DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 9, 2015

AAT Alber Antreibstechnik GmbH
c/o Ms. Stefanie D. Bankston
Official Correspondent
BEO MedConsulting Berlin GmbH
3001 Ferndale Drive
League City, TX 77573

Re: K142770
Trade/Device Name: SOLO+, SOLO and SERVO
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: April 20, 2015
Received: April 23, 2015

Dear Ms. Bankston:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142770

Device Name
SOLO+, SOLO and SERVO

Indications for Use *(Describe)*
SOLO+, SOLO and SERVO turn a manually propelled wheelchair into a powered wheelchair. They are intended for medical purposes to provide a means for a disabled person to take over the propulsion of the wheelchair and increase mobility and flexibility.

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

May 09, 2015

Office of Device Evaluation
U.S. Food & Drug Administration

Dear Madame/Sir;

In accordance with Section 510(k) of the Federal Food & Drug and Cosmetic Act, and in conformance with 21 CFR Part 807, pre-market notification is hereby made of the intention of AAT Alber Antriebstechnik GmbH to introduce into interstate commerce for commercial distribution the motorized add-on drive for wheelchairs.

Applicant: AAT Alber Antriebstechnik GmbH
Ehestetter Weg 11
D-72458 Albstadt-Ebingen
Phone: Tel. +49.7431.1295-0
Fax +49.7431.1295-35
Email: info@aat-online.de

Organization Number: 239600

Contact Person: Ms Stefanie D. Bankston / Mr Michael Vent
3001 Ferndale Dr
League City TX 77573
Phone: (713) 483 4617
Email: s.bankston@beoberlin.com

Device:

a. Proprietary: SOLO, SOLO+ and SERVO
b. Common Name: Powered wheelchair
c. Classification Name: Powered wheelchair
d. Device Class: II, 21 CFR 890.3860
e. Classification Panel: Physical Medicine
f. Product Code: ITI

Predicate Device Information:

We claim substantial equivalence for the subject devices SOLO, SOLO+ and SERVO in intended use, design and function to the predicate device e-motion (K003449) by Ulrich Alber GmbH.

Intended Use:

SOLO, SOLO+ and SERVO turn a manually propelled wheelchair into a powered wheelchair. They are intended for medical purposes to provide a means for a disabled person to take over the propulsion of the wheelchair and increase mobility and flexibility.

Device Description:

The subject devices SOLO, SOLO+ and SERVO are power-wheelchair-conversion-kits that add powered propulsion to a manual wheelchair, thereby, turning a manual wheelchair into a powered wheelchair.

They consist of two powered wheels (each incorporating an electrical motor) a control unit with its bracket and a battery pack. A battery charger and a bag for the battery pack are included in the delivery as well.

The powered wheels substitute the conventional manual wheels from selected wheelchairs. The battery-pack and the controller-unit can easily be attached to the wheelchair.

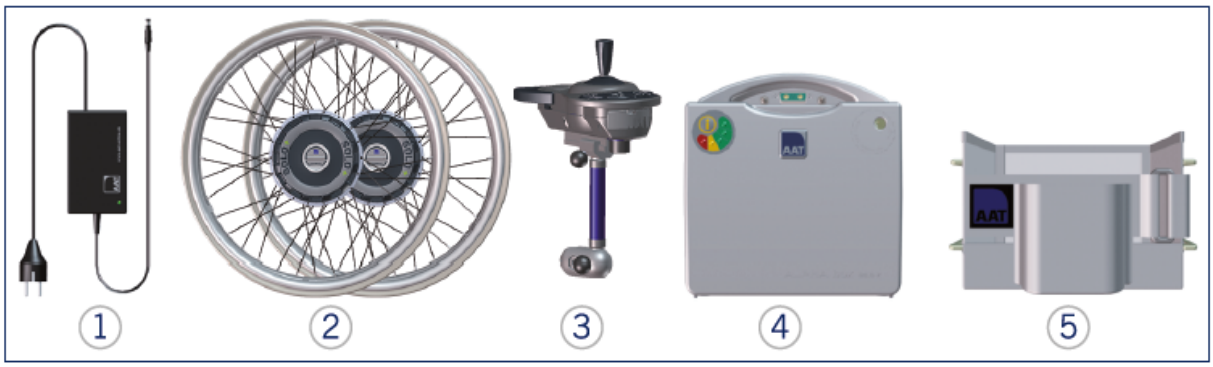
Speed, acceleration and deceleration are microprocessor-controlled. A preselection of the maximum speed can be done with buttons on the control unit. The wheelchair will accelerate or drive with steady speed when the joystick (SOLO and SOLO+) or the hand-rims (SERVO) are pushed into the travel-direction.

The motors will steadily reduce the driving force until the wheelchair stops if no driving-signal (deflection of the joystick or the rim) is provided. The safety-brakes lock automatically when the wheelchair stopped (SOLO, SOLO+). The manual parking brakes can also be used to prevent unintended movement.

After ten minutes of non-use the device turns off automatically.
The powered wheels can be disengaged if the user wants to drive with manual propulsion, only.

SERVO Set

SOLO+/SOLO Set



Charger	1
Powered wheels	2
Control unit with its bracket	3
Battery pack	4
Bag for the battery pack	5

Unsere Hausanschrift
AAT Alber Antriebstechnik GmbH · Ehestetter Weg 11 · D-72458 Albstadt-Ebingen
Tel. +49.7431.1295-0 · Fax +49.7431.1295-35 · info@aat-online.de · www.aat-online.de
Postfach 100 560 · D-72426 Albstadt-Ebingen

Amtsgericht Stuttgart HRB 1006 · Sitz: Albstadt · Ust ID Nr. DE 173669635
Geschäftsführer: Thomas Alber, Markus Alber

Unsere Bankverbindungen
Sparkasse Zollernalb · Konto 31712831 · BLZ 65351260
Swift Code: SOLADES1BAL
IBAN: DE06 6535 1260 0031 7128 31

Volksbank Ebingen eG · Konto 83153004 · 65390120
LBBW · Konto 4765671 · 60050101

Comparison to legally marketed device (Substantial Equivalence):

The SOLO, SOLO+ and SERVO are essentially equivalent in intended use, design and function with the e-motion by Ulrich Alber GmbH (K003449). However, there are some minor differences discussed below.

The Chart summarizes technical similarities and differences:

	Subject devices SOLO / SOLO+ / SERVO	**Predicate device e-motion (K003449)**
Technical data		
Wheels	24”	22” / 24”
Weight	22.9kg/22,9kg/24,8kg	22 kg
Max. user weight	160kg/200kg/150kg	130 kg
Total weight approved	210kg/250kg/200kg	180 kg
Braking technologies	Electro-magnetic spring loaded drum brakes.	same
Speed, acceleration, deceleration	Preselected max-speed, microprocessor-controlled speed, acceleration and deceleration. The user controls these parameter with the joystick or rim-propulsion.	same
User Interface	Joystick (SOLO, SOLO+) / rim with hall-sensor (SERVO)	same as SERVO
Driving force	Approx. 10N to push or pull the joystick or rim. Rim-sensor-sensitivity is adjustable.	same as SERVO
Forward/backward movement	Joystick (SOLO, SOLO+)/ rim with hall-sensor (SERVO)	same as SERVO
Locks to prevent unintended / unanticipated movement	manual parking brake (SERVO) SOLO, SOLO+ have an electro-magnetic spring loaded drum brakes in addition	same as SERVO
Foldable wheelchair still foldable?	Foldable, after detaching the battery	same
Performance		
Range (ISO 7176-14)	up to 22mil / 9.3mil / 34mil	up to 15.5 mil
Speed: forward/backward	3.8 mil/h / 1.9 mil/h	same
Electrical data		
battery	28,8V, 16Ah(Pb) 24V, 8,5 Ah(Li-Ion)	25,2V, 6,0 Ah (Li-Ion)
motor	24-28,8V; DC, 150W/70W (microprocessor controlled adaption to the power source (PB or LI-Ion))	25,2V; DC; 60W

Differences:

Differences	**Discussion**
Wheel size	The subject and the predicate devices are available with 24-inch wheels. The predicate device is also available with smaller 22-inch wheels. Some user may choose smaller wheels to reach the floor with their feet for foot-propulsion or simply because they feel a 24-inch wheelchair is too large. However, the wheel-size has no influence on the safety of the powered propulsion.
Weight differences	The weight differences occur from design details. The subject devices are able to carry a higher max. load while the basic material is the same. Therefore, the design is reinforced, more rigged and consequently a bit heavier. The weight differences have no negative influence on the safety of the subject devices.
Max. user weight	The subject devices are designed to carry a higher user-weight. This is actually an advantage. It lowers the risk of unintended overloading the wheelchair. All mechanical and driving characteristics are well approved to ensure a safe use under the max. load. The differences have no negative influence on the safety.

Total weight	The total weight of the subject devices is consequently higher because of the higher product-weight and max. user-weight. The differences have no negative influence on the safety.
Theoretical driving range	The theoretical driving distance from our subject devices differ from the predicate device because of different weight capacities and the possibility to choose different batteries. This difference has no influence on the safety of the devices. It only has an influence on the comfort of the devices. The user is free to choose the configuration that suits his habits the best. The user is able to easily reset the wheels to manual propulsion at any time if the batteries run out of energy.
Battery capacity	The user of the SOLO, SOLO+ and SERVO can choose between Pb-batteries and Li-Ion batteries. Both battery types are approved and have their advantages. While the Pb-battery is cheaper and has a higher capacity, the Li-Ion battery is faster recharged, less heavy and suitable for more recharges. The user should choose the configuration that suits his habits the best. The differences have no influence on the safety of the devices.
Battery technology	The predicate device is available with Li-Ion battery, only. The subject devices are also available with Pb-batteries. Both battery types are approved and have their advantages. While the Pb-battery is cheaper and has a higher capacity, the Li-Ion battery is faster recharged, less heavy and suitable for more recharges. The user should choose the configuration that suits his habits the best. The differences have no influence on the safety of the devices.
Motor	While the material and design is similar, the electrical data differ. The motor-characteristics may have little influence on driving characteristics but they don't result it any safety differences.
User Interface	The SOLO and SOLO+ have a Joystick to steer the wheelchair. User with a limited capability to use the rim can steer the wheelchair like a classical powered wheelchair with a joystick. This opportunity has no negative influence on the safety of the device. It expands the range of users.

Performance Standards:

To demonstrate substantial equivalence we performed non-clinical tests according recognized standards:

- To demonstrate the static stability (tilt-over-value) we performed non-clinical tests according to ISO 7176-1: Determination of static stability.
- To demonstrate the dynamic stability (tilt-over-value while driving) we performed non-clinical tests according to ISO 7176-2: Determination of dynamic stability.
- To demonstrate effectiveness of the device's brakes we performed non-clinical tests according to ISO 7176-3: Determination of effectiveness of brakes.
- To demonstrate effectiveness of the power system we performed non-clinical tests according to ISO 7176-4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance.
- To demonstrate safety related to speed, acceleration and deceleration we performed non-clinical tests according to ISO 7176-6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs.
- To ensure comparability with other test results all measurements were made in conformity with ISO 7176-7 and ANSI / RESNA WC-1:2009 section 7: method of measurement of seating and wheel dimensions
- To demonstrate mechanical strength and durability, non-clinical tests were performed according to ISO 7176-8 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths.
- To demonstrate safe use and performance under different climatic situations, non-clinical tests were performed according to ISO 7176-9 Wheelchairs - Part 9: Climatic tests for electric wheelchairs

- To ensure comparability with other test results all load tests were performed in conformity with ISO 7176-11 Wheelchairs – Part 11: Test Dummies
- To ensure comparability with other test results all driving and braking tests were performed in conformity with ISO 7176-13 Wheelchairs – Part 13 Determination Of Coefficient Of Friction Of Test Surfaces
- To demonstrate electrical safety, software-validation and performance, non-clinical tests were performed according to ISO 7176-14 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters -Requirements and test methods
- To demonstrate electromagnetic compatibility, non-clinical tests were performed according to ANSI/RESNA wc/ vol.2 and ISO 7176-21 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- To demonstrate the device's biocompatibility, we performed non-clinical tests according to ISO 10993-5: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

Quality Assurance and Manufacturing Controls:

AAT Alber Antriebstechnik GmbH operates to an established and certified quality management system according to ISO 9001, and ISO 13485 requirements.

Conclusion:

The subject devices, SOLO, SOLO+ and SERVO, are as safe, as effective and perform as well as the predicate device.

Sincerely,

AAT Alber Antriebstechnik GmbH

Stefanie D. Bankston / p.p. Michael Vent
Official Correspondent for AAT Alber Antriebstechnik