June 6, 2019

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

Re: K190568
Trade/Device Name: ComPAS2
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: May 6, 2019
Received: May 7, 2019

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,

for Michael Ryan
Director
DHT1C: Division of ENT, 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: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190568

Device Name
ComPAS2

Indications for Use *(Describe)*
The ComPAS2 software is intended to operate with the Screenstar pneumotachograph spirometer, Morgan Transflow test PFT system and the Morgan transfer test benchmark PFT system. ComPAS2 uses flow and volume from each of the devices to display the flow and volume information measured directly from patient effort. ComPAS2 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.

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.

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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."

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR 807.92

Date 510(k) summary prepared: May 06, 2019

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. 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

Substantial Equivalence is claimed with:

ComPAS - K021200 (Class 2 - Computerized Pulmonary Analysis System-product code BZG)

IV. DEVICE DESCRIPTION

ComPAS2 is designed to interface with various pieces of hardware (previously cleared pulmonary function testing devices, K142812, K042595, K022636, K953990, K013752) to capture clinical data in the performance of clinical testing. Those 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 pulmonary function testing hardware by manufacturers offering the capability to measure key pulmonary functions including: static and dynamic spirometry, bronchial challenge, maximum voluntary ventilation (MVV), 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. 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.

The user performs daily quality checks/calibrations prior to performing any tests. Once the test subject enters the Pulmonary Function Testing lab, foundation biographical information (Unique ID, Name, DOB) are either entered by the user, recalled or received in and order via Health Level 7(HL7) message from the information system. The functionality of ComPAS2 software remains the same as the predicate and provides the end user with the same experience.

Encounter information is added at the time of testing such as height, weight, diagnosis and physician. Test capability depends upon the Pulmonary Function Testing device being employed. Completed test information can be printed and handed to the physician for interpretation or data can be routed to the EMR (Electronic Medical Record).

ComPAS2 software connects using USB-powered desktop pulmonary function testing devices for the purpose of creating, adding and recalling subjects and performing pulmonary function testing on those subjects to aid in the measuring of the effect of lung disease on pulmonary function.

V. INDICATIONS FOR USE

The ComPAS2 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. ComPAS2 uses flow and volume from each of the devices to display the flow and volume information measured directly from patient effort. ComPAS2 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.

VI. TECHNICAL AND SUBSTANTIALLY EQUIVALENT CHARACTERISTICS COMPARISON WITH PREDICATE DEVICE

Technical Characteristics

The characteristics of the ComPAS2 Software are similar and substantially equivalent to those of the predicate device ComPAS listed in the comparison table. The similarities are as follows:

- **Identical functionality**
- **Conforms to ATS guidelines**

The differences between the predicate ComPAS and subject ComPAS2 software application are as follows:

- **Windows 8.1 or 10 (64 bit)**
- **Language capability supports localization**
- **.NET, C#, WPF**

The primary difference between the modified device and the predicate device is the conversion of ComPAS software from Visual Basic version 6 into .Net, C#, and WPF. The functionality and intended use of the product remain the same. The difference is not visible to the end user as a result of the coding update.

No new risks have been identified since the previously cleared predicate (ComPAS K021200). The risks have been evaluated for ComPAS2 software. No new risks have been identified for ComPAS2. The functionality of ComPAS2 is identical to its predicate ComPAS. The indications for use are the same. The diagnostic software device is to be used with previously cleared predicate hardware devices: , K142812, K042595, K022636, K953990, K013752. The software application functionality and indications for use remain unchanged.

ComPAS (K021200) and ComPAS2 (K190568) Substantial Comparison:

	Predicate ComPAS software	ComPAS2 software	Difference
Model Name	ComPAS (K021200)	ComPAS2 (K190568)	-
510(k) Number	K021200	K190568	-
Classification	Class II Device 21 CFR 868.1840	Class II Device 21 CFR 868.1840	-
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.	The ComPAS2 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. ComPAS2 uses flow and volume from each of the devices to display the flow and volume information measured directly from patient effort. ComPAS2 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.	-
Description	ComPAS is designed to operate with pulmonary function testing hardware by manufacturers offering the capability to measure key pulmonary functions including: static and dynamic spirometry, 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. 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.	ComPAS2 is designed to operate with pulmonary function testing hardware by manufacturers offering the capability to measure key pulmonary functions including: static and dynamic spirometry, 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. 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.	-
Standards and References	ATS/ERS 2005 {ATS/ERS Task Force: Standardization of Lung Function Testing} EN ISO 14971 EN 60601-1 EN 60601-1-2 IEC 62366 IEC 62304 21 CFR 820 13485:2016 SOR 98-282 IEC/TR 80002-1	ATS/ERS 2005 {ATS/ERS Task Force: Standardization of Lung Function Testing} EN ISO 14971 EN 60601-1 EN 60601-1-2 IEC 62366 IEC 62304 21 CFR 820 13485:2016 SOR 98-282 IEC/TR 80002-1	-

Software Function Substantial Comparison:

Function	ComPAS (K021200)	ComPAS2 (K190568)	Difference
Flow measurement	Pneumotachograph	Pneumotachograph	-
Flow Range	-18 L/s to + 18 L/s	-18 L/s to + 18 L/s	-
Volume Accuracy	+/- 1%	+/- 1%	-
Flow Accuracy	+/- 2.5%	+/- 2.5%	-
Sampling Rate	100 – 300 samples per second	100 – 300 samples per second	-
Number of Tests per Session	8 – Pre bronchodilator 8 – Post Bronchodilator Multiple Challenge Levels	8 – Pre bronchodilator 8 – Post Bronchodilator Multiple Challenge Levels	-
Flow Calibration	3L calibration syringe	3L calibration syringe	-
Units	Metric or Traditional	Metric or Traditional	-
ATS/ERS Review of Acceptability	Yes	Yes	-
ATS/ERS Review of Repeatability	Yes	Yes	-
Standards Compliance	ATS, ERS, SSD & OSHA	ATS, ERS, SSD & OSHA	-
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	-
Report Formats	Multiple with Report Editing available	Multiple with Report Editing available	-
Quality Control	Data stored for reporting and tracking purposes	Data stored for reporting and tracking purposes	-
Hardware Communication	USB	USB	-
Database	Microsoft SQL	Microsoft SQL	-
Operating System	**Windows 7 & 10**	**Windows 8.1 & 10 (64 bit)**	***Updated from Windows 7 & 10 to Windows 8.1 & 10 (64 bit)***
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. 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. 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.	-

Function	ComPAS (K021200)	ComPAS2 (K190568)	Difference
Patient Height Recording	Standing height, arm span, demi arm span, forearm and knee	Standing height, arm span, demi arm span, forearm and knee	-
Data backup	Automated through user-configurable scheduler	Automated through user-configurable scheduler	-
Test History/ Data Trending	Available during testing and reporting	Available during testing and reporting	-
System Security	Through configurable login rules	Through configurable login rules	-
Language Capability	**English Only**	**Supports Localization**	***Updated to include localization***
HTML Help	Yes	Yes	-

VII. TESTING AND VALIDATION

Measurement activities conducted for ComPAS2 are in accordance with the set of current standards 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) 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 ComPAS, 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. As an example of the testing and validation activities described above, results from ComPAS2 testing of the American Thoracic Society's 26 waveform loops for flow/volume validation (Hankinson & Crapo, 1995) are provided with this submission.

VIII. CONCLUSION:

ComPAS2 was found to be substantially equivalent to the predicate device ComPAS.

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