June 4, 2025

The ScottCare Corporation
Matthew Tarler
Director of Quality and Regulatory Affairs
4791 West 150th Street
Cleveland, Ohio 44135

Re: K250259
Trade/Device Name: TeleRehab Aermos Cardiopulmonary Rehabilitation
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, MWI, DRT
Dated: May 1, 2025
Received: May 2, 2025

Dear Matthew Tarler:

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,

Kimberly N. Crowley -S

Digitally signed by Kimberly N. Crowley -S

For: Jennifer Kozen
Assistant Director
DHT2A: Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
OHT2: Office of Cardiovascular 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250259

Device Name

TeleRehab Aermos Cardiopulmonary Rehabilitation

Indications for Use *(Describe)*

The TeleRehab Aermos Cardiopulmonary Rehabilitation System is intended to acquire and condition the ECG signal from a patient so that it can be transmitted wirelessly from a radiofrequency transmitter to a workstation in a hospital or a clinical setting where the data is displayed and analyzed. This device also measures heart rate and provides visual and audible alarms if the patient's heart rate goes out of a prescribed range. This device is for use with ambulatory adult patients who need monitoring while undergoing cardiovascular or pulmonary rehabilitation. The physiological data from monitoring and other patient information (such as patient demographics, exercise protocol and medical information) is stored in a database for tracking and reporting of the patients' progress through rehabilitation.

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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cardiovascular solutions

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510(k) Summary

1. Sponsor/Applicant

The ScottCare Corporation
4791 West 150th Street
Cleveland, Ohio 44135

Dr. Matthew Tarler
Phone Number: (216) 362-0550 x113
Email: regulatory@scottcare.com
Fax: (216) 267-6129

Summary Preparation Date: May 01, 2025

2. Device

Trade Name	TeleRehab® Aermos Cardiopulmonary Rehabilitation System
Model Number	102206
Classification	Class II
Product Code	DRG DRT
Regulation Number	21 CFR 870.2910 21 CFR 870.2300
Review Panel	Cardiovascular

3. Predicate Device

ers2 - ergoline Rehabilitation System ("ers2") - K212883

Reference Device

iT20 Telemetry Transmitter - Edan Instruments, Inc. - K161056

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4. Device Description

The TeleRehab® Aermos Cardiopulmonary Rehabilitation System ("Aermos") provides the ECG monitoring functionality required for performing rehabilitation of cardiovascular and/or pulmonary patients. Patients' ECG may be monitored using the Aermos system during exercise under clinical supervision. During monitoring, Aermos provides both visual and audible alarms if the patient's heart rate goes out of a prescribed range. The heart rate alarm indication is one of multiple inputs a clinician may use to modify and adjust rehabilitation activities such as decreasing the patient's level of physical exertion or halting the exercise entirely.

Aermos also provides the ability to plan a patient's rehabilitation program and document the patient's progress through the creation of various types of reports. The report types supported in Aermos include individual treatment plan reports, daily exercise session reports and various patient information reports. Additionally, the Aermos system provides the ability to transfer various report types to the hospital Electronic Medical Records system.

The main components of Aermos are Argus ECG transmitters, the Aermos Workstation and associated networking equipment.

5. Indications for Use

The TeleRehab® Aermos Cardiopulmonary Rehabilitation System is intended to acquire and condition the ECG signal from a patient so that it can be transmitted wirelessly from a radiofrequency transmitter to a workstation in a hospital or a clinical setting where the data is displayed and analyzed. This device also measures heart rate and provides visual and audible alarms if the patient's heart rate goes out of a prescribed range. This device is for use with ambulatory adult patients who need monitoring while undergoing cardiovascular and/or pulmonary rehabilitation. The physiological data from monitoring and other patient information (such as patient demographics, exercise protocol and medical information) is stored in a database for tracking and reporting of the patients' progress through rehabilitation.

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6. Technological Characteristics and Substantial Equivalence

	Subject Device	Predicate Device	Reference Device	Comparison
Device	**Aermos**	**ers2**	**iT20 Telemetry Transmitter**	
Applicant	**The ScottCare Corporation**	**ergoline GmbH**	**Edan Instruments, Inc.**	
510(k) #	**K250259**	**K212883**	**K161056**	
Device Class	Class II	Class II	Class II	Same
Regulation	21 CFR 870.2910 21 CFR 870.2300	21 CFR 870.2910	21 CFR 870.1025 21 CFR 870.2300 21 CFR 870.2700 21 CFR 882.1320 21 CFR 870.2340 21 CFR 870.2910	Similar(1)
Classification Code	DRG DRT	DRG	MHX, DSI, MLD, DRT, DQA, GXY, DPS, DRG	Similar(1)
Prescription/ OTC Use	Prescription	Prescription	Prescription	Same
Indications for Use	The TeleRehab® Aermos Cardiopulmonary Rehabilitation System is intended to acquire and condition the ECG signal from a patient so that it can be transmitted wirelessly from a radiofrequency transmitter to a workstation in a hospital or a clinical setting where the data is displayed and analyzed. This device also measures heart rate and provides visual and audible alarms if the patient's heart rate goes out of a prescribed range. This device is for use with ambulatory adult patients who need monitoring while undergoing cardiovascular and/or pulmonary rehabilitation. The physiological data from monitoring and other patient information (such as patient demographics, exercise protocol and medical information) is stored in a database for tracking and reporting of the patients' progress through rehabilitation.	The ers2 – ergoline Rehabilitation System is a device for recording of a single channel, bipolar surface ECG (frontal plane) acquired with two ECG electrodes. The ECG is transmitted to the ers2 software where it is processed for heartrate calculation, displayed for visual QRS complex assessment and to control the training load for a patient´s rehabilitation or preventive training activities. The ers2 system is not intended to be used to detect or diagnose cardiac conditions (e.g. arrhythmias, ST- elevation, etc. pp). The signal is acquired on the intact skin of adult patients. The medical device is intended for use in professional healthcare Institutions for inpatient and outpatient care.	The iT20 telemetry transmitter is intended to monitor physiological parameters including: ECG, oxygen saturation of arterial blood (SpO2) and pulse rate (PR) for adults and pediatric patients. The iT20 requires the EDAN MFM-CMS (Central Monitoring Station) to provide full functionality of the device. The iT20 telemetry transmitter is intended to be used in clinical divisions of hospital environments, including CCU and general wards (as Cardiology Dept.).	Similar(2)
Intended Population	Adult	Adult	Adult / Pediatric	Same
Intended Environment	Healthcare facility (e.g. hospital or clinic)	Healthcare facility (e.g. hospital or clinic)	Healthcare facility (e.g. hospital or clinic)	Same

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Number of ECG Channels	1	1	Multiple	Same
ECG Transmitter Patient Cable	3 lead wires	2 lead wires	3 or 5 lead wires	Similar(3)
ECG Electrode Type	Off-the-shelf standard ECG electrodes	Off-the-shelf standard ECG electrodes	Off-the-shelf standard ECG electrodes	Same
ECG Transmitter Acquisition	Frequency response: 0.05 - 100 Hz Dynamic range: ±5.0 mV	Frequency response: 0.05 – 125 Hz Dynamic range: ±6.0 mV	Monitor: 0.5Hz to 40Hz Range: ±2.0 mV	Similar(4)
ECG Transmitter Data Transmission Method to Workstation	Radiofrequency - WiFi 802.11 b/g/n, 2.4 GHz via off-the-shelf Wireless Access Point and Network Router	Radiofrequency Bluetooth 2402 – 2483.5 MHz	Radiofrequency - WiFi 802.11 b/g/n, 2.4 GHz	Similar(5)
Pacemaker Pulse Detection	Yes	No	Yes	Different
Heart Rate Display	Yes	Yes	Yes	Same
ECG Display	Yes	Yes	Yes	Same
Heart Rate Alarm	Yes	Yes	Yes	Same
Defibrillation Protection	Yes	Yes	Not Available	Same
Workstation	PC with Microsoft Windows	PC with Microsoft Windows	Requires EDAN MFM-CMA (Central Monitoring Station) - Windows based OS	Same
Key Safety and Performance Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-27 IEC 60601-1-8	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-27	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-27 IEC 60601-1-8 EC13 ISO 80601-2-61 IEC 60601-2-49 ISO 10993-1,5,5-10	Similar(6)

(1) The proposed Aermos device and predicate device both have the same indications for use, intended population, and intended environment, hence the DRT code. Based on the Aermos device having heart rate alarms the DRT code (regulation 870.2300) is also included in addition to the DRG code. The reference device includes the DRT code and serves as a predicate for presentation of heart rate alarms.

(2) Like the predicate, the proposed Aermos device is intended for monitoring ambulatory adult patients who need ECG monitoring while undergoing cardiovascular and/or pulmonary rehabilitation in a hospital or clinic setting. Both systems capture ECG signal from the patient using an ECG transmitter, transmit it to a Windows-based workstation via RF transmission and display the ECG data on a computer monitor.

(3) The subject devices and the predicate device capture and display one channel of ECG using 3 lead wires and 2 lead wires respectively. The reference device also provides a 3 lead wire option. Safety and essential performance of the Aermos system was evaluated through compliance with the IEC 60601-2- 27 standard. Safety and performance of the Aermos patient cable was evaluated through compliance with the ANSI/AAMI EC53 standard. Therefore, this difference does not raise any new concerns for safety or effectiveness for the subject device's intended use.

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(4) The ECG acquisition performance of Aermos for its intended use has been verified through compliance with the IEC 60601-2-27 standard. Therefore, any differences in this regard do not raise new concerns of safety or effectiveness for the subject device's intended use.

(5) The Aermos system and the reference device uses WiFi for transmission of ECG data from its ECG transmitter to its workstation, while the predicate uses Bluetooth 2402 – 2483.5 MHz radiofrequency band for data transmission. The safety and performance of the WiFi transmission of Aermos was evaluated through compliance with the ANSI C63.27 and IEC 60601-1-2 standards. The device was also evaluated per FDA guidance documents "Radio Frequency Wireless Technology in Medical Devices 2013" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices 2023", and consensus document "AAMI TIR69:2017 Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems." Therefore, the use of Wi-Fi does not raise new concerns of safety or effectiveness for its intended use.

7. Non-clinical Bench (Performance) testing

Aermos' specifications were verified through internal verification testing and its customer requirements and usability were evaluated through internal validation testing.

Software verification and validation testing were conducted at the unit, integration, and system levels, and documentation is provided as recommended in FDA's "Guidance for the Content of Premarket Submissions for Device Software Functions: Guidance for Industry and FDA Staff" (June 2023). The software for this device requires an Enhanced Documentation level, since the device "could present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use" and the guidance recommends that "[t]hese risks should be assessed prior to implementation of risk control measures."

Cybersecurity concerns and documentation were addressed as recommended by FDA's "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions: Guidance for Industry and FDA Staff" (Sept. 2023). A complete risk-based cybersecurity assessment and testing in accordance with the FDA guidance document was performed.

Internal and external testing for cleaning and disinfection verification and validation was performed as per FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff" (Mar. 2015).

Safety and effectiveness of Aermos is demonstrated through testing conducted in compliance with the following standards and guidance documents:

- IEC 60601-1:2020, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

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- IEC 60601-1-2:2020, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic disturbances – Requirements and Tests
- IEC 60601-1-6:2020, Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
- IEC 60601-1-8:2020, General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
- IEC 60601-2-27:2011, Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- ANSI/AAMI EC57: 2012, Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measure Algorithms
- ANSI C63.27-2017, American National Standard for Evaluation of Wireless Coexistence
- Applicable requirements from the Recognized Consensus Document “AAMI TIR69:2017 Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems”
- IEC 62304:2015, Medical device software - Software life-cycle processes
- Applicable requirements from FDA Guidance Document “Radio Frequency Wireless Technology in Medical Devices:Guidance for Industry and FDA Staff” (Aug. 2013)
- Applicable requirements from FDA Guidance Document “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff” (Sept. 2023)
- Argus Battery complies with the standard IEC 62133:2012, Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
- Argus Patient Cable complies with the standard ANSI/AAMI EC53:2013, ECG trunk cables and patient lead wires
- ISO 14971:2019, Medical Devices - Application Of Risk Management To Medical Devices
- IEC 60601-4-2 - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

8. Clinical Testing

Not applicable.

9. Conclusion:

Based on the intended use, technological characteristics, and performance data provided in the submission, the Aermos device is substantially equivalent to the predicate device. The differences between the Aermos device and the predicate do not raise any questions regarding safety and effectiveness.