July 15, 2022

Morgan Scientific, Inc.
Deborah Cornish
Quality & RA Manager
151 Essex Street STE 8
Haverhill, Massachusetts 01832

Re: K213872
Trade/Device Name: ComPAS2
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: June 13, 2022
Received: June 14, 2022

Dear Deborah Cornish:

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,

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia 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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213872

Device Name
ComPAS2

Indications for Use *(Describe)*

Morgan Scientific's ComPAS2 is a software application intended to be used to connect to compatible Morgan Scientific or third-party devices to acquire, analyze, view, store, export, and print the device outputs including measurements of flow, volume, pressure, and gas concentrations. The product is designed for use on adults and pediatrics 4 years and older, in a variety of healthcare environments such as, but not limited to, primary care, hospitals, occupational health, and research health centers under the supervision of a healthcare provider.

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

X 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.

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510(k) Summary

Date Prepared: July 15, 2022

I. Submitter:

Submitter's Name:	Morgan Scientific, Inc.
Submitter's Address:	151 Essex Street STE 8 Haverhill, MA 01832 USA
Submitter's Phone:	(978) 521-4440
Official Correspondent:	**Deborah Cornish** Quality & RA Manager, CQT Morgan Scientific, Inc. 151 Essex Street STE 8 Haverhill, MA 01832 Phone: 800.525.5002 | 978.521.4440, xt203 Email: deborah@morgansci.com

II. Subject Device:

Trade/proprietary name:	ComPAS2
Common or Usual Name:	ComPAS2
Regulation name:	Diagnostic spirometer
Classification:	21 CFR 868.1840 (product Code: BZG)
Classification name:	Diagnostic Devices
Regulatory Class:	II

III. Predicate Device:

ComPAS2 K190568

IV. Device Description:

ComPAS2 is a software application designed to provide a secure PC based medical device for creating, adding/recalling subjects, and performing cardio-pulmonary function testing on those subjects. ComPAS2 will interface and link to compatible Morgan Scientific and third-party devices to read, analyze, and display their output to allow the information to be retained with the subject. Current compatible approved devices: TransAir (K953990), SpiroAir (K042595), Body Plethysmograph (K022636), WristOx2 (K102350), tremoFlo (K170185), Pneumotrac (K142812), Micro (K160253), Model 9100 PFT/DlCO (K221030). Data can be reported directly to a printer or communicated with hospital information systems/electronic medical records. All data are preserved in an SQL database, with key sub-systems of ComPAS2 interacting with the database through an API (Application Program Interface).

ComPAS2 is designed to operate with compatible cardio-pulmonary function testing hardware by manufacturers offering the capability to measure key pulmonary functions including, but not limited to: static

and dynamic spirometry, bronchial challenge, maximum voluntary ventilation, respiratory muscle strength, cough peak flow, lung volume sub-divisions (such as but not limited to helium dilution, nitrogen washout and plethysmography), single breath diffusion, airway resistance, distribution with lung clearance index closing volume. Other features include: a task manager to manage patient data for reporting; manual entry to input additional information; and historical data review to analyze data for trending and reporting.

The overall functionality of ComPAS2 software remains the same as the predicate and provides the end user with the same experience.

V. Indications for Use:

Morgan Scientific's ComPAS2 is a software application intended to be used to connect to compatible Morgan Scientific or third-party devices to acquire, analyze, view, store, export, and print the device outputs including measurements of flow, volume, pressure, and gas concentrations. The product is designed for use on adults and pediatrics 4 years and older, in a variety of healthcare environments such as, but not limited to, primary care, hospitals, occupational health, and research health centers under the supervision of a healthcare provider.

VI. Modifications:

ComPAS2 v2022.1.0 is a modification to the software predicate ComPAS2 v2019.1.0, cleared under K190568. Use of interfacing with latest Windows technology, etc., this software application was updated to accommodate the connection to compatible Morgan Scientific and third-party devices (including, but not limited to: VitaloROV/VitaloLab and VitaloQUB) to acquire, analyze, view, store, export, and print the device output.

Software: Use of interfacing with the latest Windows technology, SQL, HL7

VII. Comparison of Technological Characteristics and Performance with the Predicate:

Technical Characteristics

The characteristics of the ComPAS2 v2022.1.0 software are substantially equivalent to those of the predicate device ComPAS2 v2019.1.0 listed in the comparison table. The similarities are as follows:

- Identical functionality
- Conforms to ATS guidelines

The differences between the predicate ComPAS2 v2019.1.0 and subject ComPAS2 v2022.1.0 software application are as follows: The addition of generalized device communications applicable to compatible Morgan Scientific and third-party devices.

ComPAS2 (K190568) and ComPAS2 Substantial Comparison:

	Predicate ComPAS2 2019.1.0 software	Subject ComPAS2 2022.1.0 software	Comparison
510(k) Number	K190568	K213872	-
Product Code	BZG	BZG	Same

Classification	Spirometer Diagnostic	Spirometer Diagnostic	Same
Indications for use	The ComPAS software is intended to operate with the Screenstar pneumotachograph spirometer, Morgan Transflow test pulmonary function testing system and the Morgan transfer test benchmark pulmonary function testing system. ComPAS uses flow and volume from each of the devices to display the flow and volume information measured directly from patient effort. ComPAS also utilizes gas analyzer readings from the Transflow test and transfer test benchmark to display helium dilution lung volume data and single breath diffusion data measured directly from patient effort. This information is formatted for use in pulmonary function testing and reports.	Morgan Scientific's ComPAS2 is a software application intended to be used to connect to compatible Morgan Scientific or third-party devices to acquire, analyze, view, store, export, and print the device outputs including measurements of flow, volume, pressure, and gas concentrations. The product is designed for use on adults and pediatrics 4 years and older, in a variety of healthcare environments such as, but not limited to, primary care, hospitals, occupational health, and research health centers under the supervision of a healthcare provider.	The indications for use have been updated from the predicate to allow for the additional capability of linking ComPAS2 to compatible Morgan Scientific or third-party devices. Otherwise, the indications for use are the same.
Fundamental Scientific Technology	Digital Data Communication	Digital Data Communications	Same
Spirometry and Bronchial Challenge acquire, analyze, view, store and print measures and waveforms of pulmonary function	Yes, from compatible device	Yes, from compatible device	Same
Diffusion acquire, analyze, view, store and	Yes, from compatible device	Yes, from compatible device	Same

print measures of spirometry and gas waveforms of pulmonary function			
Lung Volumes and Gas Distribution – acquire, analyze, view, store and print measures of spirometry and gas waveforms of pulmonary function	Yes, from compatible device	Yes, from compatible device	Same
Respiratory Pressures – acquire, analyze, view, store and print measures of spirometry and pressure waveforms of pulmonary function	Yes, from compatible device	Yes, from compatible device	Same
Plethysmography – acquire, analyze, view, store and print measures of spirometry, flow pressure waveforms of pulmonary function	Yes, from compatible device	Yes, from compatible device	Same
Oscillometry download, view	Yes, from compatible device	Yes, from compatible device	Same
Oximetry download, view	Yes, from compatible device	Yes, from compatible device	Same
Microsoft Windows Operating systems supported	Yes, Windows 10	Yes, Windows 10	Windows 8.1 was removed from this submission as it will no longer be supported by Windows after 2023
Database	MS SQL Server	MS SQL Server	Same
Where used	Hospitals, Health centers, Primary care practices, and clinics	Hospitals, Health centers, Primary care practices, and clinics	Same
Networked operations	Yes	Yes	Same
Subject Management: Demographic Entry,	Yes	Yes	Same

Maintenance, Deletion			
Report printing	Yes	Yes	Same
PFT testing	Yes	Yes	Same
Trending graphs for spirometry results	Yes	Yes	Same
PFT predicted value equations	Yes	Yes	Same
Population group management	Yes	Yes	Same
Data import/export	Yes	Yes	Same
Subject and spirometry data export	Yes	Yes	Same
Manual data entry of results	Yes	Yes	Same
Database management	Yes	Yes	Same
Color display	Yes	Yes	Same
Population groups	Adult, Pediatric	Adult, Pediatric	Same
Communication	Bluetooth, USB	Bluetooth, USB	Same
Storage	Dependent on storage media	Dependent on storage media	Same
Biocompatibility	No patient contact	No patient contact	Same
Full pulmonary testing	Yes	Yes	Same
Manual entry for blood gases	Yes	Yes	Same
Reporting	Yes	Yes	Same
Data integration to EMRs via HL7 interfacing or API	Yes	Yes	Same
Flow measurement	Pneumotachograph	Pneumotachograph	Same
Volume measurement	Integrated flow and Rolling seal spirometer	Integrated flow and Rolling seal spirometer	

Flow Range	-18 L/s to + 18 L/s	-18 L/s to + 18 L/s	Same
Volume Accuracy	+/- 1%	+/- 1%	Same
Flow Accuracy	+/- 2.5%	+/- 2.5%	Same
Sampling Rate	100 _ 300 samples per second	100 _ 300 samples per second	Same
Number of Tests per Session	8 _ Pre bronchodilator 8 _ Post Bronchodilator Multiple Challenge Levels	8 _ Pre bronchodilator 8 _ Post Bronchodilator Multiple Challenge Levels	Same
Flow Calibration	3L calibration syringe	3L calibration syringe	Same
Units	Metric or Traditional	Metric or Traditional	Same
ATS/ERS Review of Acceptability	Yes	Yes	Same
ATS/ERS Review of Repeatability	Yes	Yes	Same
Standards Compliance	ATS, ERS, SSD & OSHA	ATS, ERS, SSD & OSHA	Same
Predicted Values	Standard Sets include: GLI, NHANES III, Knudson, Rosenthal and others. Predicted formulas editable through script.	Standard Sets include: GLI, NHANES III, Knudson, Rosenthal and others. Predicted formulas editable through script	Same
Report Formats	Multiple with Report Editing available	Multiple with Report Editing available	Same
Quality Control	Data stored for reporting and tracking purposes	Data stored for reporting and tracking purposes	Same
Hardware Communication	USB; device specific communication	USB; device general communication	Updated communications code base to work with compatible Morgan Scientific and third-party devices.
Database	Microsoft SQL	Microsoft SQL	Same

Test capability	Static and dynamic spirometry, bronchial challenge, maximum voluntary ventilation, respiratory muscle strength, cough peak flow, lung volume sub-divisions (by helium dilution, nitrogen washout and plethysmography), single breath diffusion, airway resistance, distribution with lung clearance index closing volume, airwave oscillometry. Other features include a task manager in order to manage patient data for reporting, manual entry in order to input additional information and historical data in order to analyze data for trending and reporting.	Static and dynamic spirometry, bronchial challenge, maximum voluntary ventilation, respiratory muscle strength, cough peak flow, lung volume sub-divisions (by helium dilution, nitrogen washout and plethysmography), single breath diffusion, airway resistance, distribution with lung clearance index closing volume, airwave oscillometry. Other features include a task manager in order to manage patient data for reporting, manual entry in order to input additional information and historical data in order to analyze data for trending and reporting.	Same
Patient Height Recording	Standing height, arm span, demi arm span, forearm and knee	Standing height, arm span, demi arm span, forearm and knee	Same
Data backup	Automated through user-configurable scheduler	Automated through user-configurable scheduler	Same
Test History/ Data Trending	Available during testing and reporting	Available during testing and reporting	Same
System Security	Through configurable login rules	Through configurable login rules	Same
Language Capability	Supports Localization	Supports Localization	Same
HTML Help	Yes	Yes	Same

VIII. PERFORMANCE DATA

Non-Clinical Testing

Performance testing demonstrated that the subject device met its acceptance criteria. Testing included:

Software

Verification and Validation

Bench

Measurement activities conducted for ComPAS2 are in accordance with the set of current standard issued by the American Thoracic Society and European Respiratory Society's Standardization for Lung Function Testing (e.g., Laszlo, 2006; Macintyre et.al., 2005; Miller, Crapo, Hankinson, et.al., 2005; Pellegrino, et.al., 2005; Wanger et.al., 2005). In addition, the newly issued standards on methacholine challenge testing (ERS/ATS, 2017) and standards for single-breath carbon monoxide uptake in the lung (ERS/ATS, 2017), standardization of spirometry (ERS/ATS 2019) were also applied.

ComPAS2 software testing activities consisted of developing test cases and test runs for the performance of end-to-end testing with both biological and mechanical controls. Results of these tests were then validated against existing results from ComPAS2 v2019.1.0, the aforenamed predicate device. Requirements and the design specification were reviewed for consistency and accuracy. Final validation was accomplished through system level testing to ensure that the product is capable of meeting the intended use.

IX. **DIFFERENCES AND CONCLUSIONS**:

Discussion of Differences:

The identified differences do not raise new or different concerns of safety or effectiveness relative to the predicate.

Substantial Equivalence Conclusion:

The differences do not present different concerns of safety or effectiveness than the predicate device, the ComPAS2 2022.1.0 was found to be substantially equivalent to the predicate device ComPAS2 2019.1.0.