K240706 510(k) Summary

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Device Name

Device Trade Name:	PowerCube+ Series (PowerCube Body+) PowerCube+ Series (PowerCube Diffusion+) PowerCube+ Series (PowerCube Body+ / Diffusion+)
Common Name:	Volume Plethysmograph
Classification Name:	Volume Plethysmograph
Regulation Number:	868.1760, 868.1840
Product Codes:	JEH, BZG
Device Class:	2

Legally Marketed Predicate Device

Predicate #:	K072061
Trade Name:	MASTERSCREEN PFT, MASTERSCREEN PFT CT, MASTERSCREEN PFT BODY
Common/Classification Name:	Volume plethysmograph
Regulation Number:	868.1760
Product Codes:	JEH
Device Class:	2

Legally Marketed Reference Device

Reference #:	K160116
Trade Name:	SpiroScout
Common/Classification Name:	Diagnostic spirometer.
Regulation Number:	868.1840
Product Codes:	BZG
Device Class:	2

Device Description Summary

The GANSHORN PowerCube+ Series is a device that performs cooperation-dependent pulmonary function tests, including Spirometry, Body Plethysmography, Lung Diffusion measurement, Occlusive Resistance measurement and Respiratory Muscle Strength measurement. The device provides information that aids in a diagnosis by a clinician.

Spirometry is a set of non-invasive pulmonary function tests where the flow of inhaled/exhaled air is measured to determine physiological parameters such as Peak Expiratory Flow and Forced Vital Capacity. The patient's breathing flow is measured with ultrasound technology inside a breathing insert. Two ultrasound transducers measure the difference in ultrasound wave transit time to calculate breathing flow direction, speed, and volume.

Body Plethysmography provides for the measurement of physiological parameters such as Functional Residual Capacity and Specific Airway Resistance. The patient is seated in an air-tight chamber which has a fixed shape and volume. Pressure sensors measure the chamber pressure and the pressure close to the mouth, which is used as a proxy for alveolar pressure when measured under a zero-flow condition. Boyle's Law is used to infer the volume in the lungs from changes in chamber pressure.

Lung Diffusion testing is a non-invasive process for measuring diffusion capacity and lung volume. The patient inhales a test gas with known concentrations of helium and carbon monoxide. The patient's breath is held for 10 seconds during which time the helium dilutes into the lungs and the carbon monoxide diffuses through the alveoli into the blood. After 10 seconds of breath-hold time, the patient exhales and the difference between inhaled and exhaled gas concentrations is measured with a gas analyzer. The differences in gas concentration are used to determine physiological parameters such as DLCO (diffusing capacity of the lungs for carbon monoxide) and Alveolar Volume.

Occlusive Resistance measurement is an established method for measuring airway resistance during tidal breathing, using a shutter and mouth pressure sensor.

Respiratory Muscle Strength measurement is an established method for measuring the maximal strength of respiratory muscles, using a shutter and mouth pressure sensor.

The PowerCube+ Series has the following product model configurations:

- PowerCube Body+ includes Spirometry and Body Plethysmography measurement
- PowerCube Diffusion+ includes Spirometry and Lung Diffusion measurement
- PowerCube Body+ / Diffusion+ includes Spirometry, Body Plethysmography, and Lung Diffusion measurement

All product model configurations support Occlusive Resistance measurement and Respiratory Muscle Strength measurement.

The PowerCube+ Series is mains-powered and not intended for mobile/transportable use.

Intended Use/Indications for Use

The PowerCube+ Series is indicated for use in the measurement and data collection of lung function parameters. The system performs cooperation-dependent pulmonary function tests which include Spirometry/Flow-Volume measurement, Body Plethysmography measurement, Lung Diffusion measurement, Occlusive Resistance measurement and Respiratory Muscle Strength measurement. The device provides information that aids in a diagnosis by a clinician.

The PowerCube+ Series is indicated for use by a clinician in a professional healthcare setting on adult and pediatric patients who are 5 years and older that can cooperate in the testing.

Technological Comparison

Characteristic	Subject Device Ganshorn PowerCube+ Series	Predicate Device K072061 – Viasys MasterScreen	Discussion of Differences
Indications for Use	The PowerCube+ Series is indicated for use in the measurement and data collection of lung function parameters. The system performs cooperation-dependent pulmonary function tests which include Spirometry/Flow- Volume measurement, Body Plethysmography measurement, and Lung Diffusion measurement. The device provides information that aids in a diagnosis by a clinician. The PowerCube+ Series is indicated for use by a clinician in a professional healthcare setting on adult and pediatric patients who are 5 years and older that can cooperate in the testing.	The Masterscreen PFT Body is intended to be used for measurement and data collection of lung function parameters. The system performs cooperation-dependent pulmonary function tests which include Spirometry/Flow-Volume/Resistance measurements, lung diffusion measurements and body plethysmography measurement. The device provides data / information and supports help for a diagnosis. MasterScreen PFT CT (Clinical Trial version) includes Spirometry/Flow-Volume/Resistance measurements and lung diffusion measurements with individual access rights defined for different user roles (e.g. Investigator, doctor, study nurse, trainer and service personnel). MasterScreen PFT includes Spirometry/Flow-Volume/Resistance and lung diffusion measurements. Measurements will be performed under the direction of a physician in the clinic, doctor's office or hospital. It can be utilized for patients from 4 years on and older as long as they can cooperate in the performance. The MS-PFT Body is powered from 100-240V / 50-60Hz wall outlets. No energy is transferred to the patient.	Substantially equivalent. Both devices offer Spirometry, Body Plethysmography and Lung Diffusion measurement programs. Both devices provide information that aids in a diagnosis by a clinician. The predicate device offers a special clinical trial version that is outside of the Intended Use scope.
Environment of use	Professional healthcare setting	Same	N/A

Characteristic	Subject Device Ganshorn PowerCube+ Series	Predicate Device K072061 – Viasys MasterScreen	Discussion of Differences
Prescription Use only	Yes	Same	N/A
Patient population	5 years and older	4 years and older	Substantially equivalent
Measurement programs	• Spirometry (Slow Vital Capacity, Forced Vital Capacity, Maximum Voluntary Ventilation) • Body Plethysmography • Lung Diffusion (Single Breath Diffusion method) • Occlusive Resistance measurement • Respiratory Muscle Strength measurement	Same	The predicate device offers the same lung function measurement programs as the subject device.
Spirometry technology (flow measurement)	Ultrasound (transit-time between 2 ultrasound sensors)	Pneumotachograph (pressure drop across a resistive element)	Different technologies, but for same Intended Use. Subject device uses the same technology as the SpiroScout reference device (K160116).
Flow Parameters	• Range: ±18 l/s • Accuracy: ±2% or 50 ml/s, whichever is greater • Resolution: 10 ml/s	Similar	Conforms to ISO 23747:2015
Spirometry technology (volume measurement)	Integration of flow measurement data	Same	N/A

Characteristic	Subject Device Ganshorn PowerCube+ Series	Predicate Device K072061 – Viasys MasterScreen	Discussion of Differences
Volume Parameters	• Range: 0-20 liters • Accuracy: ±2% or 50 ml, whichever is greater • Resolution: 1 ml	Similar	Conforms to ISO 26782:2009
Body Plethysmography technology	An air-tight chamber of fixed shape and volume. A pressure sensor that measures the pressure inside the chamber relative to ambient pressure. A pressure sensor that measures mouth pressure, which is used as a proxy for alveolar pressure when measured under a zero-flow condition. The use of Boyle's Law to infer the volume in the lungs from changes in chamber pressure.	Similar	The subject device incorporates an airtight chamber, mouth pressure sensor, and application of Boyle's Law, which are standard and well-established principles for body plethysmography.

Characteristic	Subject Device Ganshorn PowerCube+ Series	Predicate Device K072061 – Viasys MasterScreen	Discussion of Differences
Lung Diffusion (Single Breath Diffusion method) technology	A test gas that includes known quantities of helium and carbon monoxide (provided by the customer, not part of the subject device). A gas analyzer that measures helium concentration during inhalation and exhalation. A gas analyzer that measures carbon monoxide concentration during inhalation and exhalation. A comparison of the inhaled and exhaled gas concentrations to infer lung diffusing capacity.	Similar	The subject device uses a helium and carbon monoxide test gas, alongside gas analyzers, to measure lung diffusion capacity based on established ATS/ERS standards.
Gas mixture:	• helium: 18% • carbon monoxide: 0.25% • oxygen: 17-21% • nitrogen: balance	Similar	Helium and carbon monoxide concentrations are consistent with ATS/ERS guidelines
Carbon monoxide gas analyzer	• Type: non-dispersive infrared absorption • Range: 0-3000 ppm CO • Accuracy: ±2.5% FSO	Similar	Sensor measurement range in the subject device is sufficient for Intended Use
Helium gas analyzer	• Type: ultrasound • Range: 0-20 Vol% He • Accuracy: ±2.5% FSO	Similar	Sensor measurement range in the subject device is sufficient for Intended Use

Characteristic	Subject Device Ganshorn PowerCube+ Series	Predicate Device K072061 – Viasys MasterScreen	Discussion of Differences
Occlusive Resistance Measurement technology	A pressure sensor that measures mouth pressure, which is used as a proxy for alveolar pressure when measured under a zero-flow condition. A shutter mechanism that momentarily blocks the airflow at the mouth by transient occlusion.	Similar	The subject device's use of pressure sensors and a shutter mechanism for transient occlusion aligns with well-established principles in pulmonary diagnostics and does not introduce new questions of safety or effectiveness.
Respiratory Muscle Strength Measurement technology	A pressure sensor that measures mouth pressure, which is used as a proxy for alveolar pressure when measured under a zero-flow condition. A shutter mechanism that momentarily blocks the airflow at the mouth by transient occlusion.	Similar	The subject device's use of pressure sensors and a shutter mechanism for transient occlusion aligns with well-established principles in pulmonary diagnostics and does not introduce new questions of safety or effectiveness.

Characteristic	Subject Device Ganshorn PowerCube+ Series	Predicate Device K072061 – Viasys MasterScreen	Discussion of Differences
Spirometry Slow Vital Capacity reported measurements	• VT • ERV • IRV • VC max • VC ex • VC in • VC • IC • BF	Similar	Mathematically derived based on physiological parameters. Although data for the predicate device (K072061 – Viasys MasterScreen) is not publicly available, the derivation of these measurements adheres to standard spirometric calculation principles, ensuring equivalent clinical relevance and accuracy.
Spirometry Forced Vital Capacity reported measurements	• FVC • FIVC • FEV1 • FEV6 • FEV1 / FVC • FEV1 / VCmax • FEV1 / FEV6 • FEF 25 (MEF 75) • FEF 50 (MEF 50) • FEF 75 (MEF 25) • FEF 25-75 • PEF • PIF • VC max	Similar	Bench testing in compliance with ATS/ERS standards and ISO 26782 and ISO 23747. Testing validated accurate measurements of key parameters, including FEV1, FEV6, FVC, and PEF. Other reported parameters are mathematically derived from these core measurements,

Characteristic	Subject Device Ganshorn PowerCube+ Series	Predicate Device K072061 – Viasys MasterScreen	Discussion of Differences
Spirometry Maximum Voluntary Ventilation reported measurements	• MVV	Similar	Mathematically derived based on validated spirometric measurements, such as FEV1 and tidal volume.
Body Plethysmography reported measurements	• TGV • FRCpleth • ERV • RV • TLC • VC • IC • sRaw eff • sRaw tot • sRaw mid • sRaw peak • sRaw 0.5 • Raw eff • Raw tot • Raw 0.5 • RV%TLC	Similar	SE demonstrated for the Body Plethysmography component by conducting bench testing comparing the PowerCube+ Series to the FDA-cleared MasterScreen Body device, demonstrating that measurements for Thoracic Gas Volume (TGV) and Specific Airway Resistance (sRaw) fall within a 5% deviation threshold, consistent with ATS/ERS guidelines and regulatory standards. Additionally, the device's piezo-resistive sensors and chamber design were validated to provide accurate and reliable measurements under clinical conditions

Characteristic	Subject Device Ganshorn PowerCube+ Series	Predicate Device K072061 – Viasys MasterScreen	Discussion of Differences
Lung Diffusion (Single Breath Diffusion method) reported measurements	• DLCO • DLCOc • VA • KCO • TLC • FRC • RV • RV%TLC	Similar	Bench testing using simulated inhalation and exhalation with calibrated gas mixtures, demonstrated compliance with ATS/ERS 2017 standards for single-breath carbon monoxide uptake. The testing confirmed that all measurements, including Diffusing Capacity of the Lungs for Carbon Monoxide (DLCO) and Alveolar Volume (VA), fall within acceptable tolerances, validating the accuracy and reliability of the device for clinical use.

Characteristic	Subject Device Ganshorn PowerCube+ Series	Predicate Device K072061 – Viasys MasterScreen	Discussion of Differences
Occlusive Resistance Measurement reported measurements	• ROcc • GOcc	Similar	Bench testing that demonstrated compliance with a strict acceptance criterion of ≤2% deviation. Comparative testing with the FDA-cleared MasterScreen Body device confirmed that measurements of Rocc and derived parameters such as Occlusive Conductance (Gocc) were consistent and accurate, aligning with ATS/ERS standards.
Respiratory Muscle Strength Measurement reported measurements	• PImax • PEmax • P0.1 • P0.1max • P0.1 / PImax • P0.1 / MV	Similar	Bench testing that adhered to a strict acceptance criterion of ≤2% deviation. Comparative testing with the FDA-cleared MasterScreen Body device confirmed the accuracy and reliability of these measurements, demonstrating compliance with ATS/ERS standards and validating their clinical utility.

Characteristic	Subject Device Ganshorn PowerCube+ Series	Predicate Device K072061 – Viasys MasterScreen	Discussion of Differences
Components	• Spirometry flow meter • Body Plethysmography chamber • Breathing gas analyzers • Patient-applied parts, used for the acquisition of breathing gases • Software module, running on a PC	Similar	The components of the subject device are consistent with those typically found in volume plethysmograph devices. These include a spirometry flow meter, body plethysmography chamber, breathing gas analyzers, patient-applied parts, and a software module running on a PC.
Patient-applied parts	• Spirometry breathing tube • Spirometry bacterial filter • Nose clip • Gas analysis intermediate adapter (draws an air sample for Lung Diffusion measurement)	Similar	Subject device applied parts are similar to other cleared devices of this type.
Device energy type	110-240 VAC 50/60 Hz	Same	N/A

Characteristic	Subject Device Ganshorn PowerCube+ Series	Predicate Device K072061 – Viasys MasterScreen	Discussion of Differences
Body Plethysmography chamber characteristics	• Security glass, aluminum frame • Door lock: magnetic • Standard-sized, XL-sized	Similar	Chamber is fixed in shape and volume, which is required for the measurement process. A specific volume (standard vs XL) is not required for the measurement process, as long as the volume is known and fixed in nature.
Software – user interface	LFX software module, running on a PC	Similar	Each device has its own software program, supporting the same Intended Use
Software – signal processing	LFX software module, running on a PC	Similar	Each device has its own software program, supporting the same Intended Use
EMR connectivity support	Yes	Similar	The Ganshorn PowerCube+ Series includes EMR connectivity support, enabling seamless integration with electronic medical record systems to streamline data management and improve clinical workflows.

Characteristic	Subject Device Ganshorn PowerCube+ Series	Predicate Device K072061 – Viasys MasterScreen	Discussion of Differences
Environmental Use Conditions (Operating)	• Temperature: +15 - +35°C • Relative Humidity: 10-95% (non-condensing) • Atmospheric Pressure: 700-1060 hPa	Similar	The Ganshorn PowerCube+ Series, the specified environmental use conditions for both operating and transport include a wide range of temperature, humidity, and atmospheric pressure values, ensuring reliable performance in various environment.
Environmental Use Conditions (Transport)	• Temperature: -20 - +50°C • Relative Humidity: 10-95% (non-condensing) • Atmospheric Pressure: 600-1060 hPa	Similar	The Ganshorn PowerCube+ Series, the specified environmental use conditions for both operating and transport include a wide range of temperature, humidity, and atmospheric pressure values, ensuring reliable performance in various environments.

Non-Clinical and Clinical Tests Summary

Category	Testing Summary
Cleaning Validation	The subject device and the cleaning / disinfection instructions for the subject device have been tested in accordance with FDA Guidance and the following standards: • ISO 17664-1:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
Shelf-Life Testing	The subject device has a disposable bacterial filter patient-applied part that has been tested for shelf-life stability. Test results indicate that the subject device complies with its predetermined specification.
Biocompatibility Testing	The subject device has direct surface contact with patient skin for a limited (< 24 hours) duration and indirect contact with patient gas pathway. The patient-contacting materials in the subject device have been tested for biocompatibility in accordance with the following standards: • ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system • ISO 18562-1 First edition - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process • ISO 18562-2 First edition - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter • ISO 18562-3 First edition - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds • ISO 18562-4 First edition - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate
Software/Cybersecurity Testing	The subject device has been designed and developed in accordance with internal software development processes, FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, FDA Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, and has been verified and validated. Test results indicate that the subject device complies with its predetermined specification.

Category	Testing Summary
Electrical Safety	The subject device has been tested for safety in accordance with the following standards: • IEC 60601-1 Edition 3.2 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
Electromagnetic Compatibility (EMC)	The subject device has been tested for EMC in accordance with the following standards: • IEC 60601-1-2 Edition 4.1 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
Performance Testing - Bench	The subject device has been tested in accordance with internal requirements and procedures, and test results indicate that the device complies with the predetermined requirements. The subject device has been tested for clinical accuracy performance in accordance with the following standards: • ISO 23747:2015 - 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 • ATS - Standardization of Spirometry 2019 Update • 2017 ERS/ATS standards for single-breath carbon monoxide uptake in the lung • ATS/ERS Statement on Respiratory Muscle Testing (2002) • ERS statement on respiratory muscle testing at rest and during exercise (2018) • ATS/ERS Standardization of the measurement of lung volumes (2023) Comparative bench testing against an FDA cleared device was also conducted to validate the additional parameters of the subject device. The two devices were compared against a calibrated Hans-Rudolph flow/volume simulator at a range of physiological test points, and test results indicate that the subject device complies with its predetermined specification.
Performance Testing - Animal	Animal performance testing was not performed with the subject device and is not necessary to demonstrate safety and effectiveness.

Category	Testing Summary
Performance Testing - Clinical	Clinical performance testing was not performed with the subject device and is not necessary to demonstrate safety and effectiveness.

Conclusions

The information provided above supports that the GANSHORN PowerCube+ Series is substantially equivalent to the predicate device. Although minor differences in design and technology exist between the subject and predicate device, the testing supports that these differences do not raise new questions of safety and effectiveness.

Therefore, it is concluded that the GANSHORN PowerCube+ Series is substantially equivalent to the predicate device.