#:** K974149

Parameter	Nexender to Nextation	Mortara X-12 Telemetry Module	Explanation of Differences
<b>Radio Link</b>			
Transmission scheme	Digital, frequency-shift keying	Digital, frequency-shift keying	
Radio channel spacing	n/a	80 kHz (915 MHz) and 320 kHz (2.15 GHz)	Nexsystem is a single channel system
Power output	50 mV/m at 3 m	50 mV/m at 3 m	
Frequency	433 MHz or 916 MHz	915 MHz or 2.45 GHz	433 MHz is European frequency band 915/916 are the same approved band.

**Predicate:** Reynolds Tracker Holter Recorders  
 Reynolds Pathfinder 7000 Holter Analyser  
**Parameters being compared:** Event buttons

**510(K)#:** K943278

**510(K)#:** K951902

Parameter	Nexsystem	Reynolds Holter Recorders and Analyser	Explanation of Differences
<b>Event Buttons</b>			
Number of event buttons	2	1	Provides more information.
Location of event button(s)	On Nexender: worn by patient or placed close by.	On Holter recorder, always worn by patient.	
Display of event button presses	In Nexoft, a list of all patient events can be seen; users can view raw data for each event (or download data for any event).	In Pathfinder, a summary table includes the total number of patient events; user can tab through raw ECG data for each event in turn.	

**Predicate:** Poseidon™ Cardiac Monitoring System

**510(K)#:** K964408

**Parameters being compared:** Nextation to TMS communications and Nexoft features

Parameter	Nexystem	Poseidon™ Cardiac Monitoring System	Explanation of Differences
Nextation to Nexoft Communications			
Modem	Meets V34 fax/data modem speeds and standards.	Meets V34 fax/data modem speeds and standards.	
Protocol	TCP/IP and PPP (including error detection and correction)	CEN 231, SCP Digital Transmission Error detection/correction	Nexystem uses standard Windows dial up.
<b>Nexoft Features</b>			
Operating system	Windows NT	Windows NT	
Print out	Yes	Yes	
Storage	Magnetic hard drive	Magnetic disk	
Back up	Yes - Optical disc	Yes	
Alarms	No	No	
Data triggers	Yes	Yes	



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 28 1999

Nexan Telemed Ltd.  
c/o Quintiles, Inc.  
Kenneth A. Palmer, Ph.D.  
15825 Shady Grove Road, Suite 130  
Rockville, MD 20850-4008

Re: K993643  
Nexsystem Abulatory Patient Monitor Model Nex  
Regulatory Class: II (two)  
Product Code: MWJ  
Dated: October 28, 1999  
Received: October 28, 1999

Dear Dr. Palmer:

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.

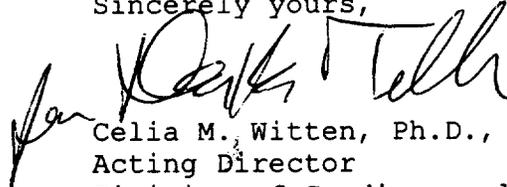
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Kenneth A. Palmer, Ph.D.

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,



Celia M. Witten, Ph.D., M.D.  
Acting Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number: K993643

Device Name: Nexsystem Ambulatory Patient Monitor

Indications For Use:

The Nexsystem ambulatory patient monitoring system is intended for use in the home or alternate care settings. It consists of a patient-worn sensor (Nexisensor), signal transfer unit (Nexender), communications module (Nextation), and a telemonitoring station computer based display and storage system (TMS) located at the health care professional's facility. The device stores and transmits ECG data, respiratory data, skin temperature, systolic and diastolic blood pressure (Non-invasive), and PEF and FEV1.

The Nexsystem is not for use as a critical care monitoring system.  
The Nexsystem is not an apnea monitor.

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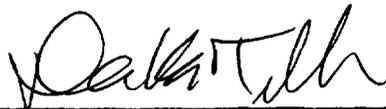
\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use     

(Optional Format 1-2-96)



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

510(k) Number K993643