May 19, 2020

Alber GmbH
Michael Vent
Official Correspondent for Alber GmbH
Vor dem Weißen Stein 21
Albstadt, 72461 DE

Re: K192016
Trade/Device Name: SMOOV O10
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: February 14, 2020
Received: February 19, 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
Acting 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192016

Device Name
SMOOV O10

Indications for Use *(Describe)*
The SMOOV O10 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.

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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K192016

510(k) SUMMARY

Applicant: Alber GmbH
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Contact Person: Mr Michael Vent
Phone: +49 30 318 045 30
Email: m.vent@beoberlin.de

Device: 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

Prepared Date: 18th May, 2020

Predicate Device Information:

We claim substantial equivalence for the subject device SMOOV O10 in intended use, design and function to the predicate device SmartDrive (MX2+) (K151199) by MaxMobility GmbH.

Indications for Use:

The SMOOV O10 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 SMOOV O10 is a medical device for active wheelchair users with a user weight of 140 kgs and who are reliant on a wheelchair as a result of their disability. The smoov is an 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.

Device Description:

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 user interacts with the SMOOV O10 via control unit mounted to the wheelchair for wireless interfacing with the drive unit. The control unit is used to switch on and off the power assistance and adjust the speed of the drive unit via the turnwheel.

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The main parts of the drive unit are as follows:

- Rotating drive wheel consisting of a brushless motor with tyre and aluminium fork
- Control Electronic for the motor and wireless interface for communication with control unit and optional smartphone App
- Integrated lithium ion battery pack with battery management system
- On/Off button and remaining capacity and operating mode indicator
- Carrying and release handle
- Magnetic charger socket for the integrated battery (Easy Connect) for connecting the battery charger
- USB-C socket to charge the control unit or a smartphone
- Position light
- Locking claw for attaching and detaching the drive unit to the bracket

The main parts of the control unit are as follows:

- Wireless interface for communicating with the drive unit
- On/Off button and speed setting knob
- 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 unit 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

Drive Unit

Range:	up to 20 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):	Double the width of the wheelchair (if using the smoov)
Maximum speed:	Standard: 6 km/h Optional: 10 km/h
Rated power of engine:	250 W
Operating voltage:	36 VDC
Operating temperature:	-25° C to +50° C
Storage temperature:	-40° C to +65° C
Weight of person:	max. 140 kg
Max. permissible overall weight:	170 kg
Protection rating:	IPX4

Battery pack

Cell type:	Lithium-ion 18650
Rated operating capacity:	36 V
Rated capacity:	6.2 Ah

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Rated energy:	224 Wh
Charging temperature:	0° C to +45° C
Operating temperature:	-25° C to +50° C
Protection rating:	IPX4

Control unit

Cell type:	Lithium-ion 18650
Rated voltage:	3.6 VDC
Rated capacity:	2.6 Ah
Rated energy:	9.36 Wh
Charging temperature:	0° C to +45° C
Operating temperature:	-25° C to +50° C

Charger

Model:	Smoov Charger
Mains voltage:	100...240 VAC, 50...60 Hz
Power output:	48 W
Output voltage:	48 VDC
Output current:	1.0 A
Protection rating:	IP X4
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

Drive unit (including battery):	7.2 kg
Control unit (including battery):	0.25 kg
Battery charger:	0.5 kg
Total weight:	7.95 kg (may differ depending on version or accessories)

Radio Frequency Wireless Technology

Drive Unit

Type of wireless technology	EEE 802.15.4 (Bluetooth Low Energy)
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)

Control Unit

Type of wireless technology:	IEEE 802.15.4 (Bluetooth Low Energy)
FCC compliance:	CFR47, Part 15
FCC ID:	ZAT26M1

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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. The chipset-manufacturers have issued patches to avoid external attacks. We have performed firmware updates on affected devices. These patches, made to address the vulnerabilities, don't affect device safety or effectiveness.

In the unlikely event a successful attack, the SMOOV O10 motor stops and the 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 SMOOV O10 (K192016)	PREDICATE DEVICE Smartdrive MX2 (K151199)
Indication For Use	The SMOOV O10 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.	The SmartDrive MX2 Wheelchair Power Assist is intended to provide auxiliary power to manual wheelchairs to reduce the pushing power needed by their users, including pediatrics. It is intended to be used by users capable of operating and maneuvering a powered and manual wheelchair.
Intended Use	The SMOOV O10 is a medical device for active wheelchair users with a user weight of 140 kgs and who are reliant on a wheelchair as a result of their disability. The smoov is an 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 Max Mobility SmartDrive Wheelchair Power Assist device is exclusively intended to provide auxiliary power to manual wheelchairs to reduce the pushing power needed by their users, including pediatrics, with a user weight of 30 to 331 lbs (14 - 150 kgs). It is intended to be used by users capable of operating and maneuvering a powered and manual wheelchair,

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	The SMOOV O10 must always be used, transported, maintained and serviced carefully to keep its performance, efficiency and safety. The SMOOV O10 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.	ultimately empowering them through enhanced mobility.
Permissible conditions of use/locations of operation **Type Environment of Use**	• 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).	• Do not operate over significantly rough terrain, very slick surfaces, extreme slopes, or loose ground. This may cause a loss of traction, leading to injury or damage to your SmartDrive and void the warranty. • The SmartDrive is not designed to drive up or down large curbs/steps. Only perform this maneuver when absolutely necessary and always ask for help. Also, be sure to turn off your SmartDrive wristband. • Use extreme caution when operating a SmartDrive at- tached wheelchair when near streets. Consider powering off the wristband to reduce the chance of accident or injury. • When crossing major roads, intersection, railway crossings or highways as well as when you drive steep, long slopes you should always consider having somebody accompany you in the interest of your safety. • With regards to driving up and down slopes, please adhere to the instructions and specifications given by the diverse wheelchair manufacturers. • Riding over curbs or obstacles can cause tipping and serious bodily harm. Turn off your SmartDrive wristband when attempting to ride in these situations. If you have any doubt that you can safely cross any curb or obstacle, ALWAYS ask for help. Be aware of your riding skills and personal limitations. Develop new skills only with the help of a companion.
Market Segment	Active	Active
Introduced to the market	spring 2019	2012 Smartdrive 2015 MX2 … MX2+

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Wheelchair Compatibility	• Rigid W/C frames: Universal brackets on the axle tube • Folding frames: adapter axle required	• Rigid W/C frames: Universal bracket on the axle tube • For folding W/C adapter axle required. This axle is firmly connected to the drive unit.
Available Wheelchair Wheel-Diameters (inch)	22" - 26"	22" - 26"
Device Wheel Dimensions (inch)	Diameter: 6.4“ Width: 3,9“	Diameter: 7.6“ Width: 2.8“
Max. user weight (kg)	140	150
System weight (kg)	7,2	6
Nominal Power (Watt)	250	250
Max. assisted Speed (km/h)	6 10	6 8,9
Nominal Range (km)	20	19,8
Assist Levels	Speed adjustments stepless via clickwheel	Keeps the speed by knocking on the wristband
Control Unit	Bluetooth clickwheel attached to W/C	Bluetooth wristband
Adjustment of drive parameters	acceleration and speed depending on the angle of the drive wheel, 4 programmable driving modes. STOP pushbutton	Acceleration and stop by tapping the wristband.
Smartphone App for end user	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	Android and iOS Primariliy statistical purpose (counting daily pushes, distance etc.), firmware updates over the air.

Both, predicate device SmartDrive MX2 and the subject device SMOOV O10 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 devices are provided as accessory to standard manual wheelchairs in order to provide assistive power for the user. Both devices are similar in their technological characteristics including their wireless controller-components. It was also demonstrated that their technological characteristics are equivalent.
Both 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, both devices are considered substantially equivalent concerning these aspects.

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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"		

Quality Assurance and Manufacturing Controls:

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

Conclusion:

It was demonstrated that the subject device is as safe, as effective and performs as well as the predicate device.

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