October 26, 2026

MD Diagnostics, Ltd.
Daniel Quirke
Director
Slip 7 Annexe The Historic Dockyard
Chatham, Kent ME4 4TZ
United Kingdom

Re: K260671
Trade/Device Name: RP Check (RP01)
Regulation Number: 21 CFR 868.2600
Regulation Name: Airway Pressure Monitor
Regulatory Class: Class II
Product Code: CAP
Dated: September 25, 2026
Received: September 25, 2026

Dear Daniel Quirke:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

ETHAN L. NYBERG -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.

510(k) Number *(if known)*
K260671

Device Name
RP Check (RP01)

Indications for Use *(Describe)*
The RP Check is intended to measure both inspiratory (MIP) and expiratory (MEP) mouth pressures and Sniff nasal pressures (SNIP) generated by a patient after being trained in the technique by a qualified healthcare professional. The RP Check is suitable for both adult and paediatric patients from 6 years and older, there is no upper age limit providing the patient can comply and perform the test as instructed. Interpretation of the values obtained should only be performed by an appropriate healthcare professional.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

Submitter's Identification:	
Applicant:	MD Diagnostics Ltd
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Registered Establishment Number:	3009896423
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Contact:	Daniel Quirke Director
Email:	daniel@mdd.org.uk
Date of Summary	16-Oct-2026

Device Information:

Below summarises the Device Classification information regarding the RP Check.

Device Proprietary Name	RP Check
Common Name:	Respiratory Pressure Monitor
Trade Name:	RP Check
Model	RP01
Product Code(s):	CAP

Identified Product Code

Device Information:	
Regulation Description	Airway pressure monitor.
Code of Federal Regulation:	21 CFR 868.2600
Identification	An airway pressure monitor is a device used to measure the pressure in a patient's upper airway. The device may include a pressure gauge and an alarm
Regulation Medical Specialty	Anesthesiology
Review Panel	Anesthesiology
Product Code:	CAP
Product Class:	II (performance standard)

Type of Submission:	510(k)

Identified Predicate

Substantial Equivalence:			
Manufacturer	Trade Name	Regulation & Product Code	510(k) Number
Micro Direct Inc	MicroMPM	21 CFR 868.2600	K940375

Submission Description

This Traditional 510(k) presents a new medical device for the measurement of respiratory pressure. Well-established methods have been used to evaluate the change and the data to be reviewed is provided in a summary in this submission.

Device Description

The RP Check is a handheld, portable, battery-operated device used for rapid assessment of respiratory muscle strength. The unit can measure mouth pressures - maximum inspiratory (MIP); maximum expiratory (MEP) pressures and sniff nasal inspiratory pressure (SNIP). The unit measures the pressures generated in cmH2O, and these are displayed on the backlit display. The unit is controlled by a microprocessor and pressure measurements are measured using a piezo pressure transducer.

The RP Check provides the following measurements:

- Mouth pressures:
  - Maximum expiratory pressure (MEP) – the highest average expiratory pressure achieved over one second
  - Maximum inspiratory pressure (MIP) – the highest average inspiratory pressure achieved over one second
  - Peak pressure (Ppeak) – the maximum pressure achieved during the test
  - Maximum Rate of Pressure Development (MRPD) – the highest rate of change of pressure on the upward stroke (before the one second average is achieved) of either a MIP or MEP test
  - Maximum Relaxation Rate (MRR) – the maximum rate of change of pressure on the downward stroke (after the one second average) of either a MIP or MEP test, divided by the one second sustainable pressure value (the MIP or MEP value respectively)
- Nasal pressure:
  - Sniff nasal inspiratory pressure (SNIP) – the peak pressure obtained from a maximum sniff nasal manoeuvre

Intended/Indications for Use

The RP Check is intended to measure both inspiratory (MIP) and expiratory (MEP) mouth pressures and Sniff nasal pressures (SNIP) generated by a patient after being trained in the technique by a qualified healthcare professional. The RP Check is suitable for both adult and paediatric patients from 6 years and older, there is no upper age limit providing the patient can comply and perform the test as instructed. Interpretation of the values obtained should only be performed by an appropriate healthcare professional.

Substantial Equivalence

The candidate device is substantially equivalent to the predicate, K940375, the MicroMPM and a comparison of the key characteristics is summarised in Table 1.

Characteristic	Subject Device	Predicate Device MicroMPM K940375	Equivalence Comparison
Intended Use	The RP Check is intended to measure both inspiratory (MIP) and expiratory (MEP) mouth pressures and Sniff nasal pressures (SNIP) generated by a patient after being trained in the technique by a qualified healthcare professional. The RP Check is suitable for both adult and paediatric patients from 6 years and older, there is no upper age limit providing the patient can comply and perform the test as instructed. Interpretation of the values obtained should only be performed by an appropriate healthcare professional.	The MicroRPM (Respiratory Pressure Meter) is a handheld diagnostic instrument designed for rapid assessment of inspiratory and expiratory muscle strength. The unit can measure the maximum inspiratory and expiratory mouth pressures, MIP and MEP, and the Sniff Nasal Inspiratory Pressure, SNIP. The system is intended for use with adults and pediatric patients over the age of 3 years in hospitals, physician offices, laboratories and occupational health testing environments.	Equivalent
Rx vs OTC	Rx	Rx	Equivalent / Same
Contraindications	Mouth or nasal pressure testing should be avoided in patients with: Aneurisms Uncontrolled hypertension Urinary incontinence	Pathological conditions resulting in relatively large pressure swings in the abdomen or thorax. Aneurisms Uncontrolled hypertension Urinary incontinence	Equivalent
Patient Population	Patients over 6 who require a respiratory mouth and/or nasal pressure measurement	Patients over 3 who require a respiratory mouth and/or nasal pressure measurement	Equivalent – the subject device is for use in over 6 years old; whereas the predicate is 3 and over.
Use Environment	Healthcare environment	Healthcare environment	Equivalent / Same
Measurement Method	Pressure sensor	Pressure sensor	Equivalent / Same
Measurements	Maximum Expiratory Pressure (MEP) Maximum Inspiratory Pressure (MIP) Sniff Nasal Inspiratory Pressure (SNIP)	Maximum Expiratory Pressure (MEP) Maximum Inspiratory Pressure (MIP) Sniff Nasal Inspiratory Pressure (SNIP)	Equivalent / Same
Additional derived measurements	Maximum Rate of Pressure Development (MRPD) Maximum Rate of Relaxation (MRR) Ppeak (maximum pressure	Maximum Rate of Pressure Development (MRPD) Maximum Rate of Relaxation (MRR)	Substantially Equivalent – both devices can show derived measures, however the RP Check performs this on screen

Characteristic	Subject Device	Predicate Device MicroMPM K940375	Equivalence Comparison
			not on connected software
Operating Pressure	± 300 cmH2O	± 300 cmH2O	Equivalent / Same
Burst Pressure	± 2000 cmH2O	± 700 cmH2O	Substantially equivalent – the subject device has a higher burst pressure for safety.
Resolution	1 cmH2O	1 cmH2O	Equivalent / Same
Accuracy	+/-5%	+/-3%	Substantially equivalent – the small difference in accuracy specification (±5% vs ±3%) is not clinically significant and does not introduce new or increased risks (see rationale).
Operating Temperature	10-30°C	32 – 104°F (*0-40°C)*	Substantially Equivalent
Operating Pressure	Atmospheric 10%	Unknown	Substantially Equivalent
Operating humidity	30% to 90% RH	30% to 90% RH	Equivalent / Same
Storage & Transport Temperature	-20 to + 70°C	-4 – 158°F (-20 to +70°C)*	Equivalent / Same
Storage & Transport Humidity	10% to 90% RH	10% to 90% RH	Equivalent / Same
Patient sample system	Single patient use inspiratory, expiratory and nasal system with filter	Single patient use inspiratory, expiratory and nasal system with filter	Equivalent / Same
Display	128 X 128 Pixels Graphic LCD	Alphanumeric display	Substantially Equivalent
Power Supply	Single 9v PP3 battery	Single 9v PP3 battery	Equivalent / Same
Weight (approximate)	160g including battery	~6ounces (170g)	Equivalent / Same
Dimensions	135mm x 65mm x 30mm	~6.5” x 2.5” x 1” (165 x 6.4 x 2.5cm)*	Equivalent / Same

Table 1: Comparison of Characteristics between the RP Check and the predicate

Technological Characteristics

The subject device and the predicate device both measure respiratory pressure and have substantially equivalent indications for use, operating principles, performance, and technical specification. The measurement types, range, resolution and accuracy are identical, and the respiratory pressure measurement test method are performed by the patient in the same way.

Summary of Non-Clinical Tests (Performance data)

The performance of the RP Check is identical to the predicate device in terms of technical specification and safety. There are no significant differences.

Verification and validation activities established the safety and performance of the RP Check based on the following tests, which were all passed:

Electrical Safety: The RP Check was tested to confirm that it met the applicable standards for electrical safety (IEC 60601-1).

Electromagnetic compatibility: The RP Check was tested to confirm it meets the applicable standards for electromagnetic compatibility (EMC) (IEC 60601-1-2).

Device verification: The device verification and validation testing was performed to verify the firmware of the RP Check and measurement accuracy.

Software & Risk Management: The subject device used the same FDA Guidance and International Standards for software development process (IEC 62304) software documentation (Content of Premarket Submissions for Device Software Functions), Risk Management process (IEC 14971), cybersecurity (Content of Premarket Submissions for Management of Cybersecurity in Medical Devices).

Biocompatibility: Analysis of the RP Check has demonstrated compliance to ISO 10993-1: Biological evaluation of medical devices – Guidance and ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process, including Parts -2, -3 & -4.

Device Ship/Transport Testing: Ensure device, enclosed in the selected shipping packaging, meets specifications.

Summary of Animal & Clinical Studies

Substantial equivalence is based on an assessment of non-clinical performance data, and no animal or clinical performance data is included.

Conclusion

Based on the information presented above and supported by the performance data, along with the risk assessment and information provided in the device labelling, the RP Check device is substantially equivalent to the predicate device (MicroMPM) in in terms of safety, performance, functionality and indications for use and is as safe and effective for its intended use.