



August 27, 2025

Fysicon BV  
% Patsy Trisler  
Consultant and Official Correspondent  
Trisler Consulting  
306 Turnberry Court  
Lebanon, Indiana 46052

Re: K241766

Trade/Device Name: QMAPP® (Hemo, Hemo Lite, PCM, GO, Hybrid)  
Regulation Number: 21 CFR 870.2300  
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)  
Regulatory Class: Class II  
Product Code: MWI, DQK  
Dated: December 9, 2024  
Received: December 9, 2024

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Stephen C. Browning -S**

LCDR Stephen Browning  
Assistant Director  
Division of Cardiac Electrophysiology,  
Diagnostics, and Monitoring Devices  
Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K241766

Device Name

QMAPP® (Hemo, Hemo Lite, PCM, GO, Hybrid)

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® 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.

☒ 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 – QMAPP® – K241766-S001

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|-------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>SUBMITTER</b>                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Submitter Name:</b>                    | Fysicon B.V.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Submitter Address:</b>                 | Hoogheuvellaan 114, 5349 BA Oss, The Netherlands                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Contact Person:</b>                    | C.W.A. (Eric) van Antwerpen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Telephone #:</b>                       | +31 412 653333                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Date Prepared:</b>                     | 25 July 2025                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>DEVICE</b>                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Device Trade Name:</b>                 | QMAPP® (Hemo, Hemo Lite, PCM, GO, Hybrid)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Common and Classification Name(s):</b> | Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Classification #:</b>                  | 21 CFR 870.2300, 21 CFR 870.1425                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Product Code</b>                       | MWI, DQK                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Regulatory Class</b>                   | 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Review Panel</b>                       | Cardiovascular                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>PREDICATE DEVICE</b>                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Primary Predicate Device</b>           | K170032, QMAPP®                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Secondary Predicate Device</b>         | K131497, McKesson Cardiology™ Hemo                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>DEVICE DESCRIPTION</b>                 | <p>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, SpO2 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, to 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 e.g. be used for analysis, calculation and reporting in various representations of patient information.</p> |

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|                             | <p>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.</p> <ul style="list-style-type: none"> <li>•The QMAPP® system works with 3rd party 510(k) cleared SpO2 module (Covidien Nellcor, K083325), NiBP module (CAS Medical Systems, MAXNIBP ND+, e.g. used in FDA cleared device CAS Medical Systems, 740 Select, K150620) and EtCO2 sensors e.g. used in FDA cleared device CLEO Patient Monitor, K142244.</li> </ul> |
| <b>PHYSICAL DESCRIPTION</b> | <p>QMAPP® Amplifier dimensions: 298 x 233 x 47 mm, Weight +/- 2200g, Power External 24 VDC</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

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| <b>INTENDED USE / INDICATIONS FOR USE</b>       | <p>QMAPP® is intended to be used 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.</p> <p>QMAPP® provides also clinical data acquisition, medical image/data processing and analytical assessment.</p> <p>QMAPP® is intended for use in the areas of, but not limited to cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology.</p> <p>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.</p> |
| <b>SUMMARY OF TECHNOLOGICAL CHARACTERISTICS</b> | <p>The QMAPP® system offers vital signs measuring, visualization, monitoring and analysis. The QMAPP Amplifier offers Surface ECG (Electrocardiogram), respiration, invasive pressures, pulse oximetry (SpO2), end tidal CO2 (EtCO2), 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</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

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|                                                     | <p>cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology.</p> <p>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>NON-CLINICAL TESTS</b>                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Bench testing</b>                                | <p>was carried out on the following characteristics:</p> <ul style="list-style-type: none"> <li>• Electrocardiograph (EGG)</li> <li>• Heart rate</li> <li>• SpO2</li> <li>• NiBP</li> <li>• IBP</li> <li>• Cardiac Output</li> <li>• Intra cardiac ECG</li> <li>• Skin Temperature</li> <li>• ECG impedance for Rate of respiratory effort</li> <li>• Measurement accuracy</li> <li>• Electromagnetic compatibility (EMC)</li> <li>• Electrical safety testing</li> <li>• Mechanical safety testing</li> <li>• Software verification and validation testing</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Usability Testing</b>                            | <p>In addition to the above, usability testing was also conducted.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Referenced Standards and Performance Testing</b> | <p>The QMAPP® system was tested and meets the requirements of following performance Standards.</p> <ul style="list-style-type: none"> <li>• AAMI/ANSI EC 60601-1:2005/(R)2012 &amp; A1:2012 C1:2009/(R)2012 &amp; A2:2010/(R)2012 Medical electrical equipment - General requirements for basic safety and essential performance.</li> <li>• IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.</li> <li>• IEC 60601-2-27:2016 Medical Electrical Equipment - Part 2-27: Particular Requirements for The Basic Safety and Essential Performance of Electrocardiographic Monitoring Equipment.</li> <li>• IEC 80601-2-30:2018 Medical Electrical Equipment - Part 2-30: Particular Requirements for The Basic Safety and Essential Performance of Automated Non-Invasive Sphygmomanometers.</li> <li>• 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.</li> </ul> |

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|                                             | <ul style="list-style-type: none"><li>• ISO 80601-2-56:2017 Medical Electrical Equipment - Part 2-56: Particular Requirements for Basic Safety and Essential Performance of Clinical Thermometers for Body Temperature Measurement.</li><li>• ISO 80601-2-61:2017 Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.</li></ul> |
| <b>CONCLUSION</b>                           | <p>The following comparison table shows the similarities and differences in technological characteristics. None of the differences raise new questions of safety and effectiveness.</p> <p>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.</p> |
| <b>STATEMENT OF SUBSTANTIAL EQUIVALENCE</b> | <p>The information and data provided in this Traditional 510(k) establish that the modified device is substantially equivalent in the intended use, design, principle of operation, technology, materials, specifications and performance to the predicates.</p>                                                                                                                                                       |

### Substantial Equivalence Summary Table

| <b>TRADE NAME &gt;<br/>FEATURE</b>                  | <b>Proposed (modified) Device:<br/>QMAPP®, QMAPP® GO, QMAPP® PCM, QMAPP Hemo and QMAPP® Hybrid</b> | <b>Primary Predicate Device:<br/>QMAPP®, QMAPP® GO, QMAPP® AP and QMAPP® EP</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Secondary Predicate Device:<br/>McKesson Cardiology™ Hemo</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
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| <b>510(k) Number</b>                                | K241766                                                                                            | K170032                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | K131497                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Regulation, Product Code and Regulatory Name</b> | Same as primary predicate device                                                                   | <b>21 CFR 870.1425, DQK</b><br>Programmable diagnostic computer<br><br><b>21 CFR 870.2300, MWI</b><br>Cardiac monitor (including cardiachometer and rate alarm)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>21 CFR 870.1425, DQK</b><br>Programmable diagnostic computer<br><br><b>21 CFR 870.2300, MWI</b><br>Cardiac monitor (including cardiachometer and rate alarm)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Manufacturer</b>                                 | Same as primary predicate device                                                                   | Fysicon B.V.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | McKesson Israel Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Device description summary</b>                   | Same as primary predicate device                                                                   | <p>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.</p> <p>The Amplifier Unit has various sensors connected with the patient, e.g. ECG, SpO<sub>2</sub> and NiBP. The Amplifier Unit is connected to the Live Monitoring CPU via a dedicated Ethernet connection.</p> <p>The acquired patient information can be visualized on a Live Monitoring CPU. Typically located in the technical room.</p> <p>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</p> | <p>McKesson Cardiology™ Hemo device is a hemodynamic monitoring system for monitoring vital signs, performing measurements and calculations, documenting procedure and patient data and interfacing to other systems and devices during and after procedures in the areas of: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology and other areas where patient/ procedural data management is needed.</p> <p>McKesson Cardiology™ Hemo also acquires patient information from other hospital information systems and makes hemodynamic information available to them. It facilitates seamless interfacing with hospital information systems and cardiac image management, archiving and reporting systems.</p> |

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|----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                    |                                                                                                                                                                                                                                                                                                                                                                                               | <p>the Monitoring unit can be connected via a dedicated Ethernet connection to a Reporting CPU, typically located in the technical room.</p> <p>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.</p> <p>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.</p> | <p>McKesson Cardiology™ Hemo incorporates the FDA cleared ARGUS PB vital signs monitoring device (K012226), which provides patient monitoring via; ECG Leads; Invasive Blood Pressure; SpO<sub>2</sub>; NiBP; Body temperature; Thermal Dilution Cardiac output and CO<sub>2</sub>.</p> <p>McKesson Cardiology™ Hemo is composed of:</p> <p>A control and documentation unit (information System) which is used for administration, performing measurements, recording full disclosure, taking samples and entering procedure notes and overall data input and management of the patient and procedure data.</p> <p>A Clinical Unit that incorporates the "Clinical Systems" and the "Front-End" unit (which incorporates the Schiller Argus PB device – K012226). The clinical unit is responsible for acquiring, analyzing and displaying patient vitals and other pertinent clinical data. The data is displayed on monitors.</p> |
| <b>Intended Use/ Indications for Use Statement</b> | <p>QMAPP® is intended to be used 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 (SpO<sub>2</sub>), End tidal CO<sub>2</sub> (EtCO<sub>2</sub>), fractional flow reserve (FFR), non-invasive blood pressure (NiBP), surface</p> | <p>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 (SpO<sub>2</sub>), end tidal CO<sub>2</sub> (EtCO<sub>2</sub>), fractional flow reserve (FFR), non-invasive blood pressure (NiBP), surface</p>                                                                                                                                                                                                                                                                                                                                                                                                             | <p>McKesson Cardiology Hemo™ is intended for complete physiological/ hemodynamic monitoring, clinical data acquisition, medical image and data processing, and analytical assessment.</p> <p>McKesson Cardiology™ Hemo is also intended for patient/procedural data management, such as documentation, logging, reporting, trending, storing, reviewing, carrying out clinical</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

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|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                             | <p>body temperature, cardiac output and intra-cardiac ECG.</p> <p>QMAPP® provides also clinical data acquisition, medical image/data processing and analytical assessment.</p> <p>QMAPP® is intended for use in the areas of, but not limited to cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology.</p> <p>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, and 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.</p> | <p>body temperature, cardiac output and intra-cardiac ECG.</p> <p>QMAPP® is intended to be used on the patient population of adults.</p> <p>QMAPP® provides also clinical data acquisition, medical image/data processing and analytical assessment.</p> <p>QMAPP® is intended for use in the areas of, but not limited to cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology.</p> <p>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.</p> | <p>calculations and exporting various representations of the acquired data. Data may also be acquired from and/or sent to other devices, such as physiological monitoring systems, information management systems, image acquisition/storage devices, and other medical devices.</p> <p>McKesson Cardiology™ Hemo is intended for use in the areas of: cardiology, cardiac catheterization, electrophysiology, radiology, invasive radiology, and other areas where patient/procedural data management is needed.</p> <p>User-adjustable alarms (both visual and audible) available in the system alert the operator to anomalous occurrences and facilitate timely responses.</p> <p>Use of the system is not intended for unattended patient monitoring or in situations where arrhythmia detection is required.</p> |
| <b>Intended Populations</b> | No restrictions or limitations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Adults                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | No restrictions or limitations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Dimensions</b>           | Same as primary predicate device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 298 x 233 x 47 mm<br>11.7 x 9.2 x 1.9 inch                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 280 x 135 x 130 mm<br>11.0 x 5.3 x 5.1 inch                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

|                                    |                                    |                                                              |                                                              |
|------------------------------------|------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|
| <b>Weight</b>                      | Same as primary predicate device   | 2200 grams<br>4.85 pounds                                    | 3800 grams<br>8.38 pounds                                    |
| <b>Energy source</b>               | Same as primary predicate device   | 90 - 264V<br>24V DC at bedside                               | 100-264V<br>24V at bedside                                   |
| <b>Amplifier – Monitor CPU</b>     | Same as primary predicate device   | 100 Mbit                                                     | RS232                                                        |
| <b>Monitor CPU – Reporting CPU</b> | Same as primary predicate device   | 100 MB                                                       | 100 MB                                                       |
| <b>CPU LAN</b>                     | Same as primary predicate device   | Intel i5, 2.00 GHz                                           | > Intel Pentium 4                                            |
| <b>Data sent to central server</b> | Same as primary predicate device   | Yes, if a networked system is chosen                         | Yes, if a networked system is chosen                         |
| <b><u>MONITORS SURFACE ECG</u></b> | Same as primary predicate device   | Yes                                                          | Yes                                                          |
| <b>Method</b>                      | Same as primary predicate device   | ECG lead wires attached to disposable electrodes to the skin | ECG lead wires attached to disposable electrodes to the skin |
| <b>Resolution</b>                  | Same as primary predicate device   | 24 bit                                                       | 12 bit                                                       |
| <b>Input impedance</b>             | Same as primary predicate device   | > 2.5 MOhm                                                   | > 2.5 MOhm                                                   |
| <b>Common mode rejection</b>       | Same as primary predicate device   | > 100 dB                                                     | > 100 dB                                                     |
| <b>Sampling frequency</b>          | Same as primary predicate device   | 2 – 32 KHz                                                   | 1 KHz                                                        |
| <b>Channels</b>                    | Same as primary predicate device   | 12                                                           | 12                                                           |
| <b><u>MONITORS HEART RATE</u></b>  | Same as primary predicate device   | Yes                                                          | Yes                                                          |
| <b>Method</b>                      | Same as primary predicate device   | QRS detection                                                | QRS detection                                                |
| <b>HR range</b>                    | Same as secondary predicate device | 15 – 300 bpm                                                 | 15 – 350 bpm                                                 |
| <b>Accuracy</b>                    | Same as primary predicate device   | ± 2%                                                         | ± 2%                                                         |

|                                            |                                  |                                               |                                                                          |
|--------------------------------------------|----------------------------------|-----------------------------------------------|--------------------------------------------------------------------------|
| <b>MONITORS<br/>RESPIRATION<br/>EFFORT</b> | Same as primary predicate device | Yes                                           | Yes                                                                      |
| Method                                     | Same as primary predicate device | Impedance Pneumography                        | Impedance Pneumography                                                   |
| Resolution                                 | Same as primary predicate device | 1/min                                         | 1/min                                                                    |
| Range                                      | Same as primary predicate device | 0 – 150 / Min                                 | 0 – 200 / Min                                                            |
| Channels                                   | Same as primary predicate device | 1                                             | 1                                                                        |
| <b>MONITORS<br/>NIBP</b>                   | Same as primary predicate device | Yes                                           | Yes                                                                      |
| Method                                     | Same as primary predicate device | Oscillometric<br>(CAS Max module)             | Oscillometric                                                            |
| Range                                      | Same as primary predicate device | 15 - 260 mm Hg                                | 15 – 200 mm Hg                                                           |
| Accuracy                                   | Same as primary predicate device | ± 5 mm Hg                                     | ± 5 mm Hg                                                                |
| (Third party)<br>Module                    | Same as primary predicate device | CAS Medical Systems, 740 Select,<br>(K150620) | Part of device:<br>ARGUS PB vital signs monitoring Device,<br>(K012226), |

|                                           |                                  |                                           |                                                          |
|-------------------------------------------|----------------------------------|-------------------------------------------|----------------------------------------------------------|
| <b>MONITORS<br/>OXYGEN<br/>SATURATION</b> | Same as primary predicate device | Yes                                       | Yes                                                      |
| Method                                    | Same as primary predicate device | Nellcor Oximax                            | Masimo Set                                               |
| Range                                     | Same as primary predicate device | 1 -100%                                   | 1 – 100%                                                 |
| Accuracy                                  | Same as primary predicate device | ± 1%                                      | ± 3%                                                     |
| Channels                                  | Same as primary predicate device | 1                                         | 1                                                        |
| (Third party)<br>Module                   | Same as primary predicate device | OxiMax N-600x Pulse Oximeter<br>(K083325) | Part of device ARGUS PB-1000 Masimo<br>Set<br>(K012226), |
| <b>MONITORS<br/>IBP</b>                   | Same as primary predicate device | Yes                                       | Yes                                                      |
| Method                                    | Same as primary predicate device | Pressure transducer                       | Pressure transducer                                      |
| Accuracy                                  | Same as primary predicate device | ± 2 mm Hg or ± 1 %                        | ± 2 mm Hg or ± 1 %                                       |

|                                          |                                  |                                                                                     |                                                                                                      |
|------------------------------------------|----------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| Range                                    | Same as primary predicate device | -30 - 320 mm Hg                                                                     | - 400 – 400 mm Hg                                                                                    |
| Channels                                 | Same as primary predicate device | 4                                                                                   | 4                                                                                                    |
| <b>MONITORS<br/>SKIN<br/>TEMPERATURE</b> | Same as primary predicate device | Yes                                                                                 | Yes                                                                                                  |
| Method                                   | Same as primary predicate device | Thermistor, YSI compatible                                                          | Thermistor, YSI compatible                                                                           |
| Range                                    | Same as primary predicate device | 20° – 45° C<br>68° – 113° F                                                         | 15° – 45° C<br>59° – 113° F                                                                          |
| Accuracy                                 | Same as primary predicate device | ± 0.1° C<br>± 0.18° F                                                               | ± 0.1° C<br>± 0.18° F                                                                                |
| Channels                                 | Same as primary predicate device | 2                                                                                   | 1                                                                                                    |
| <b>MONITORS<br/>CARDIAC<br/>OUTPUT</b>   | Same as primary predicate device | Yes                                                                                 | Yes                                                                                                  |
| Method                                   | Same as primary predicate device | Thermo Dilution and (calculated) FICK                                               | Thermo Dilution and (calculated) FICK                                                                |
| Range                                    | Same as primary predicate device | 0.1 – 20 L                                                                          | 0.1 – 20 L                                                                                           |
| Accuracy                                 | Same as primary predicate device | ± 0.1 L                                                                             | ± 0.1 L                                                                                              |
| <b>MONITORS<br/>EtCO<sub>2</sub></b>     | Same as primary predicate device | Yes                                                                                 | Yes                                                                                                  |
| Method                                   | Same as primary predicate device | Low flow Side stream                                                                | Low Flow Side stream                                                                                 |
| CO <sub>2</sub> resolution               | Same as primary predicate device | 0.1 mm Hg 0 to 49 mm Hg<br>0.2 mm Hg 49 to 152 mm Hg                                | 0.1 mm Hg 0 to 69 mm Hg<br>0.25 mm Hg 70 to 150 mm Hg                                                |
| CO <sub>2</sub> Accuracy                 | Same as primary predicate device | 0 – 40 mm Hg, ± 2 mm Hg;<br>41 – 70 mm Hg, ± 5%;<br>71-100 mm Hg, ± 8%;<br>>101 10% | 0– 40mmHg, ±2 mm Hg<br>41– 70mmHg, ±5%<br>71–100mmHg, ±8%<br>101–150mmHg, ±10%<br>Above 80 BPM, ±12% |
| (Third party)<br>Module                  | Same as primary predicate device | GoldWEL C300<br>Part of device CLEO Patient Monitor,<br>(K142244)                   | Respironics<br>Capnostat 5 sensor,<br>(K042601)                                                      |

| <b>MONITORS<br/>Intra Cardiac<br/>ECG</b> | Same as primary predicate device | Yes                            | No  |
|-------------------------------------------|----------------------------------|--------------------------------|-----|
| Method                                    | Same as primary predicate device | Electro Physiology catheter    | n/a |
| Resolution                                | Same as primary predicate device | 24 Bit                         | n/a |
| Input impedance                           | Same as primary predicate device | > 2.5 MOhm                     | n/a |
| Common mode rejection                     | Same as primary predicate device | > 100 dB                       | n/a |
| HR range                                  | Same as primary predicate device | 15 – 300 bpm                   | n/a |
| Sampling frequency                        | Same as primary predicate device | 2 - 32 kHz                     | n/a |
| Channels                                  | Same as primary predicate device | 8, 16 or 32 (bipolar) Channels | 0   |