June 2, 2023

Medopad Inc
Mani Shanmugham
Head of Quality and Regulatory
101 6th Avenue
New York, New York 10013

Re: K230214
Trade/Device Name: Huma RPM (RPM)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI, MSX
Dated: April 20, 2023
Received: May 2, 2023

Dear Mani Shanmugham:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert T. Kazmierski -S

for

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230214

Device Name

Huma RPM (RPM)

Indications for Use *(Describe)*

The Huma platform is a modular software as a medical device (SaMD) which may utilize compatible devices and software to obtain data collated via a mobile app or web app and delivered to the clinician via a web portal or web app where it may be viewed to drive clinical management. It is intended to be used for the physiological and non-physiological intermittent or spot-check monitoring of all condition patients in professional healthcare facilities, such as clinics, hospitals or skilled nursing facilities, or in the patient's home setting. It is intended for the monitoring of patients by trained healthcare professionals.

The Huma platform comprises a number of different modules and functionalities that can be selected by the customer for configuration of care plans which can be further personalized for the patients. Clinical information collected from these modules is displayed on a clinician web portal and patient app with the addition of flagging out of range datasets, trend visualization, goal setting and communication channels between clinicians and patients.

The data displayed on the mobile app, web portal or web app can be labeled, flagged and triaged for the purposes of monitoring disease or deterioration, improvement and to support clinical decision making and to encourage self-management of disease by the patients. The platform may also provide data analytics, risk scores and static algorithms that may assist in the assessment of risk prediction, diagnosis, disease monitoring and prognostication. The Huma platform can be used for adult and pediatric populations with functionality to accommodate data entry by caregivers and guardians. The Huma platform is not intended for use in high-acuity environments, such as ICU or operating rooms.

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.

510(k) SUMMARY

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

Medopad Inc
101, Avenue of the Americas Ofc 327
New York, NY 10023

1.2 Official Correspondent

Mani Shanmugham, Ph.D.
101, Avenue of the Americas Ofc 327
New York, NY 10023
Ph: 801-673-9973
Email: mani.shanmugham@huma.com

1.3 Date of Preparation

April 14, 2023

2. NAME OF THE DEVICE

2.1 Trade/Proprietary Name

Huma RPM

2.2 Common/Usual Name

Monitor, Physiological, Patient (without Arrhythmia detection or alarms)
System, Network and Communication, Physiological Monitoring

2.3 Classification Information

Classification Name:	Monitor, Physiological, Patient (without Arrythmia detection or alarms); System, Network and Communication, Physiological Monitors
Classification Regulation:	21 CFR 870.2300
Class:	2
Product Code:	MWI, MSX
Panel:	Cardiovascular

3. PREDICATE DEVICES

Predicates: AirStrip Remote Patient Monitoring (RPM) and Web Client

(1) AirStrip Remote Patient Monitoring (RPM) Remote Data Viewing, cleared under **K122133,** by AirStrip Technologies
(2) AirStrip One Web Client, cleared under **K160862**, by AirStrip Technologies

Reference Device:

(1) AirStrip One Web Client with ACM, cleared under **K211949**, by AirStrip Technologies

4. DESCRIPTION OF THE DEVICE

The Huma RPM is a digital remote patient monitoring platform that empowers patients to better manage their own health. The modular solution tracks symptoms and vital signs, flags deterioration, incorporates telemedicine functionality and can be connected to other medical devices.

Data from the App is surfaced and analyzed in the Portal which has flagging for easy triage and decision making. The Portal enables clinicians to safely monitor patients, spot deterioration and intervene early to improve outcomes and avoid unnecessary clinic, outpatient and hospital attendance.

The portal can display information about individual patients and visualize data trends. Clinicians can add notes and collaborate with colleagues to ensure the patient receives the optimal care they need. The platform also has messaging capability and telemedicine for patient video consultations. The platform can be integrated with EHR systems and existing patient portals. The clinician portal also allows for Role-Based-Access-control (RBAC) based on a person's role within the healthcare facility according to data view rights for different healthcare system personnel.

5. INTENDED USE

The Huma platform is a modular software as a medical device (SaMD) which may utilize compatible devices and software to obtain data collated via a mobile app or web app and delivered to the clinician via a web portal or web app where it may be viewed to drive clinical management. It is intended to be used for the physiological and non-physiological intermittent or spot-check monitoring of all condition patients in professional healthcare facilities, such as clinics, hospitals or skilled nursing facilities, or in the patient's home setting. It is intended for the monitoring of patients by trained healthcare professionals.

The Huma platform comprises a number of different modules and functionalities that can be selected by the customer for configuration of care plans which can be further personalized for the patients. Clinical information collected from these modules is displayed on a clinician web portal and patient app with the addition of flagging out of range datasets, trend visualization, goal setting and communication channels between clinicians and patients.

The data displayed on the mobile app, web portal or web app can be labeled, flagged and triaged for the purposes of monitoring disease or deterioration, improvement and to support clinical decision making and to encourage self-management of disease by the patients. The

platform may also provide data analytics, risk scores and static algorithms that may assist in the assessment of risk prediction, diagnosis, disease monitoring and prognostication. The Huma platform can be used for adult and pediatric populations with functionality to accommodate data entry by caregivers and guardians. The Huma platform is not intended for use in high-acuity environments, such as ICU or operating rooms.

6. INTENDED USE COMPARED TO THE PREDICATES

The Huma RPM has an intended use statement that is comprised of a combination of the intended uses from the two (2) Predicates and the reference device. The statement is very similar with the exception of several word changes specific to the subject device as the subject device is device-, condition - and system- agnostics. The devices also share the same target patient population, the same users and conditions of use (**Table 1**).

Table 1. Intended Use / Indications for Use Comparison

Devices (Subject and Predicate)	Intended Use/Indications for Use
Subject Device Huma RPM Medopad Inc	The Huma platform is a modular software as a medical device (SaMD) which may utilize compatible devices and software to obtain data collated via a mobile app or web app and delivered to the clinician via a web portal or web app where it may be viewed to drive clinical management. It is intended to be used for the physiological and non-physiological intermittent or spot-check monitoring of all condition patients in professional healthcare facilities, such as clinics, hospitals or skilled nursing facilities, or in the patient's home setting. It is intended for the monitoring of patients by trained healthcare professionals. The Huma platform comprises a number of different modules and functionalities that can be selected by the customer for configuration of care plans which can be further personalized for the patients. Clinical information collected from these modules is displayed on a clinician web portal and patient app with the addition of flagging out of range datasets, trend visualization, goal setting and communication channels between clinicians and patients. The data displayed on the mobile app, web portal or web app can be labeled, flagged and triaged for the purposes of monitoring disease or deterioration, improvement and to support clinical decision making and to encourage self-management of disease by the patients. The platform may also provide data analytics, risk scores and static algorithms that may assist in the assessment of risk prediction, diagnosis, disease monitoring and prognostication. The Huma platform can be used for adult and pediatric populations with functionality to accommodate data entry by caregivers and guardians. The Huma platform is not intended for use in high-acuity environments, such as ICU or operating rooms.
Predicate 1 AirStrip One Web Client (K160862)	Information is generated by other medical devices and patient information system, and not by this device. This device captures this information from these

Devices (Subject and Predicate)	Intended Use/Indications for Use
	other systems and displays it for clinicians. This device is intended to be used by clinicians for the following purposes: • To view the near real-time waveforms remotely • To remotely review other standard or critical near real-time patient data from the monitored system • To provide a request for remote consultation regarding a patient's waveform or other data This device software can display the following the physiologic data captured by other medical devices: ECG Waveform; Heart Rate Monitored; Manually counted chest wall movement; Oxygen Saturation; Intracranial Pressure; Central Venous Pressure; Pulmonary Capillary Wedge Pressure; Cardiac Index; Cardiac Output; Cerebral Perfusion Pressure; Systolic Blood Pressure Invasive; Mean Arterial Pressure Invasive; Diastolic Blood Pressure Invasive; Systolic Blood Pressure Cuff ;Mean Arterial Pressure Cuff ; Diastolic Blood Pressure Cuff
Predicate 2 AirStrip Remote Patient Monitoring (RPM) Remote Data Viewing (K122133)	AirStrip RPM is software capable of displaying physiologic and other patient information. This information is generated by other medical devices and patient information system, and not by AirStrip RPM. Airstrip RPM captures this information from these other systems and displays it for clinicians. AirStrip RPM is intended to be used by clinicians for the following purposes: • By using a cellular telephone or other device on which AirStrip RPM is installed, to review physiologic data of a patient when the clinician is not at the hospital • To view the near real-time waveforms remotely and to remotely review other standard or critical near real-time patient data from the monitored system • To provide a request for remote consultation regarding a patient's waveform or other data The AirStrip RPM software can display the following the physiologic data captured by other. medical devices: - ECG Waveform - Heart Rate Monitored; Manually counted chest wall movement; Oxygen Saturation; Intracranial Pressure; Central Venous Pressure - Pulmonary Capillary Wedge Pressure; Cardiac Index; Cardiac Output; Cerebral Perfusion Pressure; Urine Output - Urine/Stool Mix Output; Systolic Blood Pressure Invasive; Mean Arterial Pressure Invasive - Diastolic Blood Pressure Invasive; Systolic Blood Pressure Cuff; Mean Arterial Pressure Cuff; Diastolic Blood Pressure Cuff - Vasoactive Infusions; Antiarrhythmics - Sedation - Paralytics -Laboratory Data including - Blood Gas -Chemistry -Hematology -Coagulation; Allergies; Medications Counter-indication
Reference Device AirStrip ONE Web Client with Alarm	AirStrip ONE Web Client with ACM gathers data from the medical devices that are connected to the patient. AirStrip ONE Web Client with ACM is not directly connected to the individual, but to a networked medical device receiving data, and connects that data to individuals by medical record number

Devices (Subject and Predicate)	Intended Use/Indications for Use
Communication Management (ACM)	or defined patient ID. AirStrip ONE Web Client with ACM is intended to be used by clinicians for the following purposes: To visualize physiological data using a web viewer to assess clinical status of a patient when the source system cannot be observed directly by the clinician To view the near real-time and historic waveforms To view other near real-time patient data from a monitored system. To provide a request for remote consultation regarding a patient's waveform or other data and to send electronic images of the cardiac rhythm to the medical record To allow clinicians to manage secondary alarm transmission by suppressing non-critical alarms

7. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATES

A comparison of the technological features between the Huma RPM and the Predicates and Reference device is shown in **Table 2** below for the Remote Patient Monitoring System.

Table 2. Huma RPM's Characteristics Comparison to Predicates

Characteristics	Subject Device – Huma RPM	Predicates 1 & 2 AirStrip One Web Client (K160862) & AirStrip (RPM) Remote Data Viewing (K122133)	Reference Device AirStrip One Web Client with ACM (K211949)	Same or Different
Intended user	Clinicians and patients	Clinicians	Clinicians	Similar. Patient interface allows patients to view their own information.
Targeted users	Patients	Patients	Patients	Same
Targeted population	Adults and Pediatric	Adults	Adults and Pediatric	Same
Directly connected to patient	No	No	No	Same
Health Data collection	Patient physiological data including blood pressure, cardiac monitor, breathing pressure, breathing rate cardiac monitor,	ECG Waveform; Heart Rate Monitored; Respiratory Rate; Oxygen Saturation; Intracranial Pressure; Central Venous	- ECG Waveform - Heart Rate Monitored, Manually counted chest wall movement, Oxygen Saturation - Intracranial	Similar. The subject device allows monitoring of physiological as well as other life-style related

Characteristics	Subject Device – Huma RPM	Predicates 1 & 2 AirStrip One Web Client (K160862) & AirStrip (RPM) Remote Data Viewing (K122133)	Reference Device AirStrip One Web Client with ACM (K211949)	Same or Different
	temperature, breathing frequency, and oxygen saturation. In addition, the subject also allows other life-style related factors such as exercising, smoking-vaping, stress, nutrition, diets, menta well-being, orthopedic related information and COVID-19 symptoms.	Pressure; Pulmonary Capillary Wedge Pressure; Cardiac Index; Cardiac Output; Cerebral Perfusion Pressure; Systolic Blood Pressure Invasive; Mean Arterial Pressure Invasive; Diastolic Blood Pressure Invasive; Systolic Blood Pressure Cuff; Mean Arterial Pressure Cuff; Diastolic Blood Pressure Cuff	Pressure, Central Venous Pressure - Pulmonary Capillary Wedge Pressure, Cardiac Index, Cardiac Output, Cerebral Perfusion Pressure - Urine Output - Urine/Stool Mix Output, Systolic Blood Pressure Invasive, Mean Arterial Pressure Invasive - Diastolic Blood Pressure Invasive, Systolic Blood Pressure Cuff, Mean Arterial Pressure Cuff, Diastolic Blood Pressure Cuff - Vasoactive Infusions, Antiarrhythmics - Sedation - Paralytics - Laboratory Data including -Blood Gas -Chemistry - Hematology -Coagulation, Allergies- Medications	parameters such exercising, smoking-vaping, stress related data capturing whereas the predicates have few only physiological signs capturing and monitoring. The subject device also allows COVID-19 and orthopedic related information to be captured.
Device Type/Material Composition	Software as a medical Device (SaMD)	Software as a medical Device (SaMD)	Software as a medical Device (SaMD)	Same
Connectivity	Secured Internet	Internet	Internet	Same
Data transmission	Modem, Wi-Fi	Modem, Wi-Fi	Modem, Wi-Fi	Same
Data source location	Hospital	Hospital	Hospital	Same
Data Storage	Securely stores and manages encrypted patient measurements. Medical device data sets are provided through the user interface of choice for the patient, physicians, or other partners to securely access the patient's information.	Securely stores and manages encrypted patient measurements, medical device data sets are provided through the user interface of choice for the patient, physicians, or other partners to securely access the patient's information.	Securely stores and manages encrypted patient measurements, medical device data sets are provided through the user interface of choice for the patient, physicians, or other partners to securely access the patient's information.	Same
Use Environment	Hospital, Patient's home if the patient is at home	Hospital	Hospital	Similar. The subject device allows patients to be at their home environment and input

Characteristics	Subject Device – Huma RPM	Predicates 1 & 2 AirStrip One Web Client (K160862) & AirStrip (RPM) Remote Data Viewing (K122133)	Reference Device AirStrip One Web Client with ACM (K211949)	Same or Different
				physician-specified data
Operating System	IOS (IPhone), Android	IOS (IPhone); Android; other devices where the AirStrip App is installed	IOS (IPhone); Android; other devices where the AirStrip App is installed	Similar. The subject device program can be installed on 2 primary mobile device operating systems iOS and Android.
Ability to view real-time data/visualization	Yes	Yes	Yes	Yes
Data generated by Software	Information is collected from other devices and not by this subject device.	Information is generated by other medical devices and patient information system, and not by this device.	Information is generated by other medical devices and patient information system, and not by this device.	Same
Possibility of flagging, triaging based on algorithm	Yes; possible	No	Yes. Allows clinicians to set rules and enable triaging for alarms/alerts	Same
Data Exporting Capability	Yes	Unknown	Unknown	Different

7.1 Similarities and Differences in Technology Comparison

The Huma RPM is equivalent to the combination of the AirStrip Remote Patient Monitoring (RPM) Remote Data Viewing (K122133), AirStrip One Web Client (K160862) and the reference device AirStrip One Web Client with ACM Module (K211949).

The technology of the Subject Huma RPM combines the convenience of web portal interface and mobile device data input. This consolidation allows greater flexibility to clinicians and patients to choose their own data collection/viewing mode. In other words, Huma RPM integrates with compatible devices and software to obtain data collated via a mobile app or web app and delivered to the clinician via a web portal or web app where it may be viewed to drive clinical management.

Similar to the predicate devices, Huma platform can be accessed from any internet connected device with compatibility across multiple web browsers. The Huma remote patient monitoring (RPM) platform comprises a smartphone Patient App (available on Android and iOS) and a web-browser Clinician Portal. The patient app can also be deployed on web-browser for patients who do not have or do not wish to use a smartphone or smartphone App.

Further, Huma RPM platform allows for the simple export and download of patient data and records from the Clinician Portal via a couple of standard file formats - CSV and JSON. The export / download is configurable and can be generated based on client requirements. The export / download can be customised to include data in a required format (e.g. grouped by patient or grouped by data module - such as individual vital sign, patient notes or patient symptoms only or attached pictures / images, or call out specific data modules and dates / time periods). This offers flexibility to clinicians to further process patient data, if needed.

The data displayed on the mobile app, web portal or web app can be labelled, flagged and triaged for the purposes of monitoring disease or deterioration, improvement and to support clinical decision making and to encourage self-management of disease by the patients. The platform may also provide data analytics, risk scores and static algorithms that may assist in the assessment of risk prediction, diagnosis, disease monitoring and prognostication.

8. PERFORMANCE TESTING

Huma RPM was designed and developed according to a robust software development process and was rigorously verified and validated. As Huma RPM utilizes a modular approach in order to allow a number of different configurations on a single platform, each configuration is tailored to a specific disease area and patient cohort. The test approach consisted of the following:

Unit and Integration Testing

Unit and Integration Testing were completed against the separate components of the product, split into the following:

- Backend
- Android App
- iOS App
- Clinician Portal

Acceptance Testing

The acceptance test was completed by entering test cases, organizing test suites, executing test runs, and tracking their results, all through a robust web interface. It followed a centralized test management concept that helped in easy communication and enabled cross-checking of tasks across the Quality Acceptance Testers. Acceptance tests for all agreed requirements were executed on the Quality Acceptance environment.

Demo Smoke Testing

Smoke Testing is a type of testing that comprises a non-exhaustive set of tests that aim at ensuring that the most important functions work. Smoke tests were executed on Demo environment to see that the features are working as expected.

Demo Sanity Testing

Sanity test of the release specific features (based on the features supported on Demo deployment builds) was performed on Demo environments to ensure the readiness of the release build.

Anomalies
No anomalies were discovered during the verification/validation testing.
Furthermore, Huma RPM was tested for performance in accordance with following internal product requirements:

- Risk Control Measure Verification
- Interoperability Verification
- ISO 27001: 2013 Certification
- Network Testing
- Vulnerability Scan
- Code Analysis

Huma RPM complies with the following standards/guidance, as appropriate, through testing and/or analysis:

- FDA guidance: Off-the-shelf software use in medical devices, 27 Sep 19.
- FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.
- Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, 06 Sep 17.
- IEC 62304 A1: 2015, Medical device software – Software life cycle processes.
- ISO 14971: 2019, Medical devices – Application of risk management to medical devices.
- ISO /IEC 27001: 2013, Information technology – Security techniques – Information security management systems – Requirements.
- FDA Guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Draft Guidance for Industry and Food and Drug Administration Staff, 8 Apr 22.

- FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05.
- IEC 82304-1:2016, Health software - Part 1: General requirements for product safety.
- IEC 62366-1: 2015, Medical Devices – Part 1, Application of usability engineering to medical devices.
- ISO 60601-1-8: 2006: Part 1-8 General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems.

Biological Safety and Materials Testing

The subject product, Huma RPM, is a SaMD. Therefore, no biocompatibility and Materials Testing are required.

Packaging, Sterilization and Shelf-life

There is no primary or secondary packaging or other special packaging associated with the device. Huma platform does not contain any form of composition, dimension or sterilization requirements. The platform is a software as a medical device (SaMD). Furthermore, there is no defined shelf-life for this SaMD.

The results of the performance testing conclude the Huma RPM is substantially equivalent to the aforementioned predicate and reference devices.

9. CONCLUSIONS

The information presented in this 510(k) submission demonstrates that the Medopad Inc's Huma RPM is substantially equivalent to the predicate device.