July 15, 2022

Vitalograph Ireland Ltd.
% Paul Dryden
Consultant
ProMedic, LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K221030
Trade/Device Name: Model 9100 PFT/DlCO
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: BTY
Dated: June 15, 2022
Received: June 16, 2022

Dear Paul Dryden:

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: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221030

Device Name

Model 9100 PFT/DlCO

Indications for Use *(Describe)*

The Model 9100 PFT/DlCO is a pulmonary function testing device which uses Morgan Scientific's ComPAS2 software to measure subject respiratory parameters including FVC, SVC, MVV, CPF, RMS, SNIP, DLCO, MBN2 and SBN2.

The device is PC-based and designed for lung function testing on adults and pediatrics, 6 years and older, in a variety of professional healthcare environments e.g., primary care, hospitals, pharmaceutical research centers and physicians' offices.

The Model 9100 PFT/DlCO is intended for the assessment of respiratory function through the measurement of dynamic lung volumes i.e., spirometry and other lung functions i.e., diffusing capacity.

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

XX 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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Date Prepared: 15-Jul-22

I Submitter

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Regulatory Affairs / Quality Assurance Manager

Submission Correspondent: Paul Dryden ProMedic, LLC

II Device

Proprietary or Trade Name: Model 9100 PFT/DlCO
Common/Usual Name: Predictive Pulmonary Function Value Calculator
Classification CFR: 21 CFR 868.1890
Product Code: BTY

III Predicate Device: NDD - K161534 – EasyOne Pro Lab
Common/Usual Name: Predictive Pulmonary Function Value Calculator
Classification CFR: 21 CFR 868.1890
Product Code: BTY

Reference Device 1: Vyaire – K181524 – Vyntus ONE
Common/Usual Name: Pulmonary-Function Data Calculator
Classification CFR: 21 CFR 868.1880
Product Code: BZC

Reference Device 2: Morgan Scientific – K042595 – Medisoft SpiroAir
Common/Usual Name: Spirometer, Diagnostic
Classification CFR: 21 CFR 868.1840
Product Code: BZG

Reference Device 3: Collins Medical – K030917 – nSpire Eagle
Common/Usual Name: Spirometer, Diagnostic
Classification CFR: 21 CFR 868.1840
Product Code: BZG

IV Device Description:

The Model 9100 PFT/DlCO is composed of various sensors and valves with associated low level firmware. The firmware interfaces with the Morgan Scientific's ComPAS2 software (K213872) that resides on an on-board computer. The Model 9100 also provides for user input and present resulting data on an integral display.

The ComPAS2 software controls valves and reads unprocessed data from the sensors in the Model 9100then determines respiratory parameters including FVC, SVC, MVV, CPF, RMS (MIP and MEP), SNIP, DLCO, MBN2 and SBN2. The Model 9100 PFT/DlCO firmware does not determine any

respiratory parameters.

The ComPAS2 software uses flow and volume from the Vitalograph pneumotachograph spirometer to display the flow and volume information measured directly from patient effort. ComPAS2 also utilizes gas analyzer readings from the Model 9100 patient test and transfer test benchmark to display dilution lung volume data and single / multi breath diffusion data measured directly from patient effort. This information is then provided in a report format.

V Indications for Use:

The Model 9100 PFT/DlCO is a pulmonary function testing device which uses Morgan Scientific's ComPAS2 software to measure subject respiratory parameters including FVC, SVC, MVV, CPF, RMS, SNIP, DLCO, MBN2 and SBN2.

The device is PC-based and designed for lung function testing on adults and pediatrics, 6 years and older, in a variety of professional healthcare environments e.g., primary care, hospitals, pharmaceutical research centers and physicians' offices.

The Model 9100 PFT/DlCO is intended for the assessment of respiratory function through the measurement of dynamic lung volumes i.e., spirometry and other lung functions i.e., diffusing capacity.

VI Comparison of Technological Characteristics and Performance with the Predicate

Table 1 is a comparison – Subject Device vs. the Predicate, K161534 and References, K181524/K042595/K030917, including technological characteristics and performance.

Table 1: Comparison of the **Model 9100 PFT/DICO** vs. the Predicate and References

	Subject **Model 9100 PFT/DlCO** **(K221030)**	**Predicate** **NDD Easyone Pro Lab Respiratory Analysis System** **(K161534)**	**Reference devices** **nSpire Eagle (Collins Medical Inc)** **(K030917)** **Medisoft SpiroAir (Morgan Scientific)** **(K042595)** **Vyntus ONE (Vyaire)** **(K181524)**	**Comparison**
Product Code	**BTY**	**BTY**	**BZG, BZC / DPS**	Same
CFR	868.1890	868.1890	868.1840 868.1880	Same
Classification	Predictive pulmonary-function value calculator	Predictive pulmonary-function value calculator	Diagnostic Spirometer Pulmonary-Function Data Calculator	Same
Indications for Use	The Vitalograph Model 9100 PFT/DlCO is a pulmonary function testing device which uses Morgan Scientific's ComPAS2 software to measure subject respiratory parameters including FVC, SVC, MVV, CPF, RMS, SNIP, DLCO, MBN2 and SBN2. The device is PC-based and designed for lung function testing on adults and pediatrics, 6 years and older, in a variety of professional healthcare environments e.g., primary care, hospitals, pharmaceutical research centers and physicians' offices. The Model 9100 PFT/DlCO is intended for the assessment of respiratory function through the measurement of dynamic lung volumes i.e., spirometry and other lung functions i.e., diffusing capacity.	EasyOne Pro/LAB is designed for conducting lung function measurements in general or specialist practices or in hospitals. EasyOne Pro/LAB can also be used in clinical settings in occupational medicine for performing lung function screenings or measurements. EasyOne Pro/LAB is used to conduct lung function measurements on adults and children starting at age 4, except measurements of diffusing capacity of the lung based on CO (DLCO), which can be performed on adults and children starting at age 6.	K030917 The Collins EAGLE (Diffusion Spirometer) is a Pulmonary Function Test System. is intended as a configurable, non-invasive pulmonary function tester (PFT) testing system. These tests are suitable for both pediatric and adult patient testing. K042595 The SpiroAir PFT System is intended to operate with the ComPAS pulmonary function software. ComPAS uses flow and volume from the SpiroAir to display the flow and volume information measured directly from patient effort. ComPAS utilizes gas analyzer readings from the SpiroAir to display single breath diffusion data measured directly from patient effort. This information is formatted for use in pulmonary function testing and reports.	Similar K181524 includes the CPF / MIP/MEP and SNIP Vyntus includes many other indications which are not pertinent to the subject device.

			K181524 The Vyntus ONE / SentrySuite product line is intended to be used for measurements, data collection and analysis of lung function (PFT) 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 purposes. The products can be utilized with patients aged 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). A qualified physician has to reassess all Vyntus / SentrySuite measurements. An interpretation by Vyntus ONE / SentrySuite is only significant if it is considered in connection with other clinical findings. Additional for Vyntus ECG: The Vyntus ECG is intended for measuring the surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on the screen or printed on paper. 12-lead ECGs are analyzed automatically and suggestions for the interpretation of the resting ECG can be made by the software. ECG interpretation statements made by the Vyntus / SentrySuite represent partial qualitative and quantitative information on the patient's cardiovascular condition and no therapy or drugs can be administered based solely on the interpretation statements. The Vyntus ECG can	

			be used for non-interpretive applications in patients age 4 years and older and a weight of 20 kg or higher. The Vyntus ECG is intended to be used for routine ECG collection, recording both under resting and stress conditions. The measurement is performed by trained healthcare professionals under the direction of a physician in healthcare facilities (e.g. the doctor's office or hospital). The Vyntus ECG is not intended for intracranial use. The Vyntus ECG is not intended for use in an EMS environment (Emergency Medical Services Environment). The Vyntus ECG is not intended for use in home healthcare environments. Automatic interpretation of the ECG is not possible for pediatric and adolescent patients below 16 years of age and for patients with pacemakers	

	Subject **Model 9100 PFT/DlCO** **(K221030)**	**Predicate** **NDD Easyone Pro Lab Respiratory Analysis System** **(K161534)**	**Reference devices** **nSpire Eagle (Collins Medical Inc)** **(K030917)** **Medisoft SpiroAir (Morgan Scientific)** **(K042595)** **Vyntus ONE (Vyaire)** **(K181524)**	**Comparison**
Fundamental scientific technology	Measurement of patient air flow via Heated Lilly type pneumotachograph. The DLCO Gas Analyzer utilizes non-dispersive infrared (NDIR) technology to measure the concentrations of Carbon Monoxide (CO), Methane (CH4) and Carbon Dioxide (CO2) during the DLCO test. The N2 Washout Gas Analyzer uses laser diode absorption to measure the concentration of Oxygen (O_2) and uses an infrared sensor to measure the concentration of Carbon Dioxide (CO_2) during the Nitrogen (N2) Washout test.	Measurement of patient air flow via ultrasonic transit time flow sensor. DLCO test - determination of inhaled and exhaled gas concentrations: CO gas concentration measured by infrared absorption with CO sensor. Helium tracer gas concentration measured by molar mass sensor	'nSpire Eagle' (Collins Medical Inc) K030917 Uses a pneumotach for patient air flow including pressure sensors and multiple gas analyzers which are electrochemical and infrared. 'Medisoft SpiroAir' (Morgan Scientific) K042595 Software which calculates various PFT measurements which connected to a PFT device. 'Vyntus ONE' (Vyaire) K181524 Ultrasonic flow sensor for patient air flow and software to calculate various PFT measurements.	Similar The difference in gases used have been cleared in the reference devices.
Parameters measured	FVC SVC MVV DLCO CPF, RMS (MIP/MEP), SNIP Single and Multiple Breath Nitrogen washout (MBN2 and SBN2)	FVC FVL SVC MVV Pre-post Bronchodilator Single Breath CO Diffusion (DLCO) including Lung Volume Multiple Breathing Nitrogen washout (MWB)	'nSpire Eagle' (Collins Medical Inc) K030917 for SBN2 'Medisoft SpiroAir' (applicant was Morgan Scientific) K042595 for RMS K181524 includes the CPF / MIP/MEP and SNIP Also	Similar The references show hardware that does measure the specific parameters

			Slow Spirometry, Incentive Spirometry, Forced Spirometry, MVV, Diffusion SB Realtime, Diffusion SB Intrabreath, R Occlusion, Respiratory Drive P0.1, MIP / MEP, FRC, N2 washout	
	Subject **Model 9100 PFT/DlCO** **(K221030)**	**Predicate** **NDD Easyone Pro Lab Respiratory Analysis System** **(K161534)**	**Reference devices** **nSpire Eagle (Collins Medical Inc)** **(K030917)** **Medisoft SpiroAir (Morgan Scientific)** **(K042595)** **Vyntus ONE (Vyaire)** **(K181524)**	**Comparison**
Patient use	Multi-patient, multi-use	Multi-patient, multi-use	Multi-patient, multi-use	Similar
User Interface	Color LCD Touchscreen	Resistive touch screen for data entry and display	Various display types	Similar
Operating System	Microsoft Windows 10	Microsoft Windows 8 Embedded SQLite/Microsoft SQL server database	Not disclosed	Similar
Patient Interface	Disposable Bacteria / Viral Filter Disposable Mouthpieces	Disposable breathing tube Spirette Disposable barrier shield DLCO Barriette Disposable barrier shield FRC Barriette	Disposable mouthpiece Head gear Disposable Mask Disposable nose clip	Similar
Components	• Main Unit (embedded computer, touch screen and monitor) • Handheld flow sensor • Breathing valve assembly (for DLCO and FRC tests) • DLCO gas mix supply • 24V DC medical grade power supply from 80-240 VAC, 50/60 Hz power • 100% Oxygen gas supply	• Main Unit (embedded computer, touch screen and monitor) • Handheld Flow sensor • Internal Breathing valve assembly (for DLCO and FRC tests) • DLCO gas mix supply • 24V DC power supply • 100% Oxygen gas supply	• Components include • Main unit • Software • Flow sensor • Internal gas flow mechanism	Similar
Size	410 mm x 380 mm x 342 mm	270 mm x 335 mm x 270 mm	Not disclosed	Similar

	Subject **Model 9100 PFT/DlCO** **(K221030)**	**Predicate** **NDD Easyone Pro Lab Respiratory Analysis System** **(K161534)**	**Reference devices** **nSpire Eagle (Collins Medical Inc)** **(K030917)** **Medisoft SpiroAir (Morgan Scientific)** **(K042595)** **Vyntus ONE (Vyaire)** **(K181524)**	**Comparison**
Principle of Operation	All test types -measurement of patient air flow via heated Lilly type pneumotachograph flow sensor. DLCO test - determination of in– and exhaled gas concentrations: CO gas concentration measured by infrared absorption with CO sensor. Methane tracer gas concentration measured by molar mass sensor. MBW test - determination of in- and exhaled gas concentrations: Nitrogen tracer gas concentration determined by a combination of molar mass measurement (molar mass sensor) and CO_2 measurement (CO/CO_2 sensor).	All test types -measurement of patient air flow via ultrasonic transit time flow sensor. DLCO test - determination of in– and exhaled gas concentrations: CO gas concentration measured by infrared absorption with CO sensor. Helium tracer gas concentration measured by molar mass sensor. MBW test - determination of in- and exhaled gas concentrations: Nitrogen tracer gas concentration determined by a combination of molar mass measurement (molar mass sensor) and CO2 measurement (CO/CO_2 sensor).	All test types -measurement of patient air flow via a flow sensor. Gas analyzers for measurement of various gases. K042595 - Medisoft SpiroAir (Morgan Scientific) uses a Lilly Screen.	Similar
Test Gases for DLCO	Medical grade gas mix CO: 0.3 % CH4: 0.3 % Balance air	Medical grade gas mix CO: 0.3 % Helium: 10 % Oxygen: 18 % - 25 % Nitrogen: balance	K030917 CO CO2 CH4 K181524 Nitrogen	Similar The difference in gases used are used in cleared reference devices.
Test gas requirements for Nitrogen washout test	Oxygen: 100 % Nitrogen: balance	Oxygen: 100 % Nitrogen: balance	K181524 Oxygen: 100 % Nitrogen: balance	Same

	Subject **Model 9100 PFT/DlCO** **(K221030)**	**Predicate** **NDD Easyone Pro Lab Respiratory Analysis System** **(K161534)**	**Reference devices** **nSpire Eagle (Collins Medical Inc)** **(K030917)** **Medisoft SpiroAir (Morgan Scientific)** **(K042595)** **Vyntus ONE (Vyaire)** **(K181524)**	**Comparison**
Flow sensor Flow range Volume accuracy Flow accuracy Flow resistance	±14 L/s ±2.5 % or 0.050 L ±2 % over range of -14 to + 14 L/s <1.5 cm H_2O/L/s (at 14 L/s)	±16 L/s Greater of ±2 % or 0.050 L Greater of ±2 % or 0.020 L/s <1.5 cm H_2O/L/s (at 12 L/s)	K030917 Resistance is < 1.4 cmHzO/L/Sec @ 14 L/Sec. Volume accuracy is +/- 3%, and it is calibrated by using a known volume displacement device 3-liter syringe as a standard K042595 Software K181524 Ultrasonic Flow Sensor • Flow Accuracy (exhalation) 0 to 14 L/S: 1,5% or 0,05 L/S (whichever is greater) • Flow Accuracy (inhalation) 0 to 14 L/S: 2,5% or 0,05 L/S (whichever is greater) • Flow Range 0 to 18 L/S bidirectional • Flow Resolution 1ml/s • Volume Accuracy (exhalation) 0 to 14L: 1,5% or 0,05L (whichever is greater) • Volume Accuracy (inhalation) 0 to 14L: 2,5% or 0,05L (whichever is greater) • Volume Range +/- 30 L (software limited) • Volume Resolution 1ml Digital Volume Transducer • Flow: 0 – 15 L/s (3%) • Volume: 0 – 10 L (2%) • Resolution: 3ml • Resistance:	Similar The subject and predicate are similar in accuracy
CO / CO_2 Sensor Type Accuracy	Infrared absorption CO - ±1 % of full scale CH4 -±1% of full scale	Infrared absorption CO - ±0.001 % CO_2 - ±0.1 %	Infrared absorption	Similar Accuracy range conforms to the

				ATS / ERS guidelines for accuracy.
	Subject **Model 9100 PFT/DlCO** **(K221030)**	**Predicate** **NDD Easyone Pro Lab Respiratory Analysis System** **(K161534)**	**Reference devices** **nSpire Eagle (Collins Medical Inc)** **(K030917)** **Medisoft SpiroAir (Morgan Scientific)** **(K042595)** **Vyntus ONE (Vyaire)** **(K181524)**	**Comparison**
O_2 / CO_2 Sensor Type Accuracy	Laser diode absorption for O_2 Infrared for CO_2 O_2 - ±0.2% of Full Scale CO_2 - ±0.1% of Full Scale	Does not contain Oxygen / CO2 sensor from the IR bench mentioned above	Oxigraph Inc K971084 Laser diode absorption for O_2 Infrared for CO_2 O_2 - ±0.2% of Full Scale CO_2 - ±0.1% of Full Scale	Similar
Operating temperature range	15-32ºC	Not disclosed	K181524 10-34ºC	Labeling disclosure
Communications	USB Morgan Scientific ComPAS2	Not available	K042595 – Morgan ComPAS software	Similar
Power	24VDC output via medical grade power supply via input of 80-240 VAC 50-60 Hz	110-240 VAC	110-240 VAC	Similar
Biocompatibility	Externally communicating, Tissue and Surface Contact, Skin / Mucosa, Limited Duration	Externally communicating, Tissue and Surface Contact, Skin / Mucosa, Limited Duration	Externally communicating, Tissue and Surface Contact, Skin / Mucosa, Limited Duration	Similar

VII Difference and Substantial Equivalence Discussions

Intended Use/ Indications for Use
The indications for use are similar to the predicate. That is to conduct lung function measurements including DLCO, SBN2 and MBN2. This includes using both predicate and reference devices as presented in the above table.

Technological Characteristics and Principles of Operation
The measurement of flow is the Lilly Screen technology when using trace gases for DLCO and Nitrogen washout testing and is similar to the predicate and reference devices.

The basic difference between the subject device and the predicate is the technology of measuring and calculating flow which is ultrasonic (predicate) vs. a heated Lilly pneumotachograph for the subject device. The subject device technology uses the Lilly screen assembly which is heated to take change in temperature into account, an important influence on results. The reference Medisoft SpiroAir (Morgan Scientific) (K042595) also uses a Lilly Screen.

The subject device includes gas sensors for measuring CO. The accuracy of the sensors while different than the predicate, ± 1% of full scale vs. ± 0.001%, conform to the requirements of ATS / ERS guidelines. The difference in accuracy based upon the ATS / ERS guidelines does not raise a different concern of safety and efficacy.

The operating principle, measuring technology, range, application and use are similar to the predicate and the noted reference devices.

VIII Performance Testing

Bench

- ATS / ERS (2019) Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement
    - This testing compared the pre-set parameters and waveforms provided by ATS.
- ISO 23747:2007 - Anaesthetic and Respiratory Equipment - Peak Expiratory Flow Meters For The Assessment of Pulmonary Function in Spontaneously Breathing Humans
- ISO 26782:2009 - Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans
- Mechanical Drop Test
    - Demonstrated that the device continues to perform within pre-defined specifications after being dropped
- Cleaning – High-level disinfection
    - Demonstrated that the reusable components can be cleaned and disinfected.

Software

- Verification and Validation
    - Demonstrated that the software performed according to specifications

Electrical / EMC

- ANSI/AAMI ES60601-1:2005 (R2012) with amendments - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD) (Consolidated Text) (Includes ANSI/AAMI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012)
- IEC 60601-1-2:2010 - Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests

- AIM 7351731 - Medical Electrical Equipment & System Electromagnetic Immunity Test for RFID Readers

Biocompatibility

- ISO 18562-2: 2017 - Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 2: Tests for Emissions of Particulate Matter
- ISO 18562-3: 2017 - Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 3: Tests for Emissions of Volatile Organic Compounds (VOCs)
- ISO 18562-4: 2017 - Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 4: Tests for Leachables in Condensate
- ISO 10993-1:2003 - Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing

Transportation and Conditioning Test

- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D4332-14 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

All tested supported the safety and performance of the subject device and to be considered substantially equivalent to the predicate.

IX Substantial Equivalence Conclusion

The differences do not present different questions of safety or effectiveness than the predicate device. The Model 9100 PFT/DlCO is substantially equivalent to the predicate NDD EasyOne Pro Lab, K161534.