DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 29, 2016

Techmedic Development International B.V.
% Patsy Trisler
Regulatory Consultant, Qserve Group, Inc
Qserve Group Us Inc.
P.O Box 940
Charlestown, New Hampshire 03603

Re: K152973
Trade/Device Name: Dyna-Vision Telemonitoring System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX, MWI, DRG, DSI, DRT, FLL, DQA
Dated: March 22, 2016
Received: March 29, 2016

Dear Patsy Trisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152973

Device Name
Dyna-Vision Telemonitoring System

Indications for Use *(Describe)*

The Dyna-Vision Telemonitoring System is a wireless monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings and for normal daily activities. Physiological data recorded include: Electrocardiography (EGG), Heart Rate, Heart Rate variability (R-R interval), Peripheral capillary Oxygen saturation (SpO2), Skin Temperature and respiration effort.

Data is transmitted wirelessly in near real time to a central location where it is stored for analysis. The Dyna-Vision™ system can be configured by Authorized Persons to notify healthcare professionals when physiological data falls outside selected parameters. Data from the Dyna-Vision™ system is intended to be used by healthcare professionals as an aid to diagnosis and treatment.

The device is intended for use on general care patients aged 18 years or more, as a general patient monitor, to provide physiological information. It is not intended for use on critical care patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter Name:	Techmedic Development International B.V.
Submitter Address:	Broeker Werf 6 1721 PC Broek op Langedijk Netherlands
Phone Number:	+31(0)226 342044
Fax Number:	+31(0)226 341446
Contact Person:	Rutger Brest van Kempen
Date Prepared:	22-08-2015
Device Trade Name:	Dyna-Vision Telemonitoring System
Common Name	Patient Telemonitoring Sytem
Classification Name, Number & Product Code:	Monitor, physiological, patient (with arrhythmia detection or alarms) 870.1025 (MHX); Transmitters and Receivers, Physiological Signal, Radiofrequency 870.2910 (DRG) Monitor, Cardiac (including cardiotachometer and rate alarm, 870.2300 (DRT); Thermometer, electronic, clinical, 880.2910 (FLL); and Oximeter, 870.2700 (DQA)
Classification Panel:	Cardiology
Predicate Devices:	Vitalconnect platform, K 141167 TeleSentry Wireless Ambulatory ECO Arrhythmia Monitor, K092947 Model 7500 Digital Pulse Oximeter, K080255 Disposable Temperature Probes, K070339 Propaq CS, K012451
Device Description:	The Dyna-Vision system is a wireless multi-parameter data collection systems that monitors physiological data such as: Electrocardiography (EGG), Heart Rate, Heart Rate variability (R-R interval), Peripheral capillary Oxygen saturation (SpO2), Skin Temperature and Rate of respiratory effort. The system consist of: • A body-worn unit with sensor input modules for the near real time acquisition of the physiological data with built-in wireless

communication for data transmission.
- A telemetry server to receive the physiological data and transmit the physiological data to
- A workstation installed on a central server (or PC) equipped with software with which the physician can process the physiological data and create reports regarding the transmitted data, and read and configure alerts/notifications when a threshold value is exceeded. The alert function is an adjunct to and not intended to replace vital sign monitoring.

The software includes algorithms for Heart Rate, Heart Rate variability (R-R interval) and rate of respiratory effort.

The device is intended to be used by clinicians and medically qualified personnel in healthcare facilities. The body-worn unit for data acquisition, is a transportable battery-operated unit to record Electrocardiograph (ECG), Heart Rate variability (R-R interval), Peripheral capillary Oxygen saturation (SpO2), Skin Temperature and Rate of respiratory effort to be also used by the patient in the home setting and anywhere where WIFI or cell communication is available.

The Dyna-Vision system works with 3rd party 510(k) cleared SpO2 module (Nonin OEM III, K092101), and ECG patient lead (Scottcare K092947).

The device is intended for use on general care patients aged 18 years or more.

Physical Description:

Dyna-Vision Unit dimensions: 118 x 65 x 33 mm, Weight +/- 260 gram, Power Internal battery 3.7 V

Statement of Indication for Use:

The Dyna-Vision Telemonitoring System is a wireless monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings and for normal daily activities. Physiological data recorded include: Electrocardiography (EGG), Heart Rate, Heart Rate variability (R-R interval), Peripheral capillary Oxygen saturation (SpO2), Skin Temperature and respiration effort.

Data is transmitted wirelessly in near real time to a central location where it is stored for analysis. The Dyna-Vision™ system can be configured by Authorized Persons to notify healthcare professionals when physiological data falls outside selected parameters. Data from the Dyna-Vision™ system is intended to be used by healthcare professionals as an aid to diagnosis and treatment.

The device is intended for use on general care patients aged 18 years or more, as a general patient monitor, to provide physiological information. It is not intended for use on critical care patients.

Summary of Technological Characteristics

The Dyna-Vision system offers near real time full-disclosure streaming ECG/SpO2/temperature from anywhere using the cellular network and a telemetry service offering tele-monitoring solutions to remote locations. The Dyna-Vision unit is connected to a patient and switched on. The device automatically connects to the local cellular network to send the

data in near real time to the Dyna-Vision Server from where it can be retrieved using the Dyna-Vision software on a workstation. The collected data can be reviewed and reports can be created for sending to a cardiologist or family physician.

Non-Clinical Tests:

Bench testing was carried out on the following characteristics:

- Electrocardiograph (EGG)
- Heart rate variability (R-R interval)
- Heart rate
- SpO2
- Skin Temperature
- ECG impedance for Rate of respiratory effort
- Notification
- Measurement accuracy
- Communication, data transmission and storage
- Reliability (QoS) Wireless Quality of Service
- Electromagnetic compatibility (EMC)
- Electrical safety testing
- Wireless Coexistence Wi-Fi testing
- Software verification and validation testing
- Biocompatibility verification

In addition to the above, usability testing was also conducted.

Referenced Standards and Performance Testing:

The Dyna-Vision device was tested and meets the requirements of following performance Standards and is in accordance with FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm.

- IEC 60601-1- Medical Electrical Equipment - Part 1: Basic safety and essential performance Ed3.1 2005+A1:2012
- IEC 60601-1-2 - Medical electrical equipment-basic safety and essential performance-EMC-Edition 3: 2007-03
- IEC 60601-1-11 - Medical electrical equipment-basic safety and essential performance-used in the home healthcare-Ed. 1: 2010-04
- IEC 60601-2-47 - Basic safety and essential performance of ambulatory electrocardiographic systems 2012
- AAM1/ANSI EC38
- AAMI I ANSI EC57 - Testing and reporting performance results of cardiac rhythm and st-segment measurement algorithms 2012
- ISO 80601-2-61 - Basic safety and essential performance of pulse oximeter equipment 2011
- IEC 80601-2-59 Basic safety and essential performance of screening thermographs for human febrile temperature screening 2008

Clinical Performance Data:

No clinical studies were utilized for the purpose of obtaining safety and effectiveness data. Usability validation is part of the Clinical Performance data.

Conclusion	The comparison tabulated below demonstrates that the Dyna-Vision device is substantially equivalent to the predicate devices. The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the Dyna-Vision device should perform as intended in the specified use conditions.

Substantial Equivalence Comparison Table

Feature	Dyna-Vision	Predicate #1 (Indications for Use/Technology)	Predicate #2 (Technology)	Predicate #3 (Add on)	Predicate #4 (Add on)	Predicate #5 (Add on)
510(k) Number	**K #**	**K 141167**	**K092947**	**K080255**	**K070339**	K012451
Trade name	Dyna-Vision Telemonitoring System	VitalConnect Platform,	TeleSentry Wireless Ambulatory ECO Arrhythmia Monitor,	Model 7500 Digital Pulse Oximeter	Disposable Temperature Probes & Skin Temperature Sensor	Propaq 200 Series Monitors
Manufacturer	Techmedic Development International BV	VitalConnect Inc	Scottcare Inc	Nonin Medical Inc	Cincinnati Sub-Zero Products Inc	Welch Allyn protocol, inc.
Device description summary	Dyna-Vision Telemonitoring System relies on an ambulant, wireless device, which uses sensors to collect, transmit and remotely assess ECG and physiological parameters in near real time. The system includes alerts triggered by parameters exceeding preset limits.	The VitalConnect Platform is a wireless data collection system that monitors physiological data. The VitalConnect Platform and the predicate device contains small ambulatory monitoring sensors that measure ECG, heart rate, respiration rate, activity, body orientation, body/skin temperature.	TeleSentry is a battery powered ambulatory ECG monitor, which analyzes an electrocardiographic signal.	The Nonin® Model 7500 Digital Pulse Oximeter is a portable, table top device indicated for use in measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SPO2) and pulse rate of adult, pediatric, infant, and neonatal patients.	To detect hypo/hyperthermia, the body temperature is continuously monitored using disposable temperature sensors or probes. The basic component of these sensors is a resistance chip, which is sensitive to changes in temperature. The chip is in the form of "400" series thermistor connected to a lead wire and encapsulated in a PVC cup. At the end of the lead wires an insert molded connector or standard phone connector provides for the	The Propaq 200 Series monitors are small, lightweight, portable, multi-parameter patient monitors equipped with either a monochrome or color display. The monitors provide real time monitoring and display of ECG, respiration, invasive blood pressure, non-invasive blood pressure, temperature, CO2 and SpO2.

					interconnection with the instrument cable.	
Regulation & Product Code	**21 CFR 870.2910, DRG** **21 CFR 880.2910, FLL** **21 CFR 870.1025, MHX** **21 CFR 870.2300, DRT** **21 CFR 870.2700, DQA**	**21 CFR 870.2910, DRG** Transmitters and Receivers, Physiological Signal, Radiofrequency **21 CFR 870.1025, DSI** Arrhythmia detection and alarm (including ST-segment measurement and alarm) **MHX** Monitor, physiological, patient (with arrhythmia detection or alarm)	**21 CFR 870.1025, DSI** Arrhythmia detector and alarm (including ST-segment measurement and alarm). **DRG** Transmitters and Receivers, Physiological Signal, Radiofrequency	**21 CFR 870.2700, DQA** Oximeter	**21 CFR 880.2910, FLL** Clinical electronic thermometer	**21 CFR 870.2300, DRT** Monitor, cardiac (incl. cardiotachometer & rate alarm)
Intended Use	The Dyna-Vision Telemonitoring System is a wireless monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings and for normal daily activities. Physiological data recorded include: Electrocardiography (EGG), Heart Rate, Heart Rate variability (R-R interval),	The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This includes heart rate, electrocardiography (ECG), heart rate variability (R-R interval), respiratory rate, skin temperature, activity (including step count), and posture (body position relative	The TeleSentry device is intended for diagnostic evaluation of patients who experience transient symptoms or asymptomatic events that may suggest non-lethal cardiac arrhythmia. The device continuously monitors and records the data, automatically records alarm events triggered by an arrhythmia detection algorithm or manually by the patient, and	The Nonin® Model 7500 Digital Pulse Oximeter is a portable, for Use tabletop device indicated for use in measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, pediatric, infant, and neonatal patients. It is indicated for spot-checking and / or continuous	Skin Temperature Sensor (487M and 499B): The CSZ skin temperature sensor is intended for use in routine continuous monitoring skin temperature when the other sensors which might better reflect core body temperature are not indicated clinically. The sensor is designed for placement on the surface of the skin.	The Propaq monitor is intended to be used by skilled clinicians for multiparameter vital signs monitoring of neonatal, pediatric, and adult patients in health care facility bedside applications. It is also intended for intra-facility transport. The ECG channel is intended for five-lead or three-lead ECG monitoring. The Respiration (RESP) channel is

	Peripheral capillary Oxygen saturation (SpO2), Skin Temperature and respiration effort. Data is transmitted wirelessly in near real time to a central location where it is stored for analysis. The Dyna-Vision™ system can be configured by Authorized Persons to notify healthcare professionals when physiological data falls outside selected parameters. Data from the Dyna-Vision™ system is intended to be used by healthcare professionals as an aid to diagnosis and treatment. The device is intended for use on general care patients aged 18 years or more, as a general patient monitor, to provide physiological information. It is not intended for use on critical care patients.	to gravity including fall). Data is transmitted wirelessly to a central location where it is stored for analysis. The Vital Connect Platform can be configured by Authorized Persons to notify healthcare professionals when physiological data falls outside selected parameters. The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform is intended for use by healthcare professionals as an aid to diagnosis and treatment. It is not intended for use on critical care patients.	automatically transmits the recorded event activity associated with these symptoms for review by a licensed physician. Contraindications: a. Patients with potentially life-threatening arrhythmias who require inpatient monitoring. b. Patients who the attending physician thinks should be hospitalized.	monitoring of patients during both motion and non-motion conditions, and for patients who are well or poorly perfused.	Instrument Cables (4872MS and 4900B): The intended use of the instrument cable is to interconnect the disposable temperature sensor/probe with the temperature monitoring instrument.	intended to detect the rate or absence of respiratory effort, deriving the signal by measuring the ac impedance between selected terminals of ECG electrodes.
General specifications						

Dimensions	118 x 65 x 33 mm	115 x 40 x 7 mm (sensor + patch without transmitter)	110 x 6 x 2.6	Approximately 219 mm x 92 x 142 mm	N/A	N/A
Weight	260 gram with battery	---	280 gram with battery	Approximately 900grams (2 lbs) with battery	N/A	N/A
Interface	Foil with buttons and LCD display	---	Foil with buttons, no display	---	N/A	Foil with buttons and LCD display
Energy source	Battery	Battery	Battery	N/A	N/A	Battery/Mains
Type	3.7V lithium polymer rechargeable	Disposable zinc air battery	3.7V lithium polymer rechargeable	7.2 volt NiMH battery pack	N/A	N/A
Autonomy on single charge	22 hrs 3G streaming 36 hrs Wi-Fi streaming	3 days with ECG and 4 days without ECG for the patch. No information about the transmitter autonomy	2-3 days without streaming. 6 hours with streaming	16 hours minimum	N/A	N/A
Communication						
Wi-Fi	Yes 2,4 GHz	Bluetooth	No	N/A	N/A	N/A
Cellular	Yes 3G module	N/A	Yes 2G module	N/A	N/A	N/A
USB	Yes 2.0	No	Yes	N/A	N/A	N/A
Memory	Yes 4 GB SD card	**---**	Yes 4 GB SD card	N/A	N/A	N/A
Recording period	60 days	---	60 days	N/A		N/A
Central monitoring of remotely transmitted patient data	Yes	Yes	Yes	N/A	N/A	Yes

Data sent to central server	Yes	Yes	Yes	N/A	N/A	Yes
Physiological parameters						
PROGRAMMABLE ALERT SETTINGS AND LIMITS	Yes	Yes	Yes	N/A	N/A	Yes
MONITORS ECG	Yes	Yes	Yes	N/A	N/A	Yes
Method	ECG lead wires attached to disposable electrodes to the skin	Patch on the skin to measure single lead ECG.	ECG lead wires attached to disposable electrodes to the skin	N/A	N/A	ECG lead wires attached to disposable electrodes to the skin
Resolution	24 bit	---	12 bit	N/A	N/A	N/A
Input impedance	> 20 Mohm	---	> 20 Mohm	N/A	N/A	N/A
Common mode rejection	-80dB - 100dB	---	92 dB	N/A	N/A	N/A
Sampling frequency	1,000, 800, 400 and 200 Hz	---	1,000, 200, 100	N/A	N/A	N/A
Channels	3, 5 and 12 channels	1 channel	3, 5 and 12 channels	N/A	N/A	N/A
QRS detection AF detection	Yes - 99.8%	---	Yes > 99%	N/A	N/A	N/A
MONITORS HEART RATE	Yes	Yes	Yes	N/A	N/A	Yes
Method	QRS detection	QRS detection	QRS detection	N/A	N/A	QRS detection
Range	25-300 bpm	Not specified	Not specified	N/A	N/A	25-300 bpm

Accuracy	± 2 bpm	± 2 bpm	± 2 bpm	N/A	N/A	± 2 bpm
MONITORS RESPIRATION	Yes	Yes	No	N/A	N/A	Yes
Method	Impedancy Pneumography	---	N/A	N/A	N/A	Impedance Pneumography
Impedance dynamic range	>20 ohms	---	N/A	N/A	N/A	20 ohms
Resolution	5 seconds	---	N/A	N/A	N/A	5 seconds
Range	2 - 150 breaths/min	---	N/A	N/A	N/A	2 to 150 breaths/min
MONITORS SKIN TEMPERATURE	Yes	Yes	No	N/A	Yes	Yes
Method	Skin thermistor	---	N/A	N/A	Skin thermistor	NA
Range	0° to +50	---	N/A	N/A	0° to +50	NA
Accuracy	>10°C to +50°C: ±0.1°C >50° to +122°F: ±0.2°F	---	N/A	N/A	>10°C to +50°C: ±0.1°C >50° to +122°F: ±0.2°F	NA
MONITORS OXYGEN SATURATION	Yes	No	No	Yes	N/A	Yes
Method	Photoplethysmogram on finger. Infrared: 910 nanometers @ 1.2 mW maximum average	N/A	N/A	Photoplethysmogram on finger. Infrared: 910 nanometers @ 1.2 mW maximum average	N/A	NA

	Red: 660 nanometers @ 0.8 mW maximum average			Red: 660 nanometers @ 0.8 mW maximum average		
Range	0-100%	N/A	N/A	0-100%	N/A	NA
Accuracy	± 2 digits (from 70-100%)	N/A	N/A	± 2 digits (from 70-100%)	N/A	NA
USE IN HOME AND HEALTHCARE SETTINGS	Yes	Yes	Yes/No (not exactly specified)	Yes	N/A	Healthcare settings