July 15, 2022

ergoline GmbH
Alexandra Lertz
Quality Manager
Lindenstrasse 5
Bitz, Hessen 72475
Germany

Re: K212883
Trade/Device Name: ers2 - ergoline Rehabilitation System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: May 30, 2022
Received: June 3, 2022

Dear Alexandra Lertz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212883

Device Name
ers2 – ergoline Rehabilitation System

Indications for Use *(Describe)*
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.

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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510(k) Summary
for
ers2 - ergoline Rehabilitation System

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirement of 21 CFR 807.92

Sponsor

Sponsor: ergoline GmbH
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Germany

Contact Person: Mr. Andreas Maurer
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Date Prepared: May 31, 2022

510(k) number: K212883

Device Name and Classification

Proprietary Name: ers2 - ergoline Rehabilitation System

Common/Usual Name: Transmitters and receivers, physiological signal, radiofrequency

Classification Name: Cardiovascular Monitoring Devices
(21 CFR 870.2910, Product Code DRG)

Predicate Device

Predicate Device: TeleRehab 2004 Cardiopulmonary Rehabilitation System, K050778

Intended Use

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.

Device Description and Function

The Ergoline Rehabilitation System 2 consists of a) software (ers2) and b) hardware (ers2 1CH ECG Telemetry system).

a) The software system runs on a PC and is used by therapists to monitor, control and document the training sessions of rehabilitation patients (e.g. in endurance and strength training), whereby the patient can train on different devices or free without the support of devices. Free training can, for example, be performed on strength training equipment or through gymnastic exercises.
The central component of the ers2 system is a PC with an MS Windows operating system and special software which runs the training programs. The training ergometers are connected to the PC system via control lines or a WiFi interface. All data are shown on one to three 22-inch TFT monitors; up to eight patients can be displayed and supervised on each monitor.
The ers2 software receives the patient's physiological parameters from the ers2 1CH ECG Telemetry System and uses them for display on the monitor as well as to control the training devices.
Data are transferred between the wireless ergoline ECG transmitter and PC via Bluetooth©.

b) Via the applied part, the ers2 1CH ECG Transmitter acquires a single-channel, bipolar raw ECG signal and sends it to a medical application software or other ME equipment by radio transmission.
The ers2 1CH ECG transmitter is an ME device powered from integrated, exchangeable, rechargeable batteries

These are the components of the ers2 1CH ECG Telemetry system:

- ers2 1CH ECG Transmitter consisting of enclosure, ECG amplifier, radio transmission module, micro-controller with firmware and device connector for connection of the ECG adapter, is worn on the body near the heart and affixed to the ETS1 adapter no skin contact, accessible part, type CF.
- The ers2 1CH ECG adapter (applied part, ECG patient connection) with device socket for connection to the ECG transmitter and device socket for connection to the patient connection (ECG electrode), is worn on the body near the heart, type CF.
- ers2 ECG receiver, receives the ECG signals transmitted by radio. Permanently connected to USB port of a Windows PC. Operated outside patient environment, accessible part, protection class II.

Predicate Device Comparison

General

Table 1: Basic Device Characteristics – Comparison with Predicate Device

Characteristic	**New Device**	**Primary predicate device**	**Similar / Different**
510(k) Number	K212883	K050778	-

Device Name, Model	ers2 - ergoline Rehabilitation System	TeleRehab 2004 Cardiopulmonary Rehabilitation System	-
Manufacturer	ergoline GmbH	ScottCare	-
Regulation Number	890.2910	890.2910	Similar
Product code	DRG	DRG	Similar
Indications for Use	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.	This device is intended to acquire and condition the ECG signal from a patient so that it can be transmitted via radio frequency (WMTF) with a Stickman telemetry transmitter to a workstation in a hospital or clinical setting where the ECG is displayed and analyzed. This device is for use with ambulatory adult patients, which need monitoring while undergoing cardiac or pulmonary rehabilitation. The data output from monitoring is viewed and stored on a workstation for tracking of the patients' progress through rehabilitation. Patient demographics, exercise protocol and medical information can be entered via a variety of commercially available wireless input devices or automatically through an HL-7 hospital network interface. A database can be created for use with an Outcomes program.	Similar besides different frequency bands and a different proprietary protocol to encode the transmitted data
Transmission signal	Radiofrequency	Radiofrequency	Similar

Transmission equipment	Telemetry transmitter and receiver	Telemetry transmitter and receiver	Similar
Frequency band	2402 – 2483,5 MHz	608-614MHz	Different
Frequency response	0.05 – 125 Hz	0.05 – 100 Hz	Similar
Dynamic Range	± 6 mV	± 5 mV	Similar
Rejection Ratio	> 80 dB	80 dB	Similar
Type	CF, defibrillation protected	CF, defibrillation protected	Similar
Defibrillation Recovery	Within 5 seconds	Within 8 seconds	Similar
Maximum distance	164 feet	100 feet	Different
Displayed parameters	ECG, HR, Thr; Load and RPM, Slope and speed, BP, CAL, METS	ECG, HR, SpO2, BP, THR, CAL, METS, RHR, RBP	Similar for the intended use
Connection of the device to electrodes	Electrodes are connected via cables to the adapter and thus to the transmitter.	Electrodes are connected via cables directly to the transmitter	Different
Electrodes	2 standard 510(k) cleared sticking electrodes	3 or 5 standard 510(k) cleared sticking electrodes	Similar
Power Source(s)	Transmitter: 1 x HR03/AAA NiMH rechargeable battery, 1.2 V	Transmitter: 3x AAA, alkaline batteries, 1.5 V	Different
Battery life	6 hours, rechargeable	60 hours	Different
- Method of Line Current Isolation	Power Supply in accordance with IEC 60601-1	Power Supply in accordance with IEC 60601-1	Similar
Operator	Professional user in a clinical setting	Professional user in a clinical setting	Similar
Compliance with 21 CFR 898? **(Mandatory since May 9, 2000)**	Yes	Yes	Similar
Lead wires – cables	M-PUR: Compliant with protected lead wire and patient cable safety requirements	DIN: Compliant with protected lead wire and patient cable safety requirements	Different
Patient contact material	**Cord:** Silicone, ELASTOSIL® R Plus 4001/60 MH (WACKER) **ECG leadwires with**	**Cord:** DIN style shielded lead wire **ECG leadwires with electrode clips:**	Different

	electrode clips: **M-PUR** **Electrodes:** Standard 510(k) cleared sticking electrodes, not included with the device **Adapter base:** TPE, THERMOLAST® M TM9MED (TPE Kraiburg) Colorant: Masterbatch Blau (Pantone 7451 U) **Transmitter:** SINKRAL L 322 - ABS	**M-PUR** **Electrodes:** Standard 510(k) cleared sticking electrodes, not included with the device **Transmitter:** Polymer	
Environmental conditions:	**Temperature:** -20 – 65 °C **Relative Humidity:** 10 – 95 %	**Temperature:** **10 – 40 °C** **Relative Humidity:** **10 – 90 %**	Similar
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-27 ANSI/AAMI EC53 EN 61000-4-2 EN 61000-4-3 EN 61000-4-6 EN 61000-4-8 EN 55011 EN 55032 ISO 14971 IEC 62366-1 IEC 62304 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12 ISO 10993-18	IEC 60601-1 IEC 60601-1-2 ANSI/AAMI EC-13 EN 61000-3-2 EN 61000-3-3 EN 61000-4-2 EN 61000-4-3 EN 61000-4-4 EN 61000-4-5 EN 61000-4-6 EN 61000-4-8 EN 55011	Similar

Performance Testing

Electrical Safety and Electromagnetic Compatibility testing: ers2 - ergoline Rehabilitation System was tested according to and is in compliance with recognized standards for electrical safety and electromagnetic compatibility.

Software and System validation: The ers2 - ergoline Rehabilitation System comprises “ETS1 Transmitter firmware” and the software “ers2 software” which were verified and validated according to IEC 62304. Software validation demonstrated that the “ETS1 Transmitter firmware” and “ers2 software” met the software system requirements.

Usability validation: The overall system was validated to confirm that the device meets its intended use, i.e. can be used as intended by the specified users within the specified use environment, taking into account human factors and usability requirements.

Performance Standards

The ers2 - ergoline Rehabilitation System complies with the applicable requirements of the following international and national standards:

- IEC 60601-1:2005 + A1:2012 - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2014 - Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-27:2011 + COR1:2012 - Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- IEC 62304:2006 + A1:2015 - Medical Device Software - Software Life Cycle Processes
- ISO 14971:2019 - Medical Devices - Application Of Risk Management To Medical Devices
- IEC 62366-1:2015 + COR1:2016 - Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices
- ISO 10993-1:2018 - Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
- ISO 10993-5:2009 - Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10:2010 - Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 10993-12:2012 - Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- ISO 10993-18:2020: Biological evaluation of medical devices – Part 18: Chemical characterization of materials

- ANSI AAMI EC53:2013/(R)2020 - ECG trunk cables and patient leadwires
- EN 55011:2011 - Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
- EN 55032:2016 - Electromagnetic compatibility of multimedia equipment - Emission Requirements
- ISO 15223-1: 2016: Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements
- ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

The following FDA Guidance Documents have been applied:

- FDA: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, 2005
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, 2014
- Off-The-Shelf Software Use in Medical Devices, 2019
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", 2020
- Radio Frequency Wireless Technology in Medical Devices, 2013
- Applying Human Factors and Usability Engineering to Medical Devices, 2016
- Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, 2017
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, 2015

Conclusion

Both the subject and the predicate device have a similar intended use and use comparable technical features. They both fulfill the same applicable standards for Medical Electrical Equipment.
However, the devices differ in terms of a different frequency band and a different proprietary protocol to encode the transmitted data as well as different patient superficial contacting material.
Fulfilling all applicable FDA-recognized consensus standards for Radio Frequency Wireless Technology, Electromagnetic Compatibility and Biocompatibility, no further questions regarding safety and performance are raised. Both devices are deemed to be substantially equivalent.