September 17, 2024

TechnoPulm, Ltd.
% Bosmat Friedman
Regulatory Consultant
ProMedoss, Inc.
3521 Hatwynn Rd.
Charlotte, North Carolina 28269

Re: K240293
Trade/Device Name: STS
Regulation Number: 21 CFR 868.1880
Regulation Name: Pulmonary-Function Data Calculator
Regulatory Class: Class II
Product Code: BZC
Dated: August 13, 2024
Received: August 13, 2024

Dear Bosmat Friedman:

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240293

Device Name

STS

Indications for Use *(Describe)*

The STS device is intended to measure lung function in adult patients while at rest (including spirometry and lung volumes). The STS device is to be used by either a physician, respiratory therapist, or technician. The STS device is intended to be used in a professional healthcare environment.

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

X 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 [Traditional 510(k)]
STS
510(k) Number K240293

1. SUBMITTER

Applicant's Name:
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Date Prepared: September 17, 2024

2. DEVICE

Trade Name: STS

Classification Code:
Device: calculator, pulmonary function data
Product Code: BZC
Regulation No: 868.1880
Class: 2
Review Panel: Anesthesiology

3. PREDICATE DEVICE

Primary Predicate:

- MiniBox +, by PulmOne Advanced Medical Devices, Ltd., Product code BZC/BZG, cleared Under: K161295.

Reference Device:

- Resmon PRO FULL, by Medical Graphics Corporation, product code PNV/BZC, cleared under: K152585.

4. DEVICE DESCRIPTION

The STS is a handheld spirometer intended to measure lung function in adult patients while at rest (including spirometry and lung volumes). The STS is to be used by either a physician, respiratory therapist, or technician.

The STS device is pulmonary function testing device that measures both flow/volume (spirometry), lung volume and resistance/compliance parameters. It is a multi-use device that should be used with a compatible single-use, disposable mouthpiece which incorporates a viral-bacterial filter protecting the patient from the internal components of the device. The device is battery operated allowing for approximately 40 operating hours between charges. The measurement results, which are transmitted via Bluetooth, are displayed on the physician's computer via the STS software/App.
The STS has the following measurement capabilities:

Lung Volume Parameters:	
Total lung capacity	(TLC) L
Thoracic Gas Volume	(TGV) L
Residual volume	(RV) L
Ratio of TGV to TLC	(TGV/TLC) %
Ratio of RV to TLC	(RV/TLC) %
Flow/Volume (Spirometry) Parameters:	
Forced vital capacity	(FVC) L
Forced expiratory volume in 1second	(FEV 1) L
Ratio of FEVI to FVC	(FEV1/FVC) %
Forced expiratory volume in 6 seconds	(FEV6) L
Forced expiratory volume in 3 seconds	(FEV3) L
Ratio of FEV3 to FVC	(FEV3/FVC) %
Peak expiratory flow	(PEF) L/s
Forced expiratory flow between 25% and 75% of force vital capacity	(FEF 25-75) L/s
Vital capacity	(VC) L
Inspiratory vital capacity	(IVC) L
Peak inspiratory flow	(PIF) L/s
Resistance/Compliance Parameters:	
Airway resistance	(RAW) kPa*s/L
Lung compliance	(CL) L/kPa

5. INDICATIONS FOR USE

The STS device is intended to measure lung function in adult patients while at rest (including spirometry and lung volumes). The STS device is to be used by either a physician, respiratory therapist, or technician. The STS device is intended to be used in a professional healthcare environment.

6. SUBSTANTIAL EQUIVALENCE

The STS is substantially equivalent to the predicate device based on the following:

Intended Use

The intended use of the proposed device is the same as that of the cleared device. The only difference in the indication for use statement is the narrowing of the STS population to include only adult patients. This difference is due to the fact that the STS device has not been tested in a

pediatric population. The narrowing of the indication does not raise new questions of safety and effectiveness.

Technology

Both the STS and Minibox are used to measure lung function in adult patients. Both devices are used with an off-the-shelf FDA cleared biological filter. The predicate is to be used with 2800 PFT FILTER by Air Safety Ltd. (K051712) and the STS can be used with MicroGard by CareFusion Germany 234 GmbH (K111408).

In both devices, the test is performed by having the seated patient use a nose clip and blow through the mouthpiece filter. In both, the operator navigates through the software and is required to initiate the test prior to the patient exhaling in the device. In the STS, the patient is required to "blast" exhale into the mouthpiece; 3 successful tests are required in order to receive an output report. The Minibox procedure is slightly different; the patient first preforms 2-3 tidal breaths followed by "blast" exhale. In the Minibox, three tests are also required in order to obtain comprehensive results. Both devices require a relatively short procedure duration (approximately 15 minutes to perform 3 successful breath tests).

With respect to device design, the Minibox is a standalone unit incorporating the handheld device which is wired to the desktop unit. The desktop unit incorporates a touch screen that allows for software navigation to operate the system, control the test, input patient data, commence testing, etc.

When compared to predicate, the STS is more compact and connects via Bluetooth to the user's PC on which the STS software is installed. Additionally, while the majority of lung test parameters are the same between the two devices, some parameters are only available on one device and not the other, this difference does not raise new safety and effectiveness concerns as the obtained parameters for both devices are sufficient to perform a lung function assessment.

Attribute	Subject Device	Primary Predicate	Reference Device	Comparison
Trade Name	STS	MiniBox +	Resmon PRO FULL	
510(k) Number	K240293	K161295	K152585	
Classification	Class II, BZC, BZG	Class II, BZC, BZG	Class II, PNV, BZC	Same as primary predicate
Regulation Description	Calculator, Pulmonary Function Data	Calculator, Pulmonary Function Data	Diagnostic spirometer	Same as primary predicate
Regulation Number	868.1880 – Pulmonary-function data calculator	868.1880 – Pulmonary-function data calculator	868.1840 - Diagnostic spirometer	Same as primary predicate
Classification Panel	Anesthesiology	Anesthesiology	Anesthesiology	Same
Indications For Use	The STS is intended to measure lung function in adult patients while at rest (including spirometry and lung volumes). The STS is to be used by either a physician, respiratory therapist, or technician. The STS device is intended to be used in a professional healthcare environment.	The PulmOne MiniBox+is intended to measure lung function in adult and pediatric patients while at rest (including spirometry and lung volumes). The PulmOne MiniBox+is to be used by either a physician, respiratory therapist, or technician.	The Resmon PRO FULL is intended to measure respiratory system impedance using the Forced Oscillation Technique (FOT). Resmon PRO FULL is intended for use with pediatric and adult patients 4 years of age or older. The device is designed to be used by pulmonologists, general practitioners, nurses, respiratory therapists, laboratory technologists, medical researchers and similarly trained personnel in hospitals, clinics, and private physician offices.	Similar to the primary predicate; The STS device has a narrower patient population
Basic Operating Principle	Uses pressure data measured at the mouth to calculate TLC	Uses pressure and flow data measured at the mouth to calculate TLC	Forced Oscillation Technique (FOT)	Similar to the primary predicate
Power Source	Rechargeable Lithium Ion Battery (3.7V, 3500mAh)	100-240VAC,50-60Hz	100-240 V / 50-60Hz	The Minibox+ is connected to electricity while the STS has a rechargeable battery.
Built in screen	No	Yes	Yes	The STS data is transferred via Bluetooth to the user PC and is displayed there.
Physical properties	Small handheld device; 70x200x85 mm and weighs 400 gr.	Larger desktop device; 510x470x310 mm and weighs 8 kgs.	310X290X260 mm; 4.3 Kg	The STS device is a small handheld device that incorporates the same functionalities as the predicate.
Procedure duration	~15 minutes	15-20 minutes	A few minutes	Same
Sterilization/cleaning	Nonsterile device intended to be cleaned between uses	Nonsterile device intended to be cleaned between uses	Nonsterile device intended to be cleaned between uses	Same

Attribute	Subject Device	Primary Predicate	Reference Device	Comparison
Trade Name	STS	MiniBox +	Resmon PRO FULL	
510(k) Number	K240293	K161295	K152585	
Biocompatibility	Externally communicating device with a limited (< 24 hours) duration of patient contact due to its indirect contact with patient respiratory tissues involving inspiratory and exhalatory maneuvers	Externally communicating device with a limited (< 24 hours) duration of patient contact due to its indirect contact with patient respiratory tissues involving inspiratory and exhalatory maneuvers	Externally communicating device with a limited (< 24 hours) duration of patient contact due to its indirect contact with patient respiratory tissues involving inspiratory and exhalatory maneuvers	Same
Bacterial filter	To be used with compatible filter (MicroGard by CareFusion Germany 234 GmbH (K111408)	Used with FDA cleared compatible filter (K051712)	Used with designated disposable filter	Similar to the primary predicate
Single Use/reusable	Handheld device is reusable; to be used with single use compatible filter	Desktop device is reusable; to be used with single use compatible filter	Desktop device is reusable; to be used with single use compatible filter	Same
Measured parameters	The following parameters are displayed in the results report: TLC, TGV, RV, TGV/TLC, RV/TLC, FVC, FEV1, FEV1/FVC, FEV6, FEV3, FEV3/FVC, PEF, FEF 25-75, VC, IVC, PIF, RAW (kPa*s/L), CL (L/kPa)	The following parameters are displayed in the results report: FAV1/FVC, FVC, FEV1, FEF 25-75, Lung age, FEV1/SVC, FEV1/VC, FEV6, FEV1/FEG6, PEF, FEV3, FEV3/FVC, FET, FEF 25, FEF 50, FEF 75, Evol, FIVC, FIV1, FIV1/FIVC, PIF, PEF_m, RV, TLC, RV/TLC, IC/TLC, TGV, VC, SVC(LVM), IC(LVM), ERV(LVM), DLco, VA, DLco/VA, BHT, VI, TLco, TLco/VA, TLcp/VA-c	Calculated impedance parameters: Total Resistance (Rtot) Inspiratory Resistance (Rinsp) Expiratory Resistance (Rexp) Total Reactance (Xtot) Inspiratory Reactance (Xinsp) Expiratory Reactance (Xexp) deltaXrs R5-R19 Calculated Breathing Pattern Parameters: Tidal Volume (Vt) Inspiratory Time (Ti) Expiratory Time (Te) Respiratory Duty Cycle (Ti/Ttot) Respiratory Rate (RR) Mean Inspiratory Flow (Vt/Ti) Mean Expiratory Flow (Vt/Te) Ventilation (Ve)	Similar; while some variations in displayed parameters exist, the majority of displayed parameters are the same as the primary predicate. The reference device has been introduced to include lung compliance parameter (Rexp). Lung compliance measured by STS is a function of the RAW resistance which is measured both by STS and reference device.

Discussion
Based on the comparison presented in our submission, the STS shares the same indications for use as the primary predicate, as both are intended to measure lung function in adult patients while at rest. Additionally, while some technological differences do exist between the STS and its predicate, comprehensive testing including bench, and clinical studies have demonstrated that the device is substantially equivalent to its predicate and that the technological differences do not raise new safety and effectiveness concerns and support the company's substantial equivalency claim.

7. UTILIZATION OF STANDARDS

The following standards were used in whole or in part in the evaluation of the device's safety and effectiveness:

- AAMI ST98:2022 - Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices.
- ATS Standardization of Spirometry (2019 Update)
- ISO 17664-2: 2021: Processing of health care products- Information to be provided for the processing of medical devices- Part 2: Non-critical medical devices.
- IEC 60601-1:2005, AMD1:2012, AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance Edition 3.2
- IEC 60601-1-2:2014, IEC 60601-1+2:2014/AMD1:2020 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests Edition 4.1
- ISO 26782 Anaesthetic and respiratory equipment Spirometers intended for the measurement of time forced expired volumes in humans
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D4332-22 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ISO 10993-1:2018 Biological Evaluation of Medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 18562-1:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 23747:2015 Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
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8. PERFORMANCE DATA

Bench tests summary of nonclinical performance data:
The STS underwent nonclinical bench tests to establish substantially equivalent performance including biocompatibility testing, cleaning validation, EMC and electrical safety per IEC 60601-1 and IEC 60601-1-2, software validation, cybersecurity and environmental testing.

In addition, simulator bench testing per ISO 26782 were conducted to verify the STS accurate performance. The results of the bench testing support the safety profile of the device and demonstrate that the device functions as intended.

Clinical Study:

The main goal of the study was to evaluate the performance of STS technique in calculating resistance and compliance parameters. The accuracy of the STS device was examined by comparing with Body plethysmography (BP), which is considered as the "gold standard" for measuring lung volumes.

161 subjects including 61 females enrolled in the study, to be tested by both STS and BP. The subject population included 63 healthy subjects (39.1%), 40 (24.9%) obstructive patients and 58 (36.0%) restrictive patients. The age of enrolled subjects was 53.5±31.5 years.

The comparison results demonstrated a high correlation between the two devices. Correlation coefficients were in the range between 0.75 and 0.97, the P-value did not exceed 3%, repeatability coefficients were less than 0.3L and within-subject standard deviation values were less than 0.15L.

9. CONCLUSION

The STS has similar intended use, technological characteristics, and principles of operation as the predicate. Any differences between the subject and predicate device were evaluated through design verification and validation testing and comparative testing which demonstrated device performance and safety, and do not raise any new questions of safety and effectiveness.

Based on the information submitted in this 510(k), the STS is substantially equivalent to the currently marketed predicate Minibox+.