October 17, 2024

Medical Graphics Corporation
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: 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
Dated: September 17, 2024
Received: September 17, 2024

Dear Prithul Bom:

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: 2024.10.17 16:18:59 -04'00'

For

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

510(k) Number *(if known)*
K242809

Device Name
Ascent Cardiorespiratory Diagnostic Software

Indications for Use *(Describe)*
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, 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.

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MGC Diagnostics Corporation
through its subsidiary Medical Graphics Corporation
350 Oak Grove Parkway
St. Paul, Minnesota USA, 55127 -8599

510(k) Summary

October 17, 2024

Submitted by:
MGC Diagnostics Corporation
Through its subsidiary Medical Graphics Corporation
350 Oak Grove Parkway
St. Paul, MN 55127-8599
USA
651-484-4874

Contact Person:
Amy Fowler
Regulatory Counsel for MGC Diagnostics
Pathmaker FDA Law, P.L.L.C.
1415 Lilac Drive N
Minneapolis, MN 55422
Phone: (612) 356-9653
Email: fowler@pathmakerlaw.com

Proprietary or Trade Name: Ascent™ Cardiorespiratory Diagnostic Software

Available Model Number: v2.1

Common Name: Cardiorespiratory Diagnostic Software

Classification Names:

Calculator, Predicted Values, Pulmonary Function, 21 CFR 868.1890, BTY
Pulmonary Function Data Calculator, 21 CFR 868.1880, BZC

Predicate Devices: K181912, Ascent™ Cardiorespiratory Diagnostic Software
K133925, Vyntus SentrySuite Product Line

Intended Use/Indications for Use:

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.

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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, physician's office or similar settings.

Device Description:

Ascent™ Cardiorespiratory Diagnostic Software ("Ascent") is a stand-alone software application which can be used with several hardware devices in the Medical Graphics Corporation product line.

The core purpose of the software for measurement, data collection and analysis of testing in patients who may be suffering from pulmonary illnesses like chronic obstructive pulmonary disease (COPD), asthma, exercise intolerance, heart failure and/or cardiorespiratory concerns where diagnosis and prognosis needs to be determined.

In conjunction with diagnostic hardware, Ascent is used to collect data pertaining to the patient's degree of obstruction, lung volumes, and diffusing capacity. It is also used to present the collected lung diagnostic information so that it can be checked for quality and interpreted by a qualified physician, often a pulmonologist or cardiologist.

All the measurements are performed via a mouthpiece or a face mask.

<u>Pulmonary Function Tests</u>

The following pulmonary function tests will be supported:

1) Forced Vital Capacity (FVC)
2) Slow Vital Capacity (SVC)
3) Maximum Voluntary Ventilation (MVV)
4) Plethysmography (Pleth)
5) Functional Residual Capacity (FRC)
a) FRC Nitrogen Washout vs FRC Helium Rebreathing
6) Diffusing Capacity (DLCO), Single breath Real Time Diffusion and single-breath gas chromatography
7) Maximum Inspiratory/Expiratory Pressure (MIP/MEP)
8) Six Minute Walk (6MWT) – software supports recording of results only, does not conduct test
9) Challenge Testing (Bronchial Provocation (BRP))

Cardiopulmonary Exercise Tests (CPET)

For CPET testing, the software will be testing the patient's metabolic response while exercising or resting by collecting breath by breath data. The gas samples are dried by Nafion tubes and analyzed for O2 and CO2 content. From the breathing volume and the differences between inspiratory and expiratory O2 and CO2 concentrations, the oxygen uptake and the CO2 production (VO2 and VCO2) are calculated by the software.

The following cardiopulmonary exercise tests will be supported by the Ascent software:

1) Breath by breath Cardiopulmonary Exercise Test (CPET
   a. Test can utilize Bike, Ergometer or other exercise device (i.e., Rowing Machine)
   b. Measuring high/low FiO2, end tidal, respiratory drive
2) Indirect Calorimetry
   a. Resting Test
   b. Face Tent Test
3) High/Low FiO2 (HAST)
4) Exercise Flow Volume Loops
5) Cardiac Output
6) Six Minute Walk (6MWT)
   a. The software supports a 6MWT by accepting test result data via Bluetooth functionality from a Nonin WristOx 3150 Pulse Oximeter.

Hardware interaction

An MGCD hardware device can be connected to the computer running Ascent™ Cardiorespiratory Diagnostic Software via a USB port. Communication with hardware can be managed by the application. The software can start or stop a patient test that is administered by the hardware device. The hardware device will output test results into the software where they can be managed and displayed to the user.

Ascent™ Cardiorespiratory Diagnostic Software will display a "device dashboard" on the home screen that will allow the user to view the status of any connected MGC device. The dashboard indicates the status of the selected device, the calibration status of the device, and the current device warm-up time. The Dashboard also allows the user to start/stop the vacuum pump if the device is so-equipped.

User Information

The software is intended to be used by trained professionals within the intended environments. And to present the collected lung diagnostic information to a qualified physician, (usually a pulmonologist or cardiologist), fordiagnostic interpretation. Users of the software are expected to receive training on how to work with the software prior to using the software for diagnostic purposes.

Intended Operational Environment

The software is intended to be used in hospitals, clinics and other pulmonary function and cardiorespiratory diagnostic environments. The software can also be used in any environment that has qualified physician oversight.

The software is intended to be installed as a desktop application on a Microsoft Windows based personal computer.

Supported Devices

The software is compatible with the following devices, which have been independently cleared:

Device	Manufacturer	Device Class	Product Code	FDA 510(k) Number
Platinum Elite™ Series body plethysmograph (RTD and GC)	Medical Graphics Corporation	2	CCM	K943259
CPFS/D USB™ spirometer	Medical Graphics Corporation	2	BTY	K861486
Ultima Series™ cardiorespiratory diagnostic systems	Medical Graphics Corporation	2	BZL	K061731
Pulse Oximeter	Nonin	2	DQA	K080255
Pulse Oximeter	Nonin	2	DQA	K040589
Pulse Oximeter	Nonin	2	DQA	K102350
NIBP	Suntech Medical	2	DXN	K122401
Treadmill	Full Vision	1	IOL	N/A[1]
Treadmill	Woodway	1	IOL	N/A[1]
Treadmill	Medisoft RAM Italia	1	IOL	N/A[1]
Treadmill	Lode	1	IOL	N/A[1]
Treadmill	H/P/Cosmos	1	IOL	N/A[1]
Treadmill	Ergoline	1	IOL	N/A[1]
Ergometer	Lode	2	ISD	K851097
Ergometer	Lode	2	DXN	K060820
Ergometer	Lode	2	MUD	K060820
Ergometer	Ergoline	2	ISD	510(k) Exempt
ECG	Philips Healthcare	2	DQK	K121638
ECG	Baxter Healthcare	2	DPS	K152944
Heart Rate	Medtronic (formally Zephyr)	2	MHX, DRX	K113045

[1] – Noted Class 1 devices are exempted from premarket notification requirements.

Summary of Intended Use/Indications for Use of Device Compared to Predicate Device:

The intended use/indications for use statement for the subject device combines the intended use statements of both predicates. The addition of cardiopulmonary (CPET) testing is supported by the second predicate device. The intended patient population and intended user is the same for the subject and predicate devices.

Summary of Technological Characteristics of Device Compared to Predicate Device:

TECHNOLOGICAL CHARACTERISTICS TABLE

	Subject Device Ascent Cardiorespiratory Diagnostic Software	**Predicate Device** Ascent Cardiorespiratory Diagnostic Software	**Predicate Device** Vyntus/ SentrySuite Product Line	**Comparison**
510(k) Number	K242809	K181912	K133925	-
Decision Date	TBD	April 12, 2019	August 22, 2014	-
Manufacturer	Medical Graphics Corporation	Medical Graphics Corporation	CareFusion Germany	-
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	All use Pulmonary function data calculator, BZC
Regulations	868.1880 868.1890	868.1890 868.1880	868.1880	Similar
Product Codes	BTY, BZC	BTY, BZC	BZC	Similar
Prescription Use?	Yes	Yes	Yes	Same
Intended Use Statement	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.	Ascent Cardiorespiratory Diagnostic Software is intended to be used for measurements, data collection and analysis of lung function (PFT) 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,	The Vyntus/SentrySuite product line is intended to be used for measurements, data collection and analysis of lung function (PFT) parameters and cardio-pulmonary (CPET) parameters, aiding in the diagnosis of related conditions. The results of the test can be viewed online with the help of a computer screen and can be printed after the test. The test results can be saved for future reference or report generation	

	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, physician's office or similar settings.	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, physician's office or similar settings.	purposes. The products can be utilized with patients age 4 years and older as long as they can cooperate in the performance – no special limit to patient's sex or height exists. Measurements will be performed under the direction of a physician in a hospital environment, physician's office or similar setting (professional healthcare facilities).	
Associated Hardware	• Desktop or Notebook Computer • Trolley or Desk • Measurement Devices - CPFS/D USB Spirometer - Platinum Elite Series Body Plethysmograph - Ultima Series - Other optional items	• Desktop or Notebook Computer • Trolley or Desk • Measurement Devices - CPFS/D USB Spirometer - Platinum Elite Series Body Plethysmograph	• Desktop or Notebook Computer • Cart • Measurement Devices - Vyntus CPX unit - Vyntus table top power module - Digital Volume Transducer - Ambient module - USB cable - Other optional items	Similar
Calibration Method	• Flow 3L Syringe • O2/CO2 – integrated gas calibration • Real Time DLCO – integrated gas calibration •Plethysmography – integrated Deadweight and 50cc Cal Pump •MIP/MEP – Integrated Deadweight or water manometer	• Flow 3L Syringe • O2/CO2 – integrated gas calibration • Real Time DLCO – integrated gas calibration •Plethysmography – integrated Deadweight and 50cc Cal Pump •MIP/MEP – Integrated Deadweight	N/A	Similar
Bronchial Test	• Bronchial Test ○ Bronchospasmolysis ○ Bronchoprovocation	• Bronchial Test ○ Bronchospasmolysis ○ Bronchoprovocation	N/A	Identical to K181912
Spirometry	• Spirometry (Slow and Forced)	• Spirometry (Slow and Forced)	• Spirometry (Slow and Forced)	Identical to K181912

	• Incentive Spirometry • Flow/ Volume • MVV	• Incentive Spirometry • Flow/ Volume • MVV	• MVV	
FRC Nitrogen Washout	• FRC Nitrogen Washout	• FRC Nitrogen Washout	N/A	Identical to K181912
Real Time Single Breath Diffusion	• Real Time Single Breath Diffusion	• Real Time Single Breath Diffusion	N/A	Identical to K181912
Diffusion Single Breath CO/He	• Diffusion Single Breath CO/He	• Diffusion Single Breath CO/He	N/A	Identical to K181912
Body Plethysmography	• Body Plethysmography	• Body Plethysmography	N/A	Identical to K181912
Respiratory Drive	• PI/PE Max (MIP/MEP)	• PI/PE Max (MIP/MEP)	N/A	Identical to K181912
Breath-by-Breath	Breath-by-Breath	N/A	Breath-by-Breath	Identical to K133925
Indirect Calorimetry	Indirect Calorimetry	N/A	Indirect Calorimetry	Identical to K133925
Six Minute Walk (6MWT)	Six Minute Walk (6MWT)	Six Minute Walk (6MWT)	N/A	Similar to K181912
High Altitude Simulation Test	High/Low FiO2 (HAST)	N/A	Breath-by-Breath	Similar to K133925
Exercise Flow Volume Loops	Exercise Flow Volume Loops	Spirometry	Breath-by-Breath	Similar to K133925 and K181912
Cardiac Output	Calculated value, derived from VO2 and blood gases	N/A	Calculated value, derived from VO2 and blood gases	Similar to K133925
Software				
Software device only	Yes	Yes	No, this device has software and hardware	Identical to K181912
Software Network Options	• Use as Workstation • Data integration • Database handling • Networked database • Offline mode • Network printing	• Use as Workstation • Data integration • Database handling • Networked database • Offline mode • Network printing	• Use as Workstation • Use as Server • Online Connection • Vlink connection • GTD connection • Data integration • Database handling • JINET server	Identical to K181912

The subject device and the predicate devices are all software programs that are used with a variety of hardware systems to collect, display, manage and store patient data from pulmonary function tests and cardiorespiratory tests. Most of the test functionality is the same. There are just a few tests where there are minor differences between the subject device and one of the predicate devices:

1. Six Minute Walk Test (6MWT)
   The subject device performs an additional test which is not performed by the K133925 predicate but is similar to K181912. The 6MWT is typically performed to assess response to a medical or surgical intervention but may also be used to assess functional capacity of the subject and to help titrate oxygen as the patient walks. The object of the test is to have the subject walk as far as possible in 6 minutes. K181912 implements the 6MWT as simple lap counter allowing the medical professional to determine the total distance traveled. The subject device support input of pulse oximetry and heart rate data from an independent medical device into the test for real-time observation and subsequent reporting.

2. High Altitude Simulation Test (HAST)
   HAST is a method of assessing a patient's ability to be exposed to conditions with a reduced partial pressure of oxygen, such as air travel or a high-altitude environment. A medical professional varies the inspired O_2 concentration for subjects either at rest or during exercise. The mechanism which delivers this altered gas concentration to the patient is independent of the subject device. Measurement is accomplished via a breath-by-breath method, similar to K133925 in which both inspiratory and expiratory concentrations of oxygen (O_2) and CO_2 are measured.

3. Exercise Flow Volume Loops (ExFVL)
   ExFVL integrates a flow volume loop during an exercise gas exchange test. Both predicate devices support spirometry and K133925 supports breath-by-breath exercise testing. Subject device allows for a single maximal inhalation maneuver to be executed during the breath-by-breath exercise test. The resulting exercise flow volume loop can be overlayed over a flow volume loop collected during spirometry or the resting phase of the CPET test.

4. Breath by Breath
   Breath by breath is a comprehensive evaluation of the cardiovascular, pulmonary, and muscular systems during physical activity. The test typically involves exercising on a treadmill or stationary bike while breathing through a mouthpiece connected to a metabolic cart. Key measurements involve oxygen uptake (VO2), carbon dioxide production (VCO2), and ventilation. Subject device is similar to K133925 in the measurements of VO2, VCO2 ,and VE, however subject device includes additional derived values which are calculated values from literature.

5. Indirect calorimetry
   An indirect calorimetry test measures the amount of oxygen consumed and carbon dioxide produced by the body to estimate resting energy expenditure (REE). Subject device is equivalent in performance to predicate K133925.

6. Cardiac output
   Cardiac output is a calculated parameter using the VO2 measurement by the subject device and blood gases which are manually entered by the clinician. Subject device measures VO2 in a substantially equivalent manner as K133925. This is a calculated parameter and well-established calculation from literature via FICK method.

Determination of Substantial Equivalence Based on Nonclinical Tests

Ascent Cardiorespiratory Diagnostic Software was extensively validated per medical device software standards and guidance. Testing results support that Ascent fulfills its intended use/indications for use and substantially equivalent to the predicate device.

Non-clinical Performance:

Software validation testing involved system level tests, performance tests and safety testing based on hazard analysis. Performance validation testing was done with the subject software device and recommended hardware devices working together. Performance tests included FEV1, MVV, FRC, SVC, DLCO, VA, TGV, VO_2, VCO_2, and VE. Cybersecurity issues have been addressed. In addition to the verification and validation testing activities executed by Medical Graphics Corporation to establish the performance and functionality of Ascent Cardiorespiratory Diagnostic Software and the predicate device, some standards were utilized:

- 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 System Considerations and Content of Premarket Submissions

Ascent Cardiorespiratory Diagnostic Software was evaluated per American Thoracic Society (ATS), European Respiratory Society (ERS), and American College of Chest Physicians (ACCP) guidelines. The following statements/ standards were referenced for acceptability and repeatability guidelines and production of a standardized report:

- ATS/ ERS Standardisation of Spirometry (2019)
- ERS/ ATS Standardisation of the Measurements of Lung Volumes (2023)
- 2017 ERS/ ATS Standards for Single-Breath Carbon Monoxide Uptake in the Lung
- ERS Technical Standard on Bronchial Challenge Testing (2017)
- 2017 ATS Guidelines for a Standardized PF Report
- ATS/ ACCP Statement on Cardiopulmonary Exercise Testing (2003)

Comparison to Predicate Devices and Conclusion:
The subject device, Ascent, is identical in many ways to its predecessor, Ascent predicate. The addition of the CPET tests are supported by the Vyntus/SentrySuite predicate device and are consistent with the intended use of *measurements, data collections and analysis of lung function parameters*.

Ascent Cardiorespiratory Diagnostic Software is substantially equivalent to the predicate devices, Ascent Cardiorespiratory Diagnostic Software (K181912) and Vyntus/SentrySuite Product line (K133925). MGC Diagnostics comparisons to the predicate devices demonstrate the subject device has the same intended use and similar technological characteristics any differences do not raise new questions of safety or effectiveness.