May 25, 2023

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

Re: K223818
Trade/Device Name: Model 9160 VitaloQUB
Regulation Number: 21 CFR 868.1760
Regulation Name: Volume Plethysmograph
Regulatory Class: Class II
Product Code: JEH, BTY
Dated: April 25, 2023
Received: April 25, 2023

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,

Ethan L. Nyberg -S

*for* James Lee Ph.D.
Division 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)*

**K223818**

Device Name

Model 9160 VitaloQUB

Indications for Use *(Describe)*

The Model 9160 VitaloQUB is a whole-body plethysmograph device, when used with the Vitalograph Model 9100, is designed for lung function testing on adults and pediatrics, 6 years and older, by trained medical healthcare professionals in a variety of professional healthcare environments e.g., primary care, hospitals, and pharmaceutical research centers.

The Model 9160 VitaloQUB 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, SBN2, Thoracic Gas Volume (TGV) and Airway Resistance ($R_{aw}$)

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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**510(k) Summary**


**Date Prepared:** 24-May-23

**I Submitter**

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**Submitter Contact:** Tony O'Hanlon
Regulatory Affairs / Quality Assurance Manager

**Submission Correspondent:** Paul Dryden ProMedic, LLC

**II Device**

**Proprietary or Trade Name:** Model 9160 VitaloQUB
**Common/Usual Name:** Plethysmograph, Volume
**Classification CFR:** 21 CFR 868.1760
**Product Code**: JEH

**III**

**Primary Predicate Device:** K022636 – Morgan Scientific – Medisoft Body Box 5500
**Common/Usual Name:** Plethysmograph, Volume
**Classification CFR:** 21 CFR 868.1760
**Product Code**: JEH

**Secondary Predicate Device:** K221030 – Vitalograph Model 9100 PFT/DICO
**Common/Usual Name:** Predictive Pulmonary Function Value Calculator
**Classification CFR:** 21 CFR 868.1890
**Product Code**: BTY

**Reference Device:** K213872 - Morgan ComPAS2
**Common/Usual Name:** Diagnostic Spirometer
**Classification CFR:** 21 CFR 868.1840
**Product Code**: BZG

**IV Device Description:**

The proposed Model 9160 VitaloQUB incorporates the cleared Model 9100 (K221030) with integrated LCD display and ComPAS2 software (K213872).

The ComPAS2 software controls valves and reads unprocessed data from the sensors in the Model 9100 and from Model 9160. The ComPAS2 software then determines respiratory parameters including the 2 new parameters.

The ComPAS2 software is unchanged from K213872. The Model 9160 and Model 9100 firmware does not determine any respiratory parameters.

The Model 9160 is adding 2 additional parameters:

- TVG – Thoracic Gas Volume

  - The volume of gas contained within the chest during body plethysmography when the mouth shutter is closed.
- $R_{aw}$ – Airway resistance
  - Airway resistance ($R_{aw}$) is calculated as the change in alveolar pressure ($P_{alv}$) divided by flow, which is derived by multiplying the slope of the closed shutter maneuver and the inverse slope of the open shutter maneuver, with the lung volume terms cancelling out.

The cleared Model 9100 PFT/DlCO (K221030) has been cleared to measure respiratory parameters including FVC, SVC, MVV, CPF, RMS (MIP and MEP), SNIP, DLCO, MBN2 and SBN2.

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 and Model 9160 patient test and transfer test benchmark to display the data directly from patient effort. This information is then provided in a report format.

## V Indications for Use:

The Model 9160 VitaloQUB is a whole-body plethysmograph device, when used with the Vitalograph Model 9100, is designed for lung function testing on adults and pediatrics, 6 years and older, by trained medical healthcare professionals in a variety of professional healthcare environments e.g., primary care, hospitals, and pharmaceutical research centers.

The Model 9160 VitaloQUB 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, SBN2, Thoracic Gas Volume (TGV) and Airway Resistance ($R_{aw}$)

## VI Comparison of Technological Characteristics and Performance with the Predicate

**Table 1** is a comparison – Subject Device vs. the Predicates, K022636 – Morgan Scientific – Medisoft Body Box 5500 and K221030 – Vitalograph Model 9100 PFT/DICO including technological characteristics and performance.

## Table 1 - Comparison of Subject vs. Predicate

| | Subject<br>Model 9160 | Primary Predicate<br>Morgan Scientific – Medisoft Body Box 5500 | Comparison |
|---|---|---|---|
| **K#** | **K223818** | **K022636** | **-** |
| **Product Code** | **JEH – 868-1760 -** Volume Plethysmograph<br><br>**Secondary BTY – 868.1890 -** Predictive pulmonary-function value calculator | **JEH – 868-1760 -** Volume Plethysmograph | Similar<br>The additional of the full body enclosure adds the new product classification. |
| **Indications for Use** | The Model 9160 VitaloQUB is a whole-body plethysmograph device, when used with the Vitalograph Model 9100, is designed for lung function testing on adults and pediatrics, 6 years and older, by trained medical healthcare professionals in a variety of professional healthcare environments e.g., primary care, hospitals, and pharmaceutical research centers.<br><br>The Model 9160 VitaloQUB 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, SBN2, Thoracic Gas Volume (TGV) and Airway Resistance (Raw) | The Body Box 5500 when used in conjunction with a computer and the ComPAS pulmonary function software is intended to perform plethysmography, diffusion and spirometry to provide pulmonary function testing in adult and pediatric patients. | Similar<br>Subject device has similar indications to the predicate. |
| **Patient population** | 6 years and older | Pediatric (not defined) and adults | Similar |
| **Fundamental scientific technology** | Measurement of patient air flow via Heated Lilly type pneumotachograph.<br>Test gases – Methane (CH4), Carbon Monoxide (CO), Carbon Dioxide (CO2), Oxygen ($O_2$) and Nitrogen (N2) | Not specified | Similar<br>The subject device uses the same technology of the secondary predicate Model 9100 K221030. |

| | Subject<br>Model 9160 | Predicate<br>Morgan Scientific – Medisoft Body Box 5500 | Comparison |
|---|---|---|---|
| **Parameters measured** | FVC<br>SVC<br>MVV<br>DLCO<br>CPF, RMS (MIP/MEP), SNIP<br>Single and Multiple Breath Nitrogen washout (MBN2 and SBN2)<br>VTG<br>Raw | Plethysmography, diffusion and spirometry<br>This uses the ComPAS software and thus is able to calculate and display the same parameters | Similar<br>Subject device is adding Thoracic Gas Volume (VTG) and<br>Airway Resistance (Raw) |
| **Patient use** | Multi-patient, multi-use | Multi-patient, multi-use | Similar |
| **User Interface** | Color LCD Touchscreen | Not specified | Similar |
| **Operating System** | Microsoft Windows 10 | Not specified | Similar |
| **Patient Interface** | Disposable Bacteria / Viral Filter<br>Disposable Mouthpieces<br>Whole body enclosure | Whole body enclosure | Similar |
| **Components** | • Main Unit (embedded computer, touch screen monitor)<br>• Handheld Flow sensor<br>• Internal Breathing valve assembly (for DLCO and FRC tests)<br>• DLCO gas mix supply<br>• 24V DC via medical grade power supply<br>• 100% Oxygen gas supply<br>• Whole body enclosure | Not specified | Similar |
| **Principle of Operation** | All test types -measurement of patient air flow via heated Lilly type pneumotachograph flow sensor.<br>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. | All test types -measurement of patient air flow via pneumotachograph flow sensor. | Similar |

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|---|---|---|---|
| | MBW test - determination of in- and exhaled gas concentrations:<br>Nitrogen tracer gas concentration determined by a combination of molar mass measurement (molar mass sensor) and $CO_2$ measurement ($CO/CO_2$ sensor).<br>Measurement of VTG and Raw use the same sensors as the Model 9100 | | |
| | **Subject**<br>**Model 9160** | **Predicate**<br>**Morgan Scientific – Medisoft Body Box 5500** | **Comparison** |
| **Accuracy** | Flow range: ±14 L/s<br>Flow accuracy:<br>±2 % over range of -14 to + 14 L/s<br>Volume accuracy<br>±2.5 % or 0.050 L | Not specified | Similar |
| **Operating temperature range** | +15º-32ºC | Not specified | Similar |
| **Performance standards** | ISO 23747:2015, ISO 26782:2009,<br>ATS/ERS: 2002, 2005, 2013, 2017 and 2019 | Not specified | Similar |
| **Electrical Safety and EMC** | ES 60601-1<br>IEC 60601-1-2 | Not specified | Similar |
| **Communications** | USB<br>Morgan Scientific ComPAS2 | Morgan Scientific ComPAS | Similar |

**Table 2: Comparison of the Model 9160 vs. the Secondary Predicate**

| | Subject<br>Model 9160 | Secondary Predicate<br>Model 9100 PFT/DlCO | Comparison |
|---|---|---|---|
| **K#** | **K223818** | **K221030** | **-** |
| **Product Code** | **New – JEH – 868.1760 -** Volume Plethysmograph<br><br>**Secondary – BTY – 868.1890**<br>Predictive pulmonary-function value calculator | <br><br>**BTY – 868.1890**<br>Predictive pulmonary-function value calculator | Same, but the addition of the full body enclosure adds JEH |
| **Classification** | Predictive pulmonary-function value calculator | Predictive pulmonary-function value calculator | Same |
| **Indications for Use** | The Model 9160 VitaloQUB is a whole-body plethysmograph device, when used with the Vitalograph Model 9100, is designed for lung function testing on adults and pediatrics, 6 years and older, by trained medical healthcare professionals in a variety of professional healthcare environments e.g., primary care, hospitals, and pharmaceutical research centers.<br><br>The Model 9160 VitaloQUB 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, SBN2, Thoracic Gas Volume (TGV) and Airway Resistance (Raw) | 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.<br><br>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.<br><br>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. | Similar<br>Subject device is adding VTG and Raw parameters |
| **Patient population** | 6 years and older | 6 years and older | Similar |
| **Fundamental scientific technology** | Measurement of patient air flow via Heated Lilly type pneumotachograph.<br>The DLCO Gas Analyzer utilizes non-dispersive infrared (NDIR) technology to measure the concentrations of Carbon Monoxide (CO), | Measurement of patient air flow via Heated Lilly type pneumotachograph.<br>The DLCO Gas Analyzer utilizes non-dispersive infrared (NDIR) technology to measure the concentrations of Carbon Monoxide (CO), Methane | Similar<br>The subject device uses the same technology of the secondary predicate Model 9100 |

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|---|---|---|---|
| | 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. | (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. | |
| | **Subject**<br>**Model 9160** | **Secondary Predicate**<br>**Model 9100 PFT/DlCO** | **Comparison** |
| **Parameters measured** | FVC<br>SVC<br>MVV<br>DLCO<br>CPF, RMS (MIP/MEP), SNIP<br>Single and Multiple Breath Nitrogen washout (MBN2 and SBN2)<br>MIP/MEP<br>**Adding**<br>TVG<br>Raw | FVC<br>SVC<br>MVV<br>DLCO<br>CPF, RMS (MIP/MEP), SNIP<br>Single and Multiple Breath Nitrogen washout (MBN2 and SBN2)<br>MIP/ / MEP | Similar<br>Subject device is adding Thoracic Gas Volume (VTG) and Airway Resistance (Raw) which the predicate has |
| **Patient use** | Multi-patient, multi-use | Multi-patient, multi-use | Similar |
| **User Interface** | Color LCD Touchscreen | Color LCD Touchscreen | Similar |
| **Operating System** | Microsoft Windows 10 | Microsoft Windows 10 | Similar |
| **Patient Interface** | Disposable Bacteria / Viral Filter<br>Disposable Mouthpieces<br>Whole body enclosure | Disposable Bacteria / Viral Filter<br>Disposable Mouthpieces | Similar<br>Subject device places the Model 9100 patient interface inside a whole body enclosure |
| **Components** | • Main Unit (embedded computer, touch screen and monitor)<br>• Handheld Flow sensor<br>• Internal Breathing valve assembly (for DLCO and FRC tests)<br>• DLCO gas mix supply | • Main Unit (embedded computer, touch screen and monitor)<br>• Handheld Flow sensor<br>• Internal Breathing valve assembly (for DLCO and FRC tests)<br>• DLCO gas mix supply | Similar<br>The subject device includes a whole body enclosure similar to the predicate |

| | | | |
|---|---|---|---|
| | • 24V DC via medical grade power supply<br>• 100% Oxygen gas supply<br>• Whole body enclosure | • 24V DC via medical grade power supply<br>• 100% Oxygen gas supply | |
| | **Subject<br>Model 9160** | **Secondary Predicate<br>Model 9100 PFT/DlCO** | **Comparison** |
| **Principle of Operation** | All test types -measurement of patient air flow via heated Lilly type pneumotachograph flow sensor.<br>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.<br>MBW test - determination of in- and exhaled gas concentrations:<br>Nitrogen tracer gas concentration determined by a combination of molar mass measurement (molar mass sensor) and $CO_2$ measurement ($CO/CO_2$ sensor).<br>Measurement of VTG and Raw use the same sensors as the Model 9100 | All test types -measurement of patient air flow via heated Lilly type pneumotachograph flow sensor.<br>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.<br>MBW test - determination of in- and exhaled gas concentrations:<br>Nitrogen tracer gas concentration determined by a combination of molar mass measurement (molar mass sensor) and $CO_2$ measurement ($CO/CO_2$ sensor). | Similar<br>Subject device with the whole body enclosure can now provide data to the ComPAS2 software to calculate VTG and Raw like the predicates and reference device. |
| **Test Gases for DLCO** | Medical grade gas mix<br>CO: 0.3 %<br>CH4: 0.3 %<br>Balance air | Medical grade gas mix<br>CO: 0.3 %<br>CH4: 0.3 %<br>Balance air | Similar |
| **Test gas requirements for Nitrogen washout test** | Oxygen: 100 %<br>Nitrogen: balance | Oxygen: 100 %<br>Nitrogen: balance | Similar |
| **Flow sensor**<br>Flow range<br>Volume accuracy<br>Flow accuracy<br>Flow resistance | <br>±14 L/s<br>±2.5 % or 0.050 L<br>±2 % over range of -14 to + 14 L/s<br><1.5 cm $H_2O$/L/s (at 14 L/s) | <br>±14 L/s<br>±2.5 % or 0.050 L<br>±2 % over range of -14 to + 14 L/s<br><1.5 cm $H_2O$/L/s (at 14 L/s) | Similar |
| **CO / $CO_2$ Sensor** | Infrared absorption | Infrared absorption | Similar |

| | | | |
|---|---|---|---|
| Type<br>Accuracy | CO - ±1 % of full scale<br>$CO_2$ - ±2.5 % of full scale<br>CH4 -± 2.5% of full scale | CO - ±1 % of full scale<br>$CO_2$ - ±2.5 % of full scale<br>CH4 -± 2.5% of full scale | |
| | **Subject<br>Model 9160** | **Secondary Predicate<br>Model 9100 PFT/DlCO** | **Comparison** |
| **$O_2$ / $CO_2$ Sensor**<br>Type<br>Accuracy | Laser diode absorption for $O_2$<br>Infrared for $CO_2$<br>$O_2$ - ±0.2% of Full Scale<br>$CO_2$ - ±0.1% of Full Scale | Laser diode absorption for $O_2$<br>Infrared for $CO_2$<br>$O_2$ - ±0.2% of Full Scale<br>$CO_2$ - ±0.1% of Full Scale | Similar |
| **Operating temperature range** | 15-32ºC | 15-32ºC | Similar |
| **Performance standards** | ISO 23747:2015, ISO 26782:2009,<br>ATS/ERS: 2002, 2005, 2013, 2017 and 2019 | ISO 23747:2015, ISO 26782:2009,<br>ATS/ERS: 2002, 2005, 2013, 2017 and 2019 | Similar |
| **Electrical Safety and EMC** | ES 60601-1<br>IEC 60601-1-2 | ES 60601-1<br>IEC 60601-1-2 | Similar |
| **Communications** | USB<br>Morgan Scientific ComPAS2 | USB<br>Morgan Scientific ComPAS2 | Similar<br>Uses K213872 software |
| **Power / Energy Source** | 24VDC output via medical grade power supply via input of 80-240 VAC 50-60 Hz | 24VDC output via medical grade power supply via input of 80-240 VAC 50-60 Hz | Similar |
| **Biocompatibility** | Externally communicating, Tissue and Surface Contact, Skin / Mucosa, Limited Duration | Externally communicating, Tissue and Surface Contact, Skin / Mucosa, Limited Duration | Similar<br>Materials in patient contact are the same |

## VII Difference Between Subject and Predicates and Reference

The Model 9160 VitaloQUB is an add-on accessory to the Vitalograph Model 9100 PFT/DlCO, K221030, that incorporates the Morgan Scientific ComPAS2 software, K213872.

The main difference is the addition of a whole body enclosure that allows the collection of data to be calculated by the ComPAS 2 software. Namely – Thoracic Gas Volume (VTG) and Airway resistance (Raw) which are similar to the predicate.

These differences are addressed with the use of a predicate device, K022636 – Morgan Scientific – Medisoft Body Box 5500 which has the same intended use and has a whole body enclosure and provides parameters via ComPAS software.

The technology for flow measurements is a heated Lilly Pneumotachograph type Flowhead for the measuring technology which is identical to the secondary predicate, Model 9100, K221030.

We have updated performance testing as applicable. This would include the applicable safety and performance standards such as ES 60601-1, IEC 60601-1-2, ATS/ERS performance standards, ISO 23747 and ISO 26782, as well as industry standards and guidelines similar to the predicate.

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

## VIII Substantial Equivalence Discussion

The Model 9160 is substantially equivalent to the predicates K022636 – Morgan Scientific – Medisoft Body Box 5500 and K221030 – Vitalograph Model 9100 PFT/DICO any differences have been addressed with the secondary predicate and reference devices.

**Intended Use/ Indications for Use**
The indications for use are similar to the predicates. That is to conduct lung function measurements.

**Technological Characteristics and Principles of Operation**
The measurement of flow is Lilly Screen technology and is similar to the secondary predicate device.

**Non-clinical Testing**
Performance testing demonstrated that the subject device met its acceptance criteria. Testing included:

Bench testing that is new or leveraged from the secondary predicate Model 9100, K221030 and primary predicate K022636 – Morgan Scientific – Medisoft Body Box 5500

- ATS / ERS (2002, 2005, 2013, 2017 and 2019) Static condition
  - MEP, MIP, SNIP, DLCO, N2 washout, VTG, Raw
- ISO 23747
- ISO 26782
- Cleaning – High-level disinfection (Model 9100, K221030)
- Comparative Performance vs. Predicate

Software

- Verification and Validation

Electrical / EMC

- ES 60601-1 - Electrical Safety
- IEC 60601-1-2 – EMC

Biocompatibility (Model 9100, K221030)
Transportation

## IX Discussion of Differences

There are no significant differences between the subject device and the predicates.

This data is already cleared by the Morgan Scientific ComPAS 2 software, K213872.

These differences are addressed with the secondary predicate K221030 – Vitalograph Model 9100 PFT/DICO

These differences do not raise different risks compared to the predicates and reference.

## X Substantial Equivalence Conclusion

A comparison of the subject device has demonstrated that the subject device is substantially equivalent to the predicate and reference devices. Any differences do not raise different questions of safety or effectiveness than the predicate and reference devices.