DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 8, 2017

Fysicon B.V.
% Patsy Trisler
JD, RAC, Consultant
Qserve Group US Inc.
5600 Wisconsin Avenue
Chevy Chase, Maryland 20815

Re: K170032
Trade/Device Name: QMAPP®, QMAPP® GO, QMAPP® AP and QMAPP® EP
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQK
Dated: August 8, 2017
Received: August 9, 2017

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170032

Device Name

QMAPP, QMAPP® GO, QMAPP® AP and QMAPP® EP

Indications for Use *(Describe)*

QMAPP® is intended for use by professional healthcare providers for physiological/hemodynamic monitoring. The system may be used to display and analyze surface ECG (Electrocardiogram), respiration, invasive pressures, pulse oximetry (SpO2), end tidal CO2 (EtCO2), fractional flow reserve (FFR), non-invasive blood pressure (NiBP), surface body temperature, cardiac output and intra-cardiac ECG.

QMAPP® is intended to be used on the patient population of adults. QMAPP® is not intended for neonatal/infant, pediatric and adolescent patients.

QMAPP® provides also clinical data acquisition, medical image/data processing and analytical assessment.

QMAPP® is intended for use in the areas of, but not limited to cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology.

QMAPP® can be used standalone and in networked environments. The system is intended for patient/procedural data management, such as documentation, logging, reporting, trending, storing, reviewing, carrying out clinical calculations and exporting various representations of the acquired data. Data may also be acquired from and/or send to other devices, such as physiological monitoring system, information management systems, image acquisition/storage devices and other medical devices.

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 – K170032

Submitter Name:	Fysicon B.V.
Submitter Address:	Hoogheuvelstraat 114, 5349 BA Oss Netherlands
Phone Number:	+31 (0)412 653 333
Fax Number:	+31 (0)412 653 330
Contact Person:	C.W.A. (Eric) van Antwerpen
Date Prepared:	30-Aug-2017
Device Trade Name:	QMAPP®, QMAPP® GO, QMAPP® AP and QMAPP® EP
Common Name:	Vital Signs Monitoring System
Classification Name, Number & Product Code:	Programmable diagnostic computer, 21 CFR 870.1425 (DQK); Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms), 21 CFR 870.2300 (MWI)
Classification Panel:	Cardiovascular
Primary Predicate Device:	K131497, McKesson CardiologyTM Hemo, McKesson Israel Ltd.
Secondary Predicate Device:	K130626, Mac-Lab, CardioLab, ComboLab, SpecialsLab Recording Systems v6.9.5, GE Healthcare (GE Medical Systems Technologies, Inc.)
Device Description:	The QMAPP® system offers a complete physiological/ hemodynamic monitoring and reporting system. The system is built from three units: an Amplifier, Live Monitoring CPU and Reporting CPU. The Amplifier Unit has various sensors connected with the patient, e.g. ECG, SpO_2 and NiBP. The Amplifier Unit is connected to the Live Monitoring CPU via a dedicated Ethernet connection. The acquired patient information can be visualized on a Live Monitoring CPU, typically located in the technical room. A software application executed on the Live Monitoring CPU can visualize the patient information. Also the Amplifier Unit can be controlled, i.e. most importantly, set acquisition and filtering parameters for the different sensors, by the Live Monitoring CPU. Optionally the Monitoring unit can be connected via a dedicated Ethernet connection to a Reporting

CPU, typically located in the technical room. On the Reporting CPU a database is installed which facilitates data storage and retrieval. A software application executed on the Reporting CPU serves as a patient data management system. It can be used for analysis, calculation and reporting in various representations of patient information.

The QMAPP® system, can operate standalone or it can be part of a typical hospital network infrastructure. The latter offers the possibility to send or receive information from and to other devices. The software has several communication modules, based on HL7 or DICOM protocols to interface with third party equipment/systems.

The QMAPP® system works with 3rd party 510(k) cleared devices: SpO2 module, (Covidien Nellcor, K083325), NiBP module (CAS Medical Systems, MAXNIBP ND+, e.g. CAS Medical Systems, 740 Select, K150620) and EtCO2 sensors, e.g. CLEO Patient Monitor, K142244.

Accessories intended for use with QMAPP®:

Part#	Description
01567031	10 Lead (IEC) ECG Trunk cable, (K120010)
01567002	10 Lead (IEC) Lead wire set, (K120010)
01567032	10 Lead (AHA) ECG Trunk cable, (K120010)
01567033	10 Lead (AHA) Lead wire set, (K120010)
01567056	5 Lead (IEC) ECG Trunk cable, (K120010)
01567258	5 Lead (IEC) Lead wire set, (K120010)
01567034	Dual Pressure Adapter Cable, (K120010)
01567022	IBP Connection cable for BD/Argon (K120010)
01567024	IBP Connection cable for Medex/ACIST (K120010)
01567023	IBP Connection cable for Namic/Navilyst/Angiodynamics (K120010)
01567020	IBP Connection cable for Utah Medical (K120010)
01567021	IBP Connnection cable for Edwards/Baxter, (K120010)
01567025	SpO_2 connection cable for Nellcor, (K120010)
01567053	Reusable Adult Silicone SpO_2 finger sensor, (K120010)
01567063	Dual Temperature Adapter Cable, (K120010)
01567029	Reusable Central temperature probe – Adults, (K120010)
01567027	Reusable Skin temperature probe – Adults, (K120010)
01567026	Reusable Interconnection cable for disp. Probes (K120010)
On request	Disp. central temperature probe – Adults (24 pcs) (K120010)
On request	Disp. skin temperature probe – Adults (24 pcs) (K120010)
01567065	NiBP Hose 250 cm
01593003	UltraCheck® Reusable Cuff (18–26cm), Small adult, (K122365)

01593004	UltraCheck® Reusable Cuff (26–35cm), Adult, (K122365)
01593005	UltraCheck® Reusable Cuff (29–38cm), Adult long, (K122365)
01593006	UltraCheck® Reusable Cuff (32–42cm), Large Adult, (K122365)
01593007	UltraCheck® Reusable Cuff (35–44cm), L Adult Long, (K122365)
01593008	UltraCheck® Reusable Cuff (42–50cm), Thigh (K122365)
01567060	CO Y-Cable (K012226)
01567029	Reference probe (Central temperature probe) (K120010)

Disposables and accessories (tranducers, cannulas and intubation devices) are not part of QMAPP®, but are supplied by the end user facility as required.

Physical Description:

QMAPP® Amplifier dimensions: 298 x 233 x 47 mm, Weight +/- 2200g, Power External 24 VDC

Intended Use/ Indication for Use Statement:

QMAPP® is intended for use by professional healthcare providers for physiological/hemodynamic monitoring. The system may be used to display and analyze surface ECG (Electrocardiogram), respiration, invasive pressures, pulse oximetry (SpO2), end tidal CO2 (EtCO2), fractional flow reserve (FFR), non-invasive blood pressure (NiBP), surface body temperature, cardiac output and intra-cardiac ECG.

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QMAPP® provides also clinical data acquisition, medical image/data processing and analytical assessment.

QMAPP® is intended for use in the areas of, but not limited to cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology.

QMAPP® can be used standalone and in networked environments. The system is intended for patient/procedural data management, such as documentation, logging, reporting, trending, storing, reviewing, carrying out clinical calculations and exporting various representations of the acquired data. Data may also be acquired from and/or send to other devices, such as physiological monitoring system, information management systems, image acquisition/storage devices and other medical devices.

Summary of Technological Characteristics

The QMAPP® system offers vital signs measuring, visualization, monitoring and analysis. The QMAPP® Amplifier offers Surface ECG (Electrocardiogram), respiration, invasive pressures, pulse

oximetry (SpO_2), end tidal CO_2 ($EtCO_2$), Respiration effort, non-invasive blood pressure (NiBP), surface body temperature, cardiac output and intra-cardiac ECG measurements. Typically made in areas of, but not limited to cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology.

The vital signs data is transferred to a Live Monitoring CPU, which offers visualization of the vital sign information. The vital signs information can also be transferred to a Reporting CPU, which offers data storage, connection to Hospital Information Systems and PACS. The Reporting CPU also offers vital signs analysis and reports capabilities

The predicate devices have the same fundamental technological characteristics as the QMAPP® device. However, QMAPP® is considerably newer technology and the primary difference between the proposed and primary predicate is the primary predicate does not have the added feature of intra-cardiac monitoring using EP catheters, however, the secondary predicate includes that feature.

Feature	Subject Device	Primary Predicate	Secondary Predicate
510(k) Number	K170032	K131497	K130626
Trade name	QMAPP®, QMAPP® GO, QMAPP® AP and QMAPP® EP	McKesson Cardiology™ Hemo	Mac-Lab, CardioLab, ComboLab, SpecialsLab Recording Systems v6.9.5
Manufacturer	Fysicon BV	McKesson Israel Ltd.	GE Healthcare
Regulation & Product Code	**21 CFR 870.1425, DQK** Programmable diagnostic computer **21 CFR 870.2300, MWI** Cardiac monitor	**21 CFR 870.1425, DQK** Programmable diagnostic computer **21 CFR 870.2300, MWI** Cardiac monitor	**21 CFR 870.1425, DQK** Programmable diagnostic computer
Intended Use (summary)	physiological/hemodynamic monitoring, recording and reporting system	same	same
MONITORS SURFACE ECG	Yes	Yes	Yes
MONITORS HEART RATE	Yes	Yes	Yes
MONITORS RESPIRATION EFFORT	Yes	Yes	Yes
MONITORS NIBP	Yes	Yes	Yes
MONITORS OXYGEN SATURATION	Yes	Yes	Yes

MONITORS IBP	Yes	Yes	Yes
MONITORS SKIN TEMPERATURE	Yes	Yes	Yes
MONITORS CARDIAC OUTPUT	Yes	Yes	Yes
MONITORS $EtCO_2$	Yes	Yes	Yes
MONITORS Intra Cardiac ECG	Yes	No	Yes

Non-Clinical Tests:

Bench testing was carried out on the following characteristics:

- Electrocardiograph (EGG)
- Heart rate
- SpO2
- NiBP
- IBP
- Cardiac Output
- Intra cardiac ECG
- Skin Temperature
- ECG impedance for Rate of respiratory effort
- Measurement accuracy
- Electromagnetic compatibility (EMC)
- Electrical safety testing
- Mechanical safety testing
- Software verification and validation testing

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

Referenced Standards and Performance Testing:
The QMAPP® system was tested and meets the requirements of following performance Standards.

- IEC 60601-2-27:2011 Medical Electrical Equipment - Part 2-27: Particular Requirements for The Basic Safety and Essential Performance of Electrocardiographic Monitoring Equipment.
- IEC 80601-2-30:2010 Medical Electrical Equipment - Part 2-30: Particular Requirements for The Basic Safety and Essential Performance of Automated Non-Invasive Sphygmomanometers.
- IEC 60601-2-34:2011 Medical Electrical Equipment - Part 2-34: Particular Requirements for The Basic Safety, Including Essential Performance, Of Invasive Blood Pressure Monitoring Equipment.

- IEC 60601-2-49:2011 Medical electrical equipment -- Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment.
- ISO 80601-2-56:2009 Medical Electrical Equipment - Part 2-56: Particular Requirements for Basic Safety and Essential Performance of Clinical Thermometers for Body Temperature Measurement.
- ISO 80601-2-61:2011 Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

Clinical Performance Data:

Usability validation was presented in the Clinical Performance Section 20 of the 510(k). No clinical studies for safety and effectiveness were required.

Clinical validation is carried out on the following characteristics:

- NiBP

Referenced Standards and Performance Testing:
The QMAPP system was tested and meets the requirements of following reference standard:

- IEC 81060-2:2009 Non-invasive sphygmomanometers – Part 2: Clinical validation of automated measurement type

Conclusion:

The following comparison table shows the similarities and differences in technological characteristics. None of the differences raise new questions of safety and effectiveness.

The non-clinical data support the safety of the device and the hardware and software verification and validation testing demonstrate that the QMAPP® system should perform as intended in the specified use conditions.

Statement of Substantial Equivalence:

The intended use of the QMAPP® system is the same as both the Predicate and Reference devices, and the technological characteristics are similar. Per this information and the data provided, this 510(k) submission supports a substantial equivalence determination for the QMAPP®.