Alber GmbH
% Michael Vent
RA- Consultant
BEO MedConsulting Berlin GmbH
Helmholtzstr. 2-9
Berlin, 10587
Germany

Re: K221215
Trade/Device Name: e-motion M25 DuoDrive
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: April 11, 2022
Received: April 27, 2022

Dear Michael Vent:

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 Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Neuromodulation & Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K221215

Device Name
e-motion M25 DuoDrive

Indications for Use *(Describe)*
The e-motion M25 DuoDrive is a Power Assist Wheelchair Conversion Kit and suitable for the manual wheelchair users who are limited in their field of activities because of their physical conditions. The device can expand their field of activities by assisting their wheelchair operating force.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K221215

510(k) SUMMARY

Applicant:

Alber GmbH
Vor dem Weißen Stein 14
72461 Albstadt, Germany
Phone: +49 7432 2006-0
Fax: +49 7432 2006-299
Email: info@alber.de

Contact Person:

Mr Michael Vent
Phone: +49 30 318 045 30
Email: m.vent@beoberlin.de

Device:

Proprietary: e-motion M25 DuoDrive
Common Name: Power Assist Conversion Kit for Manual Wheelchairs
Classification Name: Powered wheelchair
Device Class: II, 21 CFR 890.3860
Classification Panel: Physical Medicine
Product Code: ITI

Predicate Device:

510(k): K192618
Proprietary: e-motion M25
Common Name: Power Assist Conversion Kit for Manual Wheelchairs
Classification Name: Powered wheelchair
Device Class: II, 21 CFR 890.3860
Classification Panel: Physical Medicine
Product Code: ITI

Secondary Predicate Device:

510(k): K192016
Proprietary: SMOOV O10
Common Name: add-on drive for wheelchairs
Classification Name: Powered wheelchair
Device Class: II, 21 CFR 890.3860
Classification Panel: Physical Medicine
Product Code: ITI

Preparation Date:

20th May 2022

Indications for Use:

The e-motion M25 DuoDrive is a Power Assist Wheelchair Conversion Kit and suitable for the manual wheelchair users who are limited in their field of activities because of their physical conditions. The device can expand their field of activities by assisting their wheelchair operating force.

Change Information:

The change is a change of our own device, previously cleared in K192618.
The e-motion M25 (K192618) was upgraded with a wireless control unit (blutooth rotary wheel, formerly also called blutooth clickwheel) that was cleared with the 510(k) of our own device smoov O10, cleared in 510(k) K192016. The detachable control unit allows access to the driving mode called "cruise mode". This mode already existed in the cleared e-motion M25, but it was only accessible by using the smartphone app.

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Alber GmbH · Vor dem Weißen Stein 14 · D-72461 Albstadt
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D-72461 Albstadt

As the manufacturer of all involved products and components, we made the change under our design control process. In the following, the modified model will be called "e-motion M25 (DuoDrive)" to make it easier to distinguish.

Comparison of the modified device to the cleared

e-motion M25 (K192618)	e-motion M25 DuoDrive
Cruise mode via smartphone app (K192618)	Cruise mode via smartphone app and control unit (K192016)
User manual without control unit instructions	User manual with control unit instructions

Device Description:

The e-motion-M25 DuoDrive is a medical device for active wheelchair users who are reliant on a wheelchair as a result of their disability. The subject device e-motion is an additional drive for wheelchairs that is attached to a manual wheelchair, converting it into an electrically driven and thus significantly increasing the wheelchair user's mobility and flexibility.
To extend functionality an **optional** remote control (ECS) a smartphone app and a detachable control unit is available.

The user interacts with the e-motion M25 DuoDrive via two push-rims that trigger the assistive power drive.

The main parts of the drive unit are as follows:

- Pushrim-wheels including a brushless DC-motor
- Control electronic for the motor and wireless interface for communication with ECS remote control and smartphone app
- Integrated lithium ion battery pack with battery management system
- Magnetic charger socket for the integrated battery (Easy Connect) for connecting the battery charger
- Quick-release axle for attaching and detaching the drive unit to wheelchair-frame

The main function of the APP are as follows:

- Status information (battery, speed)
- Live display of error messages
- Recording of tours
- Selection of preset driving profiles
- ECS functionality (extra charge, details see below)
- Wheelchair navigation (extra charge)
- Enhance maximum speed (extra charge)
- Cruise mode (extra charge)
- Activation flight mode
- System information
- Error logfile (password protected)
- Setting auto shut-off time (password protected)
- Inidivial adjustment of driving parameters (password protected)

The main function of the ECS remote control are as follows:

- Switch between 2 assist level for indooir and outdoor
- Selection of learner mode (formerly also called Training mode)
- Activation of rollback delay (hill holder)
- Switch the wheels on and off (standby mode)

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D-72461 Albstadt

The main parts of the control unit are as follows:

- Wireless interface for communicating with the drive wheels
- Rotary wheel to start and change the cruise speed
- Rotary wheel to stop cruise mode (short push on the side)
- Rotary wheel to switch the drive wheels on and off/standy mode (long push on the side)
- Integrated Li-ion battery cell including battery management system
- USB-C socket for charging via drive unit or other external USB-C charger
- Display for operating status and remaining capacity of drive wheels and control unit

To charge the battery of the drive unit a battery charger is available. Main attributes:

- Multi-range charger 100-240 VAC, 50-60 Hz
- Automatic charging and switch-off mechanism
- Indicating status and mains

Power Wheel

Range:	up to 25 km as per ISO 7176 - 4
Nominal gradient:	16% [9°] - also note the limit values specified by the wheelchair manufacturer.
Maximum downhill grade:	Depends on the user and weight of the wheelchair. Also note the limit values specified by the wheelchair manufacturer
Cornering radius (minimum):	the limit values specified by the wheelchair manufacturer
Maximum speed:	Standard: 6 km/h to 8.5 km/h
Rated power of engine:	2x80W
Operating voltage:	36.5 VDC
Operating temperature:	-25° C to +50° C
Storage temperature:	-40° C to +65° C
Weight of person:	max. 150 kg
Max. permissible overall weight:	180 kg
Protection rating:	IPx4

Battery pack

Cell type:	Lithium-ion 10ICR19/66-2
Rated operating capacity:	36.5 V
Rated capacity:	Ah
Rated energy:	Wh
Charging temperature:	0° C to +45° C
Operating temperature:	-25° C to +50° C
Protection rating:	IPX4

ECS remote control

Cell type:	AAA
Rated voltage:	3x1.5 VDC
Rated capacity:	750 … 1000mAh

Control unit

Cell type:	Lithium-ion 18650
Rated voltage:	3.6 VDC
Rated capacity:	2.6 Ah
Rated energy:	9.36W

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Charging temperature:	
Operating temperature:	

Charger

Model:	PS 4820
Mains voltage:	100...240 VAC, 50...60 Hz
Power output:	96 W
Output voltage:	2x48 VDC
Output current:	2x1.0 A
Protection rating:	IP 31
Ambient temperature:	Operation 0...40 °C
Storage	-40…+65 °C
Humidity:	Operation 10...80%
Storage	5…95%
Air pressure:	Operation 500…1060 hPa
Storage	700…1060 hPa

Weight of components

Wheel (including battery):	7.8 kg
ECS remote control (including battery):	0.25 kg
Control unit (including battery)	0.25 kg
Battery charger:	1.2 kg
Total weight:	15.6 kg

Radio Frequency Wireless Technology

Power Unit

Type of wireless technology	EEE 802.15.4 (BLE & Classic)
FCC compliance:	CFR47, Part 15
FCC ID:	A8TBM78ABCDEFGH
Wireless Coexistence Compliance:	ANSI C63.27-2017, separation distance ≥0.25m
EMC compliance	ISO 7176-21:2009
RF frequency range:	2.402 GHz to 2.480 GHz
RF maximum output power:	1.5dBm
Wireless operating range:	10m / class 2
Wireless functions:	Speed, emergency stop, operating mode (on/standby)

ECS remote control

Type of wireless technology:	IEEE 802.15.4 (Bluetooth Low Energy)
FCC compliance:	CFR47, Part 15
FCC ID:	ZAT26M1
Wireless Coexistence Compliance:	ANSI C63.27-2017, separation distance ≥0.25m
EMC compliance:	ISO 7176-21:2009
Wireless RF frequency range:	2.402 GHz to 2.480 GHz
Wireless RF maximum output power:	5dBm
Wireless operating range:	10m / class 2
Wireless functions:	Speed, emergency stop, operating mode (on/standby)

Control Unit

Type of wireless technology:	IEEE 802.15.4 (Bluetooth Low Energy)
FCC compliance:	CFR47, Part 15
FCC ID:	ZAT26M1
Wireless Coexistence Compliance:	ANSI C63.27-2017, separation distance ≥0.25m

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EMC compliance:	ISO 7176-21:2009
Wireless RF frequency range:	2.402 GHz to 2.480 GHz
Wireless RF maximum output power:	5dBm
Wireless operating range:	10m / class 2
Wireless functions:	Speed, emergency stop, operating mode (on/standby)

Cybersecurity assessment/mitigation, including SweynTooth vulnerabilities evaluation

SweynTooth affects the wireless communication technology known as Bluetooth Low Energy (BLE). BLE allows two devices to "pair" and exchange information to perform their intended functions while preserving battery life. The technology can be found in medical devices as well as other devices, such as consumer wearables. SweynTooth may allow an unauthorized user to wirelessly crash the device (crash), stop it from working (deadlock), or access device functions normally only available to the authorized user (bypass security).

These vulnerabilities cannot be exploited remotely, and all of these attacks require that the device Bluetooth is enabled and that the attacker is within close physical proximity (i.e., within Bluetooth range) of the device.

Our preventive actions to avoid harm: All wireless communication is encrypted.

In the unlikely event a successful attack, the e-motion M25 DuoDrive:

- Normal drive mode - An attack during this mode has no influence on driving behaviour as the e-motion M25 (DuoDrive) acts in this mode independent from any wireless devices.
- Cruise Mode - The motor driving support stops in order to enter the safe state of the system (=no more auxiliary power provision). Unintended movements are impossible. In any cases the connection is lost; you are always able to react to avoid dangerous situations by moving away from the danger zone by propelling the system like an e-motion M25 DuoDrive in the normal drive mode.
- Remote Mode - (Wheelchair is un-occupied – see App instruction for use): The motor driving support stops in order to enter the safe state of the system (=no more auxiliary power provision). Unintended movements are impossible.

Comparison to the Predicate Device

	SUBJECT DEVICE e-motion M25 DuoDrive	PREDICATE DEVICE e-motion M25 (K192618)	SECONDARY PREDICATE DEVICE SMOOV O10 (K192016)
Indication For Use	The e-motion M25 is a Power Assist Wheelchair Conversion Kit and suitable for the manual wheelchair users who are limited in their field of activities because of their physical conditions. The device can expand their field of activities by assisting their wheelchair operating force.	The e-motion M25 is a Power Assist Wheelchair Conversion Kit and suitable for the manual wheelchair users who are limited in their field of activities because of their physical conditions. The device can expand their field of activities by assisting their wheelchair operating force.	The "SMOOV" add-on drive for wheelchairs is intended to provide auxiliary power to manual wheelchairs to reduce the pushing power needed by their users. It is designed to provide support to active wheelchair users who are physically and mentally able to safely control a manual wheelchair in typical situations, including inclines, even manually.
Intended Use	The e-motion M25 is a medical device for active wheelchair users who are reliant on a wheelchair as a result of their disability.	The e-motion M25 is a medical device for active wheelchair users with a user weight of 150 kgs and who are reliant on a wheelchair as a result of their	The SMOOV is a medical device for active wheelchair users who are reliant on a wheelchair as a result of their disability. The SMOOV is an

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	The e-motion M25 replaces the wheels that are attached to a manual wheelchair, converting it into an electrically driven wheelchair and thus significantly increasing the wheelchair user's mobility and flexibility. The e-motion M25 must always be used, transported, maintained and serviced strictly according to the manufacturer's instructions. The e-motion M25 must only be attached to and operated with wheelchairs that are listed in Alber's mounting database. The selection is made by the specialist dealer or by Alber itself.	disability. The e-motion M25 replaces the wheels that are attached to a manual wheelchair, converting it into an electrically driven wheelchair and thus significantly increasing the wheelchair user's mobility and flexibility. The e-motion M25 must always be used, transported, maintained and serviced strictly according to the manufacturer's instructions. The e-motion M25 must only be attached to and operated with wheelchairs that are listed in Alber's mounting database. The selection is made by the specialist dealer or by Alber itself.	add-on drive for wheelchairs that is attached to a manual wheelchair, converting it into an electrically driven wheelchair and thus signific- antly increasing the wheelchair user's mobility and flexibility. The SMOOV must always be used, transported, maintained and serviced as described in this operating manual. The SMOOV must only be attached to and operated with wheelchairs that are listed in Alber's mounting database. The selection is made by the specialist dealer or by Alber itself.
Permissible conditions of use/locations of operation **Type Environment of Use**	• Observe the permissible conditions of use of the wheelchair to which the e-motion M25 (DuoDrive) is attached. • In addition to observing the information provided about the e-motion M25 (DuoDrive), it is also imperative to observe the information provided by the wheelchair manufacturer (e.g. maximum gradeability, maximum permissible height of obstacles, maximum user weight, maximum speed, etc.). The lowest values always apply. • Any limits regarding the operation of your wheelchair (e.g. maximum gradeability, maximum permissible height of obstacles, maximum user weight etc.) must also be observed when using the M25. • The e-motion M25 (DuoDrive) must only be operated at temperatures between -25 °C and +50 °C. Therefore, do not expose the smoov to any heat sources (such as intense sunlight) as this may cause surfaces to reach high temperatures. • The e-motion M25 (DuoDrive) is designed for indoor and outdoor use (e.g. solid pavement), avoid using the wheelchair on soft ground (e.g. loose chipping, sand, mud, snow, ice or deep puddles).	• Observe the permissible conditions of use of the wheelchair to which the M25 is attached. • In addition to observing the information provided about the M25, it is also imperative to observe the information provided by the wheelchair manufacturer (e.g. maximum gradeability, maximum permissible height of obstacles, maximum user weight, maximum speed, etc.). The lowest values always apply. • Any limits regarding the operation of your wheelchair (e.g. maximum gradeability, maximum permissible height of obstacles, maximum user weight etc.) must also be observed when using the M25. • The e-motion M25 must only be operated at temperatures between -25 °C and +50 °C. Therefore, do not expose the smoov to any heat sources (such as intense sunlight) as this may cause surfaces to reach high temperatures. • The e-motion M25 is designed for indoor and outdoor use (e.g. solid pavement), avoid using the wheelchair on soft ground (e.g. loose chipping, sand, mud, snow, ice or deep puddles).	• Observe the permissible conditions of use of the wheelchair to which the smoov is attached. • In addition to observing the information provided about the smoov, it is also imperative to observe the information provided by the wheelchair manufacturer (e.g. maximum gradeability, maximum permissible height of obstacles, maximum user weight, maximum speed, etc.). The lowest values always apply. • Any limits regarding the operation of your wheelchair (e.g. maximum gradeability, maximum permissible height of obstacles, maximum user weight etc.) must also be observed when using the smoov. • The SMOOV O10 must only be operated at temperatures between -25 °C and +50 °C. Therefore, do not expose the smoov to any heat sources (such as intense sunlight) as this may cause surfaces to reach high temperatures. • The SMOOV O10 is designed for light outdoor use (e.g. solid pavement), avoid using the wheelchair on soft ground (e.g. loose chipping, sand, mud, snow, ice or deep puddles).

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Market Segment	Active	Active	Active
Wheelchair Compatibility	• manually propelled wheelchairs with rigis or folding frames • Quick-release-axle	• manually propelled wheelchairs with rigis or folding frames • Quick-release-axle	• Rigid W/C frames: Universal brackets on the axle tube • Folding frames: adapter axle required
Available Wheelchair Wheel-Diameters (inch)	22", 24", 25"	22", 24", 25"	Compatible with wheel diameter 22" - 26"
Device Wheel Dimensions (inch)	22", 24", 25"	22", 24", 25"	Diameter: 6.4" Width: 3,9"
Max. user weight (kg)	150kg	150kg	140
System weight (kg)	15.85kg	15.6kg	7,95kg
Nominal Power (Watt)	2x80W	2x80W	250W
Max. assisted Speed (km/h)	6…8.5km/h	6…8.5km/h	6 / 10km/h
Nominal Range (km)	25km	25km	20km
Assist Levels	Push-force support	Push-force support	Speed adjustments stepless via clickwheel
Control Units	Pushrims & ECS remote control & smartphone app & Control unit attached to W/C	Pushrims & ECS remote control & smartphone app	Control unit = Bluetooth clickwheel attached to W/C
Adjustment of drive parameters	Acceleration in 2 modes: indoor, outdoor, learner mode	Acceleration in 2 modes: indoor, outdoor, learner mode (formerly also called Training mode)	acceleration and speed depending on the angle of the drive wheel, 4 programmable driving modes. STOP pushbutton
Smartphone App & ECS & Control unitfor end user	App • Cockpit (drive-, tour-data) • Navigation • Drive-Mode (Cruise/Speed) • Remote • ECS (find below) ECS • Pairing • Reset • Assist level (indoor / outdoor) • Learner mode • Roll-Back-Prevention • Sleep-Mode Control unit • Pairing • Reset • Turn on/off • Drive mode (Cruise/Speed)	App • Cockpit (drive-, tour-data) • Navigation • Drive-Mode (Cruise/Speed) • Remote • ECS (find below) ECS • Pairing • Reset • Assist level (indoor / outdoor) • Learner mode (formerly also called Training mode) • Roll-Back-Prevention • Sleep-Mode	App Android and iOS Free features: Cockpit, battery capacity, range, tour computer via GPS, 4 programmable driving modes, On/Off rear light, worldwide service contact details, firmware updates over the air, failure and warnings chargeable: Navigation Control unit • Pairing • Reset • Turn on/off • Drive mode (Cruise/Speed)

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Conclusion:

The conclusions drawn from the nonclinical tests including a benefit-risk assessment demonstrate that the changed device is as safe, as effective, and performs as well as the legally marketed predicate device.

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