



December 9, 2024

GANSHORN Medizin Electronic GmbH
% Jim Chickering
Regulatory Consultant
15 Belleau Woods
Georgetown, New Hampshire 01833

Re: K240706

Trade/Device Name: PowerCube+ Series (PowerCube Body+);
PowerCube+ Series (PowerCube Diffusion+);
PowerCube+ Series (PowerCube Body+ / Diffusion+)
Regulation Number: 21 CFR 868.1760
Regulation Name: Volume Plethysmograph
Regulatory Class: Class II
Product Code: JEH, BZG
Dated: November 4, 2024
Received: November 4, 2024

Dear Jim Chickering:

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.

Assistant Director

DHT1C: Division of Anesthesia,

Respiratory, and Sleep Devices

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K240706

Device Name

PowerCube+ Series (PowerCube Body+)

PowerCube+ Series (PowerCube Diffusion+)

PowerCube+ Series (PowerCube Body+ / Diffusion+)

Indications for Use (Describe)

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.

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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K240706 510(k) Summary

Contact Details

Date Prepared: December 9, 2024

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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	<p>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.</p> <p>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.</p>	<p>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.</p> <p>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).</p> <p>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.</p> <p>The MS-PFT Body is powered from 100-240V / 50-60Hz wall outlets. No energy is transferred to the patient.</p>	<p>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.</p>
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	<ul style="list-style-type: none"> • 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)	<p>Different technologies, but for same Intended Use.</p> <p>Subject device uses the same technology as the SpiroScout reference device (K160116).</p>
Flow Parameters	<ul style="list-style-type: none"> • Range: ± 18 l/s • Accuracy: $\pm 2\%$ 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	<ul style="list-style-type: none"> • Range: 0-20 liters • Accuracy: $\pm 2\%$ or 50 ml, whichever is greater • Resolution: 1 ml 	Similar	Conforms to ISO 26782:2009
Body Plethysmography technology	<p>An air-tight chamber of fixed shape and volume.</p> <p>A pressure sensor that measures the pressure inside the chamber relative to ambient pressure.</p> <p>A pressure sensor that measures mouth pressure, which is used as a proxy for alveolar pressure when measured under a zero-flow condition.</p> <p>The use of Boyle's Law to infer the volume in the lungs from changes in chamber pressure.</p>	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	<p>A test gas that includes known quantities of helium and carbon monoxide (provided by the customer, not part of the subject device).</p> <p>A gas analyzer that measures helium concentration during inhalation and exhalation.</p> <p>A gas analyzer that measures carbon monoxide concentration during inhalation and exhalation.</p> <p>A comparison of the inhaled and exhaled gas concentrations to infer lung diffusing capacity.</p>	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:	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Type: non-dispersive infrared absorption • Range: 0-3000 ppm CO • Accuracy: $\pm 2.5\%$ FSO 	Similar	Sensor measurement range in the subject device is sufficient for Intended Use
Helium gas analyzer	<ul style="list-style-type: none"> • Type: ultrasound • Range: 0-20 Vol% He • Accuracy: $\pm 2.5\%$ 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	<p>A pressure sensor that measures mouth pressure, which is used as a proxy for alveolar pressure when measured under a zero-flow condition.</p> <p>A shutter mechanism that momentarily blocks the airflow at the mouth by transient occlusion.</p>	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	<p>A pressure sensor that measures mouth pressure, which is used as a proxy for alveolar pressure when measured under a zero-flow condition.</p> <p>A shutter mechanism that momentarily blocks the airflow at the mouth by transient occlusion.</p>	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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • MVV 	Similar	Mathematically derived based on validated spirometric measurements, such as FEV1 and tidal volume.
Body Plethysmography reported measurements	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • ROcc • GOcc 	Similar	Bench testing that demonstrated compliance with a strict acceptance criterion of $\leq 2\%$ 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	<ul style="list-style-type: none"> • PImax • PEmax • P0.1 • P0.1max • P0.1 / PImax • P0.1 / MV 	Similar	Bench testing that adhered to a strict acceptance criterion of $\leq 2\%$ 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Security glass, aluminum frame • Door lock: magnetic • Standard-sized, XL-sized 	Similar	<p>Chamber is fixed in shape and volume, which is required for the measurement process.</p> <p>A specific volume (standard vs XL) is not required for the measurement process, as long as the volume is known and fixed in nature.</p>
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)	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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	<p>The subject device and the cleaning / disinfection instructions for the subject device have been tested in accordance with FDA Guidance and the following standards:</p> <ul style="list-style-type: none"> • 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	<p>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.</p>
Biocompatibility Testing	<p>The subject device has direct surface contact with patient skin for a limited (< 24 hours) duration and indirect contact with patient gas pathway.</p> <p>The patient-contacting materials in the subject device have been tested for biocompatibility in accordance with the following standards:</p> <ul style="list-style-type: none"> • 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	<p>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.</p>

Category	Testing Summary
Electrical Safety	<p>The subject device has been tested for safety in accordance with the following standards:</p> <ul style="list-style-type: none"> • IEC 60601-1 Edition 3.2 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
Electromagnetic Compatibility (EMC)	<p>The subject device has been tested for EMC in accordance with the following standards:</p> <ul style="list-style-type: none"> • 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	<p>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.</p> <p>The subject device has been tested for clinical accuracy performance in accordance with the following standards:</p> <ul style="list-style-type: none"> • 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) <p>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.</p>
Performance Testing - Animal	<p>Animal performance testing was not performed with the subject device and is not necessary to demonstrate safety and effectiveness.</p>

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.