Medibyt , Ltd.
% Shawnnah Monterrey
Final Reviewer
Beanstock Consulting
8885 Rio San Diego Dr. #237
San Diego, California 92108

Re: K260242
Trade/Device Name: CPETWise Platform
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: BTY, BZC
Dated: January 26, 2026
Received: January 26, 2026

Dear Shawnnah Monterrey:

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

Sincerely,

Binoy J. Mathews -S

Digitally signed by Binoy J. Mathews -S
Date: 2026.08.20 09:58:36 -04'00'

For

James J. Lee, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260242

Device Name
CPETWise Platform

Indications for Use *(Describe)*
The CPETWise Platform is a software device that is intended to be used for already measured cardiopulmonary data for the analysis of cardiopulmonary testing (CPET) parameters and lung function (PFT) parameters, aiding in the diagnosis of related conditions.

The test results can be viewed online using a computer screen and printed after the test. The test results can be saved for further referral or report generation purposes.

The device can be utilized for patients aged 18 and older as long as they can cooperate in the CPET performance. The CPETWise platform is intended to be used in healthcare environments such as a hospital, a physician's office, or similar settings.

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

Medibyt Ltd. CPETWise Platform: K260242

Submitter

Medibyt Ltd.

Greenwork

Yakum 6097200, Israel

Phone: +972-544531477

Contact Person: Or Inbar

Date Prepared: August 20, 2026

Name of Device: CPETWise Platform

Common or Usual Name: CPETWise

Classification	Class II
Classification Name	1. Calculator, Predicted Values, Pulmonary Function. 2. Pulmonary function data calculator,
Regulations	21 CFR 868.1890 21 CFR 868.1880
Product Code	BTY, BZC

Predicate Device

K242809
Trade/Device Name: Ascent Cardiorespiratory Diagnostic Software
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: BTY, BZC

Reference Device

K153654
Trade/Device Name: Sentry Web SmartInterp
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, BZC

Intended Use / Indications for Use

The CPETWise Platform is a software device that is intended to be used for already measured cardiopulmonary data for the analysis of cardiopulmonary testing (CPET) parameters and lung function (PFT) parameters, aiding in the diagnosis of related conditions.

The test results can be viewed online using a computer screen and printed after the test. The test results can be saved for further referral or report generation purposes.

The device can be utilized for patients aged 18 and older as long as they can cooperate in the CPET performance. The CPETWise platform is intended to be used in healthcare environments such as a hospital, a physician's office, or similar settings.

Device Description

CPETWise, a clinical decision support system, assists physicians and physiologists in interpreting cardiopulmonary exercise testing (CPET) results. The platform guides users through three key stages: data input, interpretation screen, and report generation. Users can view results via summary tables, graphical displays (including CPET results summary tables, Wasserman 9-panel and Inbar 12-panel graphical views), and a ventilatory anaerobic threshold identification screen. The platform allows the user to edit the final reports. The application is online, allowing users to save their work on the platform and return to it for additional observation.

Principle of Operation / Mechanism of Action

The CPETWise platform is a medical software which aims to be used as an aid in the evaluation and interpretation of already measured cardiopulmonary data. The CPETWise assists physicians and physiologists in the interpretation of the Cardiopulmonary Exercise Test (CPET) results.

CPETWise is a web-based platform that supports post-measurement CPET tasks, such as analyzing, severity-grading, and interpreting CPET and PFT measured data.

The platform guides users through a structured workflow designed to support accurate data interpretation and clinical decision-making.

The CPETWise Platform is intended to import previously acquired CPET data from compatible CPET metabolic cart systems using supported import formats. System-level validation was performed using data generated from FDA-cleared CPET systems representative of the intended use environment. The validated compatibility applies only to the supported data formats and interfaces identified in the device labeling.

Conditions of Use

The CPETWise platform is designed as a standalone system. The CPETWise platform utilizes standard CPET data and can integrate with CPET metabolic carts via API. Data exchange with CPET metabolic cart systems is limited to the import of previously acquired CPET data, and validated compatibility applies only to the supported data formats and interfaces identified in the device labeling. CPETWise automatically generates a report for users, which can be reviewed and updated by the physician.

CPETWise can be used in various environments as a "post-measurement" solution, such as a hospital setting, a physician's office, or similar settings. It can be used under the Medibyt cloud-based platform service or under a customer-owned server.

CPETWise main acquired parameters

Parameters acquired	**Test origin**
VCO_2, VO_2, VE/BF/Vt (2 out 3), $PETO_2$ & $PETCO_2$ (End Tidal - optional)	CPET
Personal data: ID, test date, name, gender, age, height, weight	CPET
Ergometer	CPET
Additional CPET-related information, such as ECG findings, underlying conditions, reason for the test, symptoms observed during the test, test protocol, smoking status, race, family history of illness, activity level, and lab results.	Manually added
HR	From ECG (part of the common CPET export data)
FEV1, FVC, MVV (optional - Can be calculated from FEV1), $FEF_{25\%-75\%}$, F/V loops findings	From Spirometry (Pre and Post) – Optional. From the CPET export data or manually added.
FV loops findings (Flow Limitation and Volume limitation in %)	From Spirometry (during Test Effort) – Optional. From the CPET export data or manually added.

Technological Comparison with predicate

	Subject Device: **CPETWise Platform**	**Predicate Name:** **Ascent Cardiorespiratory Diagnostic Software** **K242809**	**Reference Device:** **Sentry WEB SmartInterp** **K153654**	**Comparison**
510(k) Number	K260242	K242809	K153654	N/A
Manufacturer	Medibyt	Medical Graphics Corporation	CareFusion (Vyaire)	N/A
Classification	Class II	Class II	Class II	Identical
Classification Name	1. Calculator, Predicted Values, Pulmonary Function; BTY 2. Pulmonary function data calculator, BZC	1. Calculator, Predicted Values, Pulmonary Function; BTY 2. Pulmonary function data calculator, BZC	Pulmonary function data calculator, BZC	Identical to K242809
Regulations	21 CFR 868.1890 21 CFR 868.1880	21 CFR 868.1890 21 CFR 868.1880	21 CFR 868.1880 21 CFR 870.1425	Identical to K242809
Product Code	BTY, BZC	BTY, BZC	BZC, DQK	Identical to K242809
Prescription for Use	Yes	Yes	Yes	Identical

Intended Use / Indications for Use	The CPETWise Platform is a software device that is intended to be used for already measured cardiopulmonary data for the analysis of cardiopulmonary testing (CPET) parameters and lung function (PFT) parameters, aiding in the diagnosis of related conditions. The test results can be viewed online using a computer screen and printed after the test. The test results can be saved for further referral or report generation purposes. The device can be utilized for patients aged 18 and older as long as they can cooperate in the CPET performance. The CPETWise platform is intended to be used in healthcare environments such as a hospital, a physician's office, or similar settings.	Ascent Cardiorespiratory Diagnostic Software is intended to be used for measurements, data collection and analysis of lung function (PFT) parameters, and cardiopulmonary testing (CPET) parameters, aiding in the diagnosis of related conditions. All the measurements are performed via a mouthpiece or a mask. The results of the test can be viewed on-line with the help of a computer screen and can be printed after the test. The test results can be saved for further referral or report generation purposes. For use of the Bronchial Challenge option, the medical director of the laboratory, physician, or person appropriately trained to treat acute bronchoconstriction, including appropriate use of resuscitation equipment, must be close enough to respond quickly to an emergency. The product can be utilized for patients from 4 years old and older as long as they can cooperate in the performance -- no special limit to patient's sex or height. Measurements will be performed under the direction of a physician in a hospital environment, a physician's office, or similar settings	Sentry WEB SmartInterp is a medical software which is intended to be used as an aid in the evaluation and diagnosis of already measured cardiopulmonary data. Access to data will be realized via network or internet with assigned access rights. Patient population is not assigned as it is defined by the measuring devices itself.	Intended Use: Equivalent

	Subject Device: CPETWise Platform	Predicate Name: Ascent Cardiorespiratory Diagnostic Software K242809	Reference Device: Sentry WEB SmartInterp K153654	Comparison
Patient Population	18 years and older	4 years and older	Patient population is not assigned as it is defined by the measuring device.	Similar: The subject device is limited to adults (18years and older), whereas the predicate includes patients ≥4 years. This represents a narrower intended patient population and does not alter the intended use or raise new questions of safety or effectiveness.
Principles of Operation	Stand-alone software device which performs analysis of already measured PFT and CPET data	Stand-alone software application which interacts with several HW devices in the MGC product line	Stand-alone software device which performs analysis of already measured PFT and CPET data	Similar: compared to reference, Both devices are stand-alone software applications that analyze previously acquired CPET/PFT data to assist with interpretation and report generation. Any differences in workflow do not alter the fundamental operating principle.
Validated Interoperability / Compatible Systems	Imports previously acquired CPET/PFT data from compatible FDA-cleared CPET systems using supported import formats. Compatibility is based on validated data formats, required parameters, metadata, and supported interfaces identified in the labeling, rather than a specific manufacturer or software	Interfaces with MGC CPET/PFT measurement systems and associated hardware within the MGC product ecosystem to acquire, analyze, and manage CPET/PFT data.	Imports previously acquired CPET/PFT data from SentrySuite version 2.11 and higher, operating within the CareFusion/Vyaire software ecosystem.	Similar: The subject device defines compatibility based on validated data formats and supported interfaces rather than specific manufacturers. Because CPETWise performs post-measurement analysis of imported data, this interoperability approach

	platform.			does not alter the intended use or raise new questions of safety or effectiveness.
Associated Hardware	• Desktop or Notebook Computer • Server	• Desktop or Notebook Computer • Trolley or Desk • Measurement Devices: - CPFS/D USB Spirometer - Platinum Elite Series Body Plethysmograph - Ultima Series - Other optional items	• Workstation/server/ notebook/Tablet	Similar: Both devices interface with external CPET/PFT measurement systems. The subject device receives previously acquired data from compatible FDA-cleared measurement devices rather than directly acquiring physiologic signals, which does not affect safety or effectiveness.

Spirometry	• Spirometry • Flow/ Volume • MVV	• Spirometry (Slow and Forced) • Incentive Spirometry • Flow/ Volume • MVV	• Spirometry • Flow/Volume • MVV	Identical to K153654 The subject device utilizes spirometry parameters (e.g., FEV_1, FVC, MVV, flow-volume data) that are imported from CPET export data generated by an FDA-cleared device or manually entered by the user. CPETWise does not perform spirometry measurements or independently calculate these parameters; rather, it incorporates the previously acquired values into its post-measurement analytical workflow to support clinical interpretation. This technological difference does not alter the

				intended use or raise new questions of safety or effectiveness.
Breath-by-Breath	Breath-by-Breath	Breath-by-Breath	Breath-by-Breath	Identical
Exercise Flow Volume Loops	Flow and Volume limitation results	Exercise Flow Volume Loops	Flow / Volume	Similar: Both devices evaluate volume and flow information to support interpretation of CPET results. Differences in display or presentation do not alter the underlying analytical function or intended use.
Cardiac Output	• Calculated value, derived from VO2 and HR • Rest, exercise and recovery ECG findings	Calculated value, derived from VO2 and blood gases	Stress & Resting ECG	Similar: Both devices provide derived cardiopulmonary parameters to support clinical interpretation. Differences in the specific inputs used to derive cardiac output do not alter the intended analytical purpose or raise new questions of safety or effectiveness.

Software device only	Yes	Yes	Yes	Identical

Software Network Options	• Web Interface • Database Handling • Cloud environment • Network Printing (to confirm)	• Use as Workstation • Data integration • Database handling • Networked database • Offline mode • Network printing	Workstation/server	Similar: Both devices support networked operation, database management, and report generation. Differences in deployment architecture (e.g., cloud-based versus workstation/server configurations) do not alter the intended use or analytical performance.
Software Characteristics	• Display recorded signals from measuring devices • Logging already measured values • Aid in identifying and classifying measured data • Provide analysis of captured data • Evaluate measured physiological data	• Control measuring device • Display recorded signals online	• Display recorded signals from measuring devices • Logging already measured values • Aid in identifying and classifying measured data • Provide analysis of captured data • Evaluate measured physiological data	Similar: like the reference the subject device log previously acquired physiological data, analyze CPET/PFT parameters, and assist clinicians in interpreting test results. Differences in software implementation or workflow do not alter the intended analytical functions.

	Subject Device: CPETWise Platform	Predicate Name: Ascent Cardiorespiratory Diagnostic Software K242809	Reference Device: Sentry WEB SmartInterp K153654	Comparison
Displayed Information	Commonly used CPET-related parameters: • Analysis of already captured data • Evaluation of measured physiological data: ▪ Wasserman: 9-graphs panel ▪ Inbar: 12- graphs panel ▪ Summary Tables	Commonly used CPET related parameters: • Wasserman: 9-graphs panel • Summary Tables	• Displays recorded signals • Analysis of already captured data • Evaluation of measured physiological data	Similar: All displayed data are acquired from the measuring devices (for CPET and PFT parameters). Differences in graphical presentation (e.g., Inbar 12-panel) represent additional display functionality and do not affect the intended analytical function.
Software Output	• Tables • Graphs • Support to physician interpretation	• Tables • Graphs	• Tables • Graphs	Similar: Both devices generate graphical and tabular outputs that support physician interpretation of previously acquired CPET/PFT data. Minor differences in output presentation do not affect clinical interpretation or device performance
Report	• Editable Summary report • Supported parameters • PDF / EMR ready	• Editable report	• Report	Similar: Both devices generate editable reports summarizing CPET/PFT analysis. Differences in report formatting or export capabilities do not alter the intended use or raise new questions of safety or effectiveness.

Non-Clinical Performance

- ISO 14971 Applications of Risk Management to Medical Devices
- IEC 62304:2006+AMD1:2015 Medical Device Software – Software Life Cycle Processes
- FDA Guidance – Content of Premarket Submissions for Device Software Functions
- FDA Guidance - Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions

Verification and validation testing activities have been executed by Medibyt to establish the performance and functionality of the CPETWise platform. Software verification & validation testing involved unit and component tests, system-level tests, performance tests, and safety testing based on hazard analysis.

The system-level validation testing compared the CPETWise platform generated outputs with calculated reference results based on real-world data of the CPET FDA-cleared device, covering the full expected range of input values in alignment with the indication for use and including calculation accuracy, graphical outputs, and reproducibility as detailed in the system-level validation report.

System-level validation was performed using previously acquired CPET data generated from FDA-cleared CPET metabolic cart systems representative of the intended use environment, imported via the supported data formats and interfaces identified in the device labeling.

The validation dataset spans parameter ranges that map directly onto established CPET/PFT clinically meaningful interpretation thresholds under the intended use conditions, covering key parameters such as peak VO_2, VE/VCO_2 slope, VAT, O_2 pulse, peak heart rate, and spirometry values.

Testing results demonstrate that the CPETWise platform fulfills its intended use/indications for use and is substantially equivalent to the predicate device.

Conclusion:

The subject device “CPETWIse Platform” and the predicate “Ascent” device have the same intended use and similar indication for use. Although there are minor differences in the indication for use, these minor differences do not raise different questions of safety or effectiveness. Furthermore, the CPETWise device is similar to the predicate and to the reference device in technological characteristics and principles of operation. As discussed above, minor differences in the device design and output do not raise any new questions of safety or effectiveness. The subject device went through SW verification and validation as well as bench testing to demonstrate that it has comparable safety and performance results. Accordingly, we can conclude that the CPETWise Platform is substantially equivalent to the predicate.