



June 23, 2026

Microlife Corporation
% Vaibhav Rajal
Official Correspondent for Microlife Corporation
Mdi Consultants Inc.
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K253180

Trade/Device Name: Microlife Digital Peak Flow Meter, Model PF200B (PF200B)

Regulation Number: 21 CFR 868.1860

Regulation Name: Peak-Flow Meter For Spirometry

Regulatory Class: Class II

Product Code: BZH,

Dated: May 15, 2026

Received: May 15, 2026

Dear Vaibhav Rajal:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

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For

Rachana Visaria
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

Indications for Use

510(k) Number (if known)
K253180

Device Name
Microlife Digital Peak Flow Meter, Model PF200B

Indications for Use (Describe)

The Microlife Digital Peak Flow Meter (Model PF200B) is intended for monitoring Peak Expiratory Flow (PEF) and Forced Expiratory Volume in one second (FEV1) for patient home use. The device is designed for pediatric (≥ 5 years of age) to adult patients.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

The assigned 510(k) number is: K253180 .

1. Submitter's Identification:

Microlife Corporation
9F, 431, RuiGuang Road, NeiHu,
Taipei 11492, Taiwan, China

Date Summary Prepared: June 22, 2026

Contact: Mr. Jimmy Deng
Global Regulatory Affairs & Quality Management Director
Microlife Corporation
Tel: 886-2-87971288 # 376
Email: Jimmy.Deng@microlife.com.tw

2. Name of the Device:

Microlife Digital Peak Flow Meter, Model PF200B

Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-flow meter for
spirometry.
Regulatory Class: II
Product Code: BZH

3. Information for the 510(k) Cleared Device (Predicate Device):

K040723: Microlife Electronic Peak Flow Meter with PEF and FEV1, Models PF-100 and PF-100-1 (with software), K040723, Microlife Intellectual Property GmbH

4. Device Description:

Microlife digital peak flow meter PF200B is a medical device that utilizes the principles of flow turbine with optical interruption detection and digital signal processing to compute and provide a measurement of peak expiratory flow and other pulmonary functional parameters.

This device is intended for monitoring PEF (Peak Expired Flow Rate) and FEV1 (Forced Expiratory Volume in one second) for patient home use. The device is designed for pediatric (≥ 5 years of age) to adult patients.

5. Indications for Use:

This Microlife Digital Peak Flow Meter (Model PF200B) is intended for monitoring Peak Expiratory Flow (PEF) and Forced Expiratory Volume in one second (FEV1) for patient home use. The device is designed for pediatric (≥ 5 years of age) to adult patients.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

Item	Subject Device: Microlife Digital Peak Flow Meter PF200B Microlife Corporation	Predicate Device: Microlife Peak Flow Meter PF100 and PF100-1 (with software) (K040723) Microlife Intellectual Property GmbH	Substantial Equivalence
Measuring principle	Respiratory flow is determined using a combination of flow turbine, optical interruption detection, and digital signal processing.	Respiratory flow is determined using a combination of flow turbine, optical interruption detection, and digital signal processing.	Substantially equivalent
Measurement Algorithm	Turbine rotation frequency computation with empirical method algorithm	Turbine rotation frequency computation with empirical method algorithm	Substantially equivalent
Measurement Site	Mouth	Mouth	Substantially Equivalent
Parameters measured	Peak expiratory flow (PEF) Forced expiratory volume 1-second (FEV1)	Peak expiratory flow (PEF) Forced expiratory volume 1-second (FEV1)	Substantially Equivalent

Indications for Use	The PF200B is intended for monitoring Peak Expiratory Flow (PEF) and Forced Expiratory Volume in one second (FEV1) for patient home use. The device is designed for pediatric (≥ 5 years of age) to adult patients.	The PF100 is intended for monitoring PEF (Peak Expiratory Flow Rate) and FEV1 (Forced Expiratory Volume in one second) for patient home use. The device is designed for pediatric to adult patients.	Different The device is designed for pediatric (≥ 5 years of age) to adult patients.
Maximum record flow rate	900 L/min	Not Publicly Available	Different The maximum flow rate recorded of the subject device conforms to the latest relevant standards recognized by US FDA and internationally (ATS/ERS 2019 update and ISO 23747) and does not present additional risks.
Flow rate measurement accuracy	± 10 L/min or $\pm 10\%$ of the reading, whichever is greater	Not Publicly Available	Different The flow rate measurement accuracy of the subject device conforms to the latest relevant standards recognized by US FDA and internationally (ATS/ERS 2019 update and ISO 23747) and does not present additional risks.
Flow measurement linearity	≤ 10 L/min or $\pm 5\%$ of the reading, whichever is greater.	Not Publicly Available	Different The flow measurement linearity of the subject device conforms to the latest relevant standards recognized by US FDA and internationally (ATS/ERS 2019 update and ISO 23747) and does not present additional risks.

Flow measurement resistance to flow	≤0.36 kPa/l/s	Not Publicly Available	Different The flow measurement resistance to flow of the subject device conforms to the latest relevant standards recognized by US FDA and internationally (ATS/ERS 2019 update and ISO 23747) and does not present additional risks.
Flow measurement frequency response	≤0.25 l/s, or 12 %, whichever is greater	Not Publicly Available	Different The flow measurement frequency response of the subject device conforms to the latest relevant standards recognized by US FDA and internationally (ATS/ERS 2019 update and ISO 23747) and does not present additional risks.
Maximum recorded volume	9.99 liters	Not Publicly Available	Different The maximum recorded volume of the subject device conforms to the latest relevant standards recognized by US FDA and internationally (ATS/ERS 2019 update and ISO 26782) and does not present additional risks.
Volume measurement accuracy	±0.05L or ±2.5% of the reading, whichever is greater.	±0.1 liter or ±5% of the reading, whichever is greater	Different The volume measurement accuracy of the subject device conforms to the latest relevant standards recognized by US FDA and internationally (ATS/ERS 2019 update and ISO 26782) and does not present additional risks.
Volume measurement repeatability	≤0.05L or 2.5% of the reading, whichever is	Not Publicly Available	Different The volume

	greater.		measurement repeatability of the subject device conforms to the latest relevant standards recognized by US FDA and internationally (ATS/ERS 2019 update and ISO 26782) and does not present additional risks.
Volume measurement linearity	<2.5%	Not Publicly Available	Different The volume measurement linearity of the subject device conforms to the latest relevant standards recognized by US FDA and internationally (ATS/ERS 2019 update and ISO 26782) and does not present additional risks.
Volume measurement impedance	≤0.15 kPa/(l/s)	Not Publicly Available	Different The volume measurement impedance of the subject device conforms to the latest relevant standards recognized by US FDA and internationally (ATS/ERS 2019 update and ISO 26782) and does not present additional risks.
Visual output	Liquid crystal display (LCD)	Not Publicly Available	Different This difference does not affect safety or effectiveness because the display serves only to present measured values to the user and does not alter the method of measurement, calculation algorithms, or performance of the device
Biocompatibility Contact Type	Surface/oral mucosa contact device	Surface/oral mucosa contact	Substantially Equivalent

		device	
Biocompatibility Contact Duration	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Substantially Equivalent
Device service life	10,000 measurements	Not Publicly Available	Different The specified service life reflects device durability and longevity rather than measurement methodology. Performance testing demonstrates that the subject device maintains accuracy over its intended service life; therefore, this difference does not affect safety or effectiveness.
Wired data connection interface	USB 2.0 interface with USB-C connector for data transfer to computer-based software as "USB datalink function"	USB 2.0 interface with micro-USB connector for data transfer to computer-based software as "USB datalink function"	Different Both the predicate device and subject device have wired data connection to realize a "USB datalink" function, enabling transfer of measurement record data from device memory to computer-based software via USB 2.0 interface for the purpose of data storage and display on the software. The difference between the predicate device and subject device are the different components implemented in the design to realize the USB function (e.g., USB connector).
Wireless data connection interface	Bluetooth 5.0 interface for data transfer to mobile device-based software as "Bluetooth datalink function"	None	Different The main difference between the predicate device and subject device is the addition of Bluetooth datalink function, for transfer of measurement record data from device memory to a mobile

			device- (e.g., smartphone) based software application (i.e., mobile app) for the purpose of data storage and display.
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Based on information from the comparison chart:

The predicate device PF100-1 and subject device PF200B are equivalent in most specifications and characteristics; the differences between the devices have been justified.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating the safety and effectiveness of the Microlife Digital Peak Flow Meter, Model PF200B in the intended environment of use is supported by testing performed in accordance with the principles outlined in The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] as well as applicable FDA-recognized consensus standards.

The following testing was conducted to prove safety and effectiveness as well as substantial equivalence to the predicate device:

The following Guidance documents and National/International Standards were utilized for testing the subject device:

Electrical Safety, Electromagnetic Compatibility:

- 1) ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
- 2) IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- 3) IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- 4) IEC TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-

2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

- 5) Electromagnetic Compatibility (EMC) of Medical Devices Guidance Document (June 6, 2022)

Performance testing:

- 6) ISO 23747 Second edition 2015-08 Anesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
- 7) ISO 26782 First edition 2009-07 Anesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans
- 8) ATS/ERS Task Force: Standardization of lung function testing - Standardization of spirometry 2019

Usability

- 9) IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- 10) IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices
- 11) ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices

Biocompatibility: The subject Microlife Digital Peak Flow Meter (Model PF200B) is a surface-contacting medical device with limited-duration patient contact (≤ 24 hours).

- 12) ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 13) ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- 14) ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- 15) ISO 10993-12 Fifth edition 2021-01 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- 16) ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

- 17) Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

Cleaning

- 18) ISO 17664-1:2021 Processing of Health Care products- Information to be provided by the medical device manufacturer for the processing of medical devices
- 19) Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance Document (March 2015)

Software/Cybersecurity

- 20) The Documentation Level for the Microlife Digital Peak Flow Meter, Model PF200B is classified as Basic Documentation, in accordance with the FDA guidance document "Content of Premarket Submissions for Device Software Functions" (June 2023).
- 21) The cybersecurity documentation for the Microlife Digital Peak Flow Meter, Model PF200B was prepared in accordance with the FDA guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (September 2023).

None of the testing demonstrated any design characteristics that violated the requirements of the reviewer guidance and standards or resulted in any safety hazards. It was our conclusion that Microlife Digital Peak Flow Meter, Model PF200B tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The subject device has substantially equivalent intended use and characteristics as the predicate device. Moreover, non-clinical testing provided in the submission demonstrates that there are no differences in their technological characteristics that raise new questions of safety or effectiveness. Thus, the subject device is substantially equivalent to the predicate devices