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

Re: K192618
Trade/Device Name: e-Motion M25
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: July 28, 2020
Received: August 6, 2020

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,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K192618

Device Name
e-motion M25

Indications for Use *(Describe)*
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.

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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K192618

510(k) SUMMARY

Applicant: Alber GmbH
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Contact Person: Mr Michael Vent
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Email: m.vent@beoberlin.de

Device: 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

Prepared Date: 25th October 2020

Predicate Device Information:

We claim substantial equivalence for the subject device "e-motion M25" in indications for use, design and function to the primary predicate device twion M24 (K151717) and in wireless technology to the secondary predicate device SMOOV O10 (K192016), both PDs by Alber GmbH.

Indications 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.

Intended Use:

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 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.

Device Description:

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 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) and a Smartphone App is available.

The user interacts with the e-motion M25 via push-rim that triggers 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 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-Funtionality (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 are as follows:

- Drive-Mode
- Settings
- Diagnostics

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

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

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 (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

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)

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 in the:

- Normal drive mode - An attack during this mode has no influence on driving behaviour as the e-motion M25 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 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 (K192618)	PRIMARY PREDICATE DEVICE Twion M24 or T24 (K151717)	SECONDARY PREDICATE DEVICE SMOOV O10 (K192016)
Indication For 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 subject device e-motion is an additional drive for wheelchairs that is attached to a manual wheelchair, by amplifying the user's push the device significantly increases the wheelchair user's mobility and flexibility. The e-motion M25 offers wireless connectivity.	The twion M24 Wheelchair Drive System is a Power Wheelchair Conversion Kit that adds a power assist to a manual wheelchair, thereby, turning a manual wheelchair into a power-assisted wheelchair. It is a push-and-brake assist working in both directions. The intended use is to provide mobility to persons limited to a seated position that are capable of operating a powered and manual wheelchair.	The SMOOV O10 drive unit is attached and detached to rigid wheelchairs via a bracket or alternatively to a foldable wheelchair with an optional adapter. The SMOOV O10 converts the user´s manual wheelchair, when needed, in a partly motorized wheelchair to extend the mobility and flexibility of the wheelchair user. To extend functionality an optional Smartphone App is available. The smoov add-on drive offers the same

	Certain features can be controlled by a smartphone app via Bluetooth connectivity.	The twion doesn't offer wireless connectivity.	wireless connectivity as the e-motion M25. Certain features can be controlled by a smartphone app via Bluetooth connectivity.
Permissible conditions of use/locations of operation **Type Environment of Use**	• 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 T24 is attached. • In addition to observing the information provided about the T24, 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 T24. • The twion M24 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 twion M24 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).
Market Segment	Active	Active	Active

Introduced to the market	spring 2020	2014	spring 2019
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"	24"	22" - 26"
Device Wheel Dimensions (inch)	22", 24", 25"	24"	Diameter: 6.4" Width: 3,9"
Max. user weight (kg)	150kg	120kg	140
System weight (kg)	15.6kg	12kg	7,95kg
Nominal Power (Watt)	2x80W	2x60W	250W
Max. assisted Speed (km/h)	6…8.5km/h	6…10km/h	6 / 10km/h
Nominal Range (km)	25km	15km	20km
Assist Levels	Push-force support	Push-force support	Speed adjustments stepless via clickwheel
Control Unit	Pushrim & ECS & Smratphone App	Pushrim	Bluetooth clickwheel attached to W/C
Adjustment of drive parameters	Acceleration in 2 modes: indoor, outdoor , Training Mode	none	acceleration and speed depending on the angle of the drive wheel, 4 programmable driving modes. STOP pushbutton
Smartphone App & ECS for end user	App • Cockpit (drive-, tour-data) • Navigation • Drive-Mode (Cruise/Speed) • Remote • ECS (find below) ECS • Pairing • Reset • Turn on/off • Drive-Mode (indoor / outdoor) • Training-Mode • Roll-Back-Prevention • Sleep-Mode		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

Predicate devices and the subject device are 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.
Both SD and PDs are provided as accessory to standard manual wheelchairs in order to provide assistive power for the user. Both devices, PD1 and SD are similar in their technological and performance characretistics The PD2 includs the wireless controller-components. It was also demonstrated that their technological characteristics are equivilant.
The devices are meant for Over-the-counter sale and do not require any set-up or training besides the instructions on the labeling.
Even the wording to describe the indications for use and the intended use slightly differ, the devices are considered substantially equivalent concerning these aspects.

The subject device is in conformity with the technical and performance requirements of the following FDA recognized Standards and Guidance Documents:

We declare the conformity with the recognized standards:

Standard	Name	Recognition#
ISO 10993-1:2009	Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process	2-220
ISO 10993-5:2009	Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	2-245
ISO 10993-10:2010	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	2-174
IEC 60335-2-29:2016	Safety of household and similar electrical appliances Part 2-29: Particular requirements for battery chargers	-
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 [Including: Corrigendum 1 (2013)]	19-13
UN 38.3	Recommendations of the TRANSPORT OF DANGEROUS GOODS, Manual of Test and Criteria, Part III, Lithium metal and lithium ion batteries	-
ISO 7176-1: 2014	Wheelchairs - Part 1: Determination Of Static Stability	16-195
ISO 7176-2: 2017	Wheelchairs - Part 2:Determination Of Dynamic Stability Of Electrically Powered Wheelchairs	16-202
ISO 7176-3: 2012	Wheelchairs - Part 3: Determination Of Effectiveness Of Brakes	16-192
ISO 7176-4: 2008	Wheelchairs - Part 4: Energy Consumption Of Electric Wheelchairs And Scooters For Determination Of Theoretical Distance Range	16-162
ISO 7176-5: 2008	Wheelchairs - Part 5: Determination Of Overall Dimensions, Mass And Manoeuvring Space	16-163
ISO 7176-6: 2018	Wheelchairs - Part 6: Determination Of Maximum Speed, Acceleration And Deceleration Of Electric Wheelchairs	16-204
ISO 7176-8: 2014	Wheelchairs - Part 8: Requirements And Test Methods For Static, Impact And Fatigue Strengths	16-197
ISO 7176-9: 2009	Wheelchairs - Part 9: Climatic Tests For Electric Wheelchairs	16-167
ISO 7176-10: 2008	Wheelchairs - Part 10: Determination Of Obstacle-Climbing Ability Of Electrically Powered Wheelchairs	16-164
ISO 7176-11: 2012	Wheelchairs - Part 11: Test Dummies	16-190
ISO 7176-13: 1989	Wheelchairs - Part 13: Determination Of Coefficient Of Friction Of Test Surfaces	16-25
ISO 7176-14: 2008	Wheelchairs - Part 14: Power And Control Systems For Electrically Powered Wheelchairs And Scooters - Requirements And Test Methods	16-165
ISO 7176-15: 1996	Wheelchairs - Part 15: Requirements For Information Disclosure, Documentation And Labeling	16-27
ISO 7176-21: 2009	Wheelchairs - Part 21: Requirements And Test Methods For Electromagnetic Compatibility Of Electrically Powered Wheelchairs And Scooters, And Battery Chargers	16-166
ISO 14971: 2007	Medical Devices - Application Of Risk Management To Medical Devices	5-40
ANSI C63.27-2017	American National Standard For Evaluation Of Wireless Coexistence	19-29
Guidance Document for the Preparation of Premarket Notification [510k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles		
Guidance for Industry and Food and Drug Administration Staff - Radio Frequency Wireless Technology in Medical Devices		
Guidance for Industry and Food and Drug Administration Staff - Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices		

Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

Non-clinical tests

Non-clinical tests according to the above listed recognized standards were performed to demonstrate safety and efficiency of the subject device. The testing included mechanical, electrical and biological safety as well as performance and other relevant aspects.

Clinical tests

Clinical tests were not conducted.

Quality Assurance and Manufacturing Controls:

Alber GmbH operates to certified quality managementsystem according to EN ISO 13485.

Conclusion:

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