



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 23, 2016

Alber Gmbh
% Susan Goldstein-Falk
Official Correspondent for Alber Gmbh
Mdi Consultants, Inc
55 Northern Blvd. Ste 200
Great Neck, New York 11021

Re: K151717
Trade/Device Name: twion
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: January 27, 2016
Received: January 29, 2016

Dear Susan Goldstein-Falk:

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" (21 CFR 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,

Michael J. Hoffmann -A

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

Indications for Use

510(k) Number (if known)

K151717

Device Name

twion

Indications for Use (Describe)

The twion 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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."

510(k) Summary

The assigned 510(k) number is: K151717

Alber GmbH – twion device

1. Date Prepared: February 22, 2016
2. Submitter's Name: Alber GmbH
and Address Vor dem Weissen Stein 21
D-72461 Albstadt (Germany)
3. Contact Person: Mr. Bernd Engels
Head of Product Management
TEL: +49 (0) 7432-2006-180
Fax: +49 (0) 7432-2006-189
Email: bernd.engels@alber.de
4. Device Trade/Proprietary Name: twion

Common Name: Wheelchair, Powered

Classification Name: Regulation Number: 21 CFR Part 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: II
Product Code: ITI
Classification Panel: Physical Medicine
5. Predicate Device:

The twion device is substantially equivalent to the Yamaha JWX-2 device (K140204). FDA granted 510(k) clearance for this predicate device on August 28, 2014 under K140204.

6. Device Description

The twion is a power assist drive system. Its basic functionality can be compared to a power steering of a car. By pushing the push rim attached to the wheel, a motor assists in turning the wheel – like a power steering does when turning the steering wheel.

The intent of the twion device is to expand the field of activities for those wheelchair drivers who are limited in their physical condition.

The twion is designed to fit most standard manual wheelchairs available on the market. It is lightweight and with motors and batteries designed inside the wheel-hubs it does not compromise the usability and safety of such wheelchairs. The twion can be driven without power assist very close to a manual wheelchair.

Each hub motor is equipped with a DC motor and an integrated battery. A push rim sensor detects the force applied by the wheelchair driver. An integrated microcontroller converts this signal into a proportional motor output which generates an additional torque to the wheel. This torque by itself is very low but enables the driver to drive the wheelchair manually.

The benefit for the wheelchair driver is such that he can keep driving in his manual wheelchair. Without a device like the twion, the patient would have to use a fully electrical wheelchair (with joystick).

7. Indications for Use:

The twion 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.

8. Comparison to the Predicate Device:

Item description	Subject Alber twion device	Predicate device JWX-2 of YAMAHA MOTOR CO., LTD.
510 (k) Number	Not known	K140204
Indications for Use (IFU)	twion 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 device JWX-2 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.
Total weight	12 kg (Li-ion)	17 kg (Ni-MH) 17.7 kg (Li-ion)
Drive Unit Width (Hub Height)	89 mm	91 mm

Max. User Weight	120 kg	130 kg
Speed Range with Power Assist	Up to 10 km/h	Up to 6 km/h
Max. Safe Slope	6°	6°
Max Range per Charge	15 km & above (Li-ion)	40 km & above (Li-Ion) 20km & above (Ni-MH)
Type of Motor	DC Brushless Motor	AC servometer (DC Brushless Motor)
Rated Power of Motor	2 x 60 W	30 minSs rated 110Wx2
Battery	Type Li-ion Capacity: 37 V 2.25 Ah (Nom.)	Type: Ni-MH (Dry) Capacity: 24V 6.7 Ah (Nom.) Type: Li-ion(Dry) Capacity 25V11.8 AH (Nom.)
Wheel Size	24"	24"/22"
Tire	Pneumatic	Pneumatic
Quick Release Axle	QR only	QR only
Left/Right wheel Synchronized Control	Individual control	Provided
Regenerative Brake	Provided	Provided
Down Slope Speed Regulation	Provided	Provided
Driving Mode Selector (user operable)	Option (2 modes)	Option (2 modes)
Handrim (Patient-Contact)	Stainless Steel	-Stainless steel

Handrim (Patient-Contact)	Aluminum push rim, powder-coated black/matt	-Stainless Steel
Certification	EN 12184:2009 (Electrically powered wheelchairs, scooters and their chargers – Requirements and test methods)	EN 12184:2009 (Electrically powered wheelchairs, scooters and their chargers – Requirements and test methods)

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the subject device in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical, Environmental and Performance Requirements.

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was Alber's conclusion that testing met all relevant requirements of the FDA's November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions".

The following National and International Standards were utilized for testing the subject device:

Performance Standards:

ISO 7176-21 Second edition 2009-04-01 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers

ISO 7176-15 First edition 1996-11-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling

ISO 7176-14 Second edition 2008-02-15 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods

ISO 7176-8 Wheelchairs - Part 8: Static, Impact and Fatigue Strength for Manual Wheelchairs, 1998.

ISO 7176-9: Third edition 2009-11-15 Wheelchairs - Part 9: Climatic tests for electric wheelchairs

ISO 7176-1 Second edition 1999-10-01 Wheelchairs - Part 1: Determination of static stability

ISO 7176-2 Second edition 2001-06-15 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs

ISO 10993-5:2009: Biological evaluation of medical devices –part 5: tests for in vitro cytotoxicity (Biocompatibility)

ISO 10993-10 Third Edition 2010-08-01, biological evaluation of medical devices – part 10: tests for irritation and skin sensitization

EN 12184:2009: Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods

IEC 62133: 2002, 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

IEC 62304: 2006, Medical device software – Software life-cycle processes

ANSI/AAMI ES60601-1:2005, Medical electrical equipment- Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

Only battery charger was tested to this standard.

10. Discussion of Clinical Tests Performed:

Not applicable as there are no new indications for use which must be supported by a clinical data.

11. Software Information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices".

12. Conclusions:

Conclusions drawn from the performance, bench and non-clinical tests demonstrate that the subject device is as safe, effective and performs as well as the predicate device.