January 10, 2025

KLAXON Mobility GmbH
Riccardo Colomba
Quality
Industriestrasse,1
Arnoldstein, 9601
Austria

Re: K240267
Trade/Device Name: Klaxon (Twist); Klaxon (Twist R)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 3, 2024
Received: December 3, 2024

Dear Riccardo Colomba:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tushar Bansal -S

for 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K240267

Device Name

KLAXON (TWIST);
KLAXON (TWIST R)

Indications for Use *(Describe)*

The TWIST and TWIST R are add-on drive accessories for wheelchairs.
The TWIST and TWIST R devices are intended to provide auxiliary power to manual wheelchairs to reduce the pushing power needed by their users.
TWIST and TWIST R devices 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.

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."*

# 1 510(K) SUMMARY (21 CFR 807.92 A)

## *1.1 SUBMITTER'S DATA*

**Name**: Klaxon-Mobility GmbH
**Address**: Industriestrasse, 1 ZIP 9601, Arnoldstein Austria
**Telephone Nr**: +43 (0)6644681294
**Contact Person**: Mr Riccardo Colomba (r.colomba@klaxon-klick.com); 0043(0)6763213105
**Issue date**: 2023, November, the 20th

## *1.2 SUBJECT DEVICE'S DATA*

**510(k) Number**: K240267
**Name**: TWIST (main device); TWIST R(variation included in the 510(k))
**Classification regulation**: Powered Wheelchairs
**Regulatory Class**: Class II 21 CFR 890.3860
**Classification Panel**: Physical Medicine
**Product code**: ITI

## *1.3 PREDICATE DEVICE'S DATA*

Klaxon claims substantial equivalence for the subject device TWIST (in the variations TWIST and TWIST R) to the predicate device SMOOV O10 by Alber GmbH.

The equivalence is based on same intended use, where technical differences are not affecting the safety.

**510(k) Number**: K192016
**Trade/Device Name**: SMOOV O10
**Regulation Number**: 21 CFR 890.3860
**Regulation Name**: Powered Wheelchair
**Regulatory Class**: Class II
**Product Code**: ITI
**Classification Panel**: Physical Medicine
**Dated**: May 19th, 2020
**Received**: July 29th, 2019

## 2 SUBJECT DEVICE DESCRIPTION

### *2.1 INDICATIONS FOR USE*

The TWIST and TWIST R are add-on drive accessories for wheelchairs.

The TWIST and TWIST R devices are intended to provide auxiliary power to manual wheelchairs to reduce the pushing power needed by their users.

TWIST and TWIST R devices 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.

### *2.2 INTENDED USE*

The TWIST and TWIST R are medical devices for active wheelchair users with a user weight of 120 kgs and who are reliant on a wheelchair as a result of their disability. The TWIST and TWIST R are add-on drive for wheelchairs 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 TWIST and TWIST R must always be used, transported, maintained and serviced carefully to keep their performance, efficiency and safety. The TWIST and TWIST R must only be attached to and operated with wheelchairs that are selected by the specialist dealer or by Klaxon itself.

### *2.3 VARIATIONS*

TWIST is available in two (2) variations (TWIST and TWIST R).

The main difference between TWIST and TWIST R is given by the number of possible configurations. The TWIST has five (5) possible configurations (following table, points 1 to 5)

The TWIST R has two (2) possible configurations (following table, points 6 and 7). It is basically a simplified system available for the rear installation only.

The configurations could be considered as variations themselves, nevertheless, it is not possible to assign to the single configuration a Commercial name, because each product variation (TWIST and TWIST R) can be sold with all the components to be used in all the available configurations.

| Variation | Commercial name | Power (W) | Max speed (km/h - mph) | Combination | Notes |
| --- | --- | --- | --- | --- | --- |
| 1 | TWIST | 250 | 6 – 3.7 | Front mounted without handlebar, user | The system is connected with the front central connector, the castor wheels are lifted off the ground.<br>The controller position is reachable by the wheelchair's occupant. |
| 2 | TWIST | 250 | 6 – 3.7 | Front mounted without handlebar, attendant | The system is connected with the front central connector, the castor wheels are lifted off the ground.<br>The controller position is reachable by the occupant's attendant. |

| | | | | | |
|---|---|---|---|---|---|
| **3** | TWIST | 250 | 6 (10 optional) – 3.7 (6.2 optional) | Rear mounted, user | The system is connected with the rear connector, the castor wheels are on the ground.<br>The controller position is reachable by the wheelchair's occupant. |
| **4** | TWIST | 250 | 6 – 3.7 | Rear mounted, attendant | The system is connected with the rear connector, the castor wheels are on the ground.<br>The controller position is reachable by the occupant's attendant. |
| **5** | TWIST | 250 | 10 – 6.2 | Front mounted with handlebar | The system is connected with the front central connector, the castor wheels are lifted off the ground.<br>The handlebar is mounted. |
| **6** | TWIST R | 250 | 6 (10 optional) 3.7 (6.2 optional) | Rear mounted, user | The system is connected with the rear connector, the castor wheels are on the ground.<br>The controller position is reachable by the wheelchair's occupant. |
| **7** | TWIST R | 250 | 6 – 3.7 | Rear mounted, attendant | The system is connected with the rear connector, the castor wheels are on the ground.<br>The controller position is reachable by the occupant's attendant. |

### *2.4 TECHNICAL DESCRIPTION*

**Materials used on the main components**

| Description | Material |
| --- | --- |
| ECU | Various, ECU is RoHS compliant |
| Battery 36V, 4Ah | Various, battery's materials RoHS compliant |
| Handlebar | Aluminium alloy Al6061 |
| Handle grips | polyvinyl chloride (PVC) |
| Hub frame | Aluminium alloy Al6082 and Al7075 |
| Hub motor complete with wheel | Various, motor's materials RoHS compliant |
| Front Hook | Aluminium alloy Al6082 and Al7075 |
| Rear Hook | Aluminium alloy Al 7075 |
| Connector | Aluminium alloy Al 6060 |
| Crossbeam | Aluminium alloy Al 7075 |
| Clamps | Aluminium alloy Al 7075 |

**The main parts of the drive unit are as follows:**

- For TWIST with front mounting without handlebar: drive wheel consisting of a brushless motor with tire and aluminium steering system
- For TWIST with front mounting with handlebar: drive wheel consisting of a brushless motor with tire and aluminium steering system connected to a handlebar
- For TWIST with front mounting without handlebar: drive wheel consisting of a brushless motor with tire and aluminium steering system
- For TWIST with rear mounting and TWIST R variation: drive wheel consisting of a brushless motor with tire, no steering.
- Electronic Control Unit / ECU (drive unit) for the motor and wireless interface for communication with controller or handlebar
- and optional smartphone WebApp
- Removable lithium ion battery pack with battery management system and recharge connector socket
- On/Off button and remaining capacity and operating mode indicator
- Carrying and release handle
- Battery charger
- Front and rear light
- Locking pins to connect the device to the connection system

**The main parts of the controller are:**

- Wireless interface for communicating with the ECU
- On/Off button
- Controller battery level LEDs indicator
- Speed selection lever and brake button
- Integrated Li-ION battery cell including battery management system
- USB-C socket for charging the controller
- Display for operating status and remaining capacity of drive unit and control unit

**The main parts of the handlebar unit are:**

- Wireless interface for communicating with the ECU
- On/Off button
- Controller battery level LEDs indicator
- Accelerator to adjust speed
- Brake lever for electronic brake (first part of the lever stroke)
- Brake lever for mechanical brake (second part of the lever stroke)
- Integrated Li-ION battery cell including battery management system
- USB-C socket for charging the controller
- 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
- Indicating status
- Output 42V 2A

**Drive Unit:**

- **Range**: up to 21 km (13 mi) as per ISO 7176 - 4
- **Nominal gradient**: 10% [6°] - also note the limit values specified by the wheelchair manufacturer.
- **Maximum downhill grade:** 10% [6°] - also note the limit values specified by the wheelchair manufacturer
- **Maximum speed front mounted with handlebar**: 10 km/h (6.2 mph)
- **Maximum speed front mounted without handlebar**: 6 km/h (3.7 mph)
- **Maximum speed rear mounted**: Standard 6 km/h; Optional: 10 km/h (6.2 mph)
- **Maximum speed for all configurations with attendant control**: 6km/h (3.7 mph)
- **Rated power of engine**: 250 W
- **Operating voltage (nominal)**: 36 VDC
- **Operating temperature**: -25° C to +50° C (-13° F to +122° F)
- **Storage temperature**: -40° C to +65° C (-40° F to +149° F)
- **Weight of person**: max. 120 kg (265 lbs)
- **Protection rating**: IPX4

**Battery pack:**

- **Cell type**: Lithium-ion 21700
- **Rated operating capacity**: 36 V
- **Rated capacity**: 4Ah
- **Rated energy**: 144 Wh
- **Charging temperature**: 0° C to +45° C (32° F to +113° F)
- **Operating temperature**: -25° C to +50° C (-13° F to +122° F)
- **Protection rating**: IPX4

**Controller battery:**

- **Cell type**: Lithium-ion 14500
- **Rated voltage**: 3.6 VDC
- **Rated capacity**: 950 Ah
- **Rated energy**: 3.42 mWh
- **Charging temperature**: 0° C to +45° C (32° F to +113° F)
- **Operating temperature**: -25° C to +50° C (-13° F to +122° F)

**Handlebar battery**

- **Cell type**: Lithium-ion 18350
- **Rated voltage**: 3.7 VDC
- **Rated capacity**: 1000 Ah
- **Rated energy**: 3.7 Wh
- **Charging temperature**: 0° C to +45° C (32° F to +113° F)
- **Operating temperature**: -25° C to +50° C (-13° F to +122° F)

**Main Battery Charger OFF BOARD**

- **Output voltage:** 42 VDC
- **Output current**: 2.0 A
- **Ambient temperature**: Operation -20°C to +60°C (-4° F to +140° F)
- **Ambient temperature**: Storage -30°C to +80°C (-22° F to +176° F)
- **Humidity**: Operation 1% to 95%
- **Humidity**: Storage 1% to 95%
- **Air pressure**: Operation 750 to 1060 hPa (10.88 to 15.37 psi)
- **Air pressure**: Storage 750 to 1060 hPa (10.88 to 15.37 psi)

**Weight of the TWIST and TWIST R**

- **TWIST without handlebar (without battery)**: 7.4 kg (16.3 lbs)
- **TWIST with handlebar (without battery)**: 9.8 kg (21.6 lbs)
- **TWIST R (without battery)**: 6.5 kg (14.3 lbs)
- **Battery**: 1.4 kg (3 lbs)

### *2.5 WIRELESS TECHNOLOGY*

#### *2.5.1 Drive Unit:*

- **Type of wireless technology:** EEE 802.15.4 (Bluetooth Low Energy)
- **FCC compliance**: Part 15c;
- **FCC ID**: 2AC7Z-ESP32WROOM32E
- **Wireless Coexistence Compliance**: ANSI C63.27-2017, Tier 1
- **EMC Compliance**: ISO 7176-21
- **RF frequency range**: 2.402 GHz to 2.480 GHz
- **RF maximum output power**: 9dBm
- **Wireless operating range**: 10m (32.8 ft) / class 2
- **Wireless functions**: Speed, Emergency stop, Operating mode (handlebar, controller, front, rear)

#### *2.5.2 Controller:*

- **Type of wireless technology**: IEEE 802.15.4 (Bluetooth Low Energy)
- **FCC compliance**: Part 15c;
- **FCC ID**: 2AC7Z-ESP32WROOM32E
- **Wireless Coexistence Compliance**: ANSI C63.27-2017, Tier 1
- **EMC Compliance**: ISO 7176-21
- **Wireless RF frequency range**: 2.402 GHz to 2.480 GHz
- **Wireless RF maximum output power**: 9dBm
- **Wireless operating range**: 10m (32.8 ft) / class 2
- **Wireless functions**: Speed Level, Brake command, On/Off

#### *2.5.3 Handlebar/Attendant control:*

- **Type of wireless technology**: IEEE 802.15.4 (Bluetooth Low Energy)
- **FCC compliance**: Part 15c;
- **FCC ID**: 2AC7Z-ESP32WROOM32E
- **Wireless Coexistence Compliance**: ANSI C63.27-2017, Tier 1
- **EMC Compliance**: ISO 7176-21
- **Wireless RF frequency range**: 2.402 GHz to 2.480 GHz
- **Wireless RF maximum output power**: 9dBm
- **Wireless operating range**: 10m (32.8 ft) / class 2
- **Wireless functions**: Speed, Electronic Brake, On/Off

### *2.5.4 Cybersecurity Assessment*

The Klaxon TWIST and TWIST R use the wireless communication technology known as Bluetooth Low Energy (BLE). BLE allows two devices to exchange information in real time.

BLE is used to control the device at all times through the use of a controller or handlebar. The communication is encrypted and requires a preexisting pairing to activate the motor.

Due to the communication structure of the Klaxon TWIST and TWIST R, the BLE communication happens in a different and independent control unit from the motor drive unit.

This means that in the unlikely event of a successful attack the device would be safely stopped and all power is removed from the motor. In this state no energy is provided to the motor and any unintended movement is impossible.

Even in the case of a successful attack to imitate a BLE command, the device would not be able to operate outside of the established limits (speed, acceleration, braking, ecc.).

In the case unforeseen vulnerabilities are found, the firmware on the TWIST and TWIST R can be fully patched remotely by the user using Over-The-Air updates.

Any vulnerabilities would not be exploited remotely and any attack requires that the device Bluetooth is enabled and that the attacker is within close physical proximity (i.e., within Bluetooth range) of the device.

The chipset used on the Klaxon TWIST and TWIST R is up to date with modern vulnerabilities of the BLE stack and in particular already implements patches to the SweynTooth vulnerabilities.

**The detail of the cybersecurity assessment according to FDA guidelines is available in the e-Star submission for the 510(k) K240267 (Klaxon TWIST and TWIST R).**

## 3 TECHNOLOGICAL COMPARISON BETWEEN THE SUBJECT DEVICE AND THE PREDICATE DEVICE

| Topic | Subject device | Predicate device | Substantial Equivalence Remarks |
|---|---|---|---|
| **Indication For Use** | The TWIST and TWIST R are add-on drive accessories for wheelchairs.<br>The TWIST and TWIST R devices are intended to provide auxiliary power to manual wheelchairs to reduce the pushing power needed by their users.<br>TWIST and TWIST R devices 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. | 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.<br>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. | There are no significant differences between indications for use. |
| **Intended Use** | The TWIST and TWIST R are medical devices for active wheelchair users with a user weight of 120 kgs and who are reliant on a wheelchair as a result of their disability. The TWIST and TWIST R are add-on drive for wheelchairs 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.<br>The TWIST and TWIST R must always be used, transported, maintained and serviced carefully to keep their performance, efficiency and safety. The TWIST and TWIST R must only be attached to and operated with wheelchairs that are selected by the specialist dealer or by Klaxon itself. | 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.<br>The SMOOV 010 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.<br>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.<br>The selection is made by the specialist dealer or by Alber itself. | There are no significant differences with regard to the intended use. |
| **Permissible conditions of use/locations of operation**<br><br>**Type Environment of Use** | -The TWIST and TWIST R devices are manufactured to be coupled to the majority of wheelchairs on the market.<br>- The TWIST and TWIST R devices can be used both indoors and outdoors, within the limits stated in the Instruction for Use document and, in general, according to the same limitations of use as those of the manual wheelchair (as established by its manufacturer)<br>- Temperature range for use is minus 25 to 50 °C (minus 13 to 122°F).<br>. Do not use TWIST and TWIST R devices on slopes greater than 6°/10%. The rated slope's limit shall be reduced in accordance with the pavement and the environmental condition.<br>- Maximum negotiable step is 30mm (1.18 inch).<br>- TWIST and TWIST R must not be used if not coupled with a manual wheelchair. | . Observe the permissible conditions of use of the wheelchair to which the SMOOV O10 is attached.<br>. In addition to observing the information provided about the SMOOV O10, 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.<br>. 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 O10.<br>. The SMOOV O10 must only be operated at temperatures between - 25 °C and +50 °C. Therefore, do not expose the SMOOV O10 to any heat sources (such as intense sunlight) as this may cause surfaces to reach high temperatures. | There are no differences affecting the safety related to differences in the reported indications. |

| | | | |
| --- | --- | --- | --- |
| | - TWIST and TWIST R must not be used after intake of alcohol or if the user's psycho- physical conditions are unsuitable.<br>- TWIST and TWIST R must not be used on roads with unsuitable pavement.<br>- TWIST and TWIST R must not be used in poor visibility (at night, in fog, etc.).<br>- TWIST and TWIST R must not be used if the user weighs over 120 kg (265 lbs) or is heavier than allowed for the wheelchair used.<br>- TWIST and TWIST R must not be used in adverse weather (rain, strong wind, etc.). | . 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 | The Market segment is the same for both the devices, thus the safety level is considered equivalent |
| **Introduced to the market** | Spring 2022 (Europe) | spring 2019 | |
| **Wheelchair Compatibility** | Both rigid and foldable wheelchairs, instructions and eventual accessories are depicted in the Installation Manual indications | Rigid W/C frames: Universal brackets on the axle tube<br>Folding frames: adapter axle required | The wheelchair compatibility is formally the same, thus the safety level is considered equivalent |
| **Available Wheelchair Wheel- Diameters (inch)** | 22" - 26" front mount<br><br>24" – 26" rear mount | 22" - 26" Rear mount | |
| **Device Wheel Dimensions (inch)** | Diameter: 10" | Diameter: 6.4"<br>Width: 3,9" | |
| **Max. user weight (kg)** | 120 (265 lbs) | 140 (309 lbs) | The maximum allowed weight is lower for the subject device |
| **System weight (kg)** | **Weight without battery**<br>TWIST with handlebar: 9.8 (21.6 lbs)<br>TWIST without handlebar: 7.4 (16,3 lbs)<br>TWIST R: 6.5 (14.3 lbs)<br>Battery weight: 1.4 (3 lbs) | 7.2 (15.9 lbs) | |
| **Motor** | Brushless motor | Brushless motor | The devices use the same technology, thus the safety level is considered equivalent |
| **Battery** | Lithium-Ion | Lithium-Ion | The devices use the same technology, thus the safety level is considered equivalent |
| **Display** | LEDs for battery levels, device's Status information and BT connection | LEDs for battery levels, device's status information and BT connection | The devices use the same technology, thus the safety level is considered equivalent |
| **Nominal Power (Watt)** | 250 | 250 | Same nominal Power, thus the safety level is considered equivalent |
| **Max. assisted Speed (km/h)** | TWIST front with handlebar: 10 km/h (6.2 mph)<br>TWIST front without handlebar: 6 km/h (3.7 mph)<br>TWIST and TWIST R rear: 6 km/h (3.7 mph);<br>TWIST and TWIST R (optional): 10 km/h (6.2 mph) | 6 km/h (3.7 mph)<br>Optional: 10 km/h (6.2 mph) | Same speed<br>FOR HANDLEBAR THE COMMENT SHALL BE PROVIDED AFTER TUEV SUED TEST |
| **Nominal Range (km)** | 21 km (13 mi) | 20 km (12.4 mi) | Same declared range, thus the safety level is considered equivalent |
| | Four (4) speeds selected by controller for all configurations without handlebar | Speed adjustments stepless via click wheel | The existing differences in the assist levels are considered not to affect the safety |

| | | | |
|---|---|---|---|
| **Assist Levels** | Speed adjustments are stepless via handlebar's throttle | | |
| **Controller/s** | BLE remote controller for all versions without handlebar .<br><br>BLE remote controller with input from throttle and brake lever for handlebar version | Bluetooth click wheel attached to wheelchair | The devices use the same technology, thus the safety level is considered equivalent |
| **Adjustment of drive parameters** | **Controller:**<br>- Four (4) speed levels, stop pushbutton<br>- ON/OFF button<br>- Battery state of charge LEDs<br>**Attendant controller:**<br>- Throttle for managing the speed when pushed and brake (front mounting) or disengaging the motor when released.<br>- ON/OFF button<br>**Handlebar:**<br>- Throttle for speed management<br>- ON/OFF button<br>**Main battery:**<br>- ON/OFF button | Acceleration and speed depending on the angle of the drive wheel, Four (4) programmable driving modes. STOP pushbutton | The differences do not affect safety, thus the safety level is considered equivalent |
| **Smartphone App for end user** | WebApp for:<br><br>- Drive information<br>- ON/OFF light<br>- Parameters change (within pre-set limits), firmware updates over the air, failure and warnings | Android and iOS<br>Free features:<br>Cockpit, battery capacity, range, tour computer via GPS, four (4) programmable driving modes, ON/OFF rear light, worldwide service contact details, firmware updates over the air, failure and warnings<br>Chargeable: Navigation | In both cases, the App or WebApp is not necessary to the functioning of the device and any change that can be done by user, is within safety limits imposed by the manufacturer. The safety level is considered the same. |
| **Brake means** | **Front mounted with handlebar:**<br>- Mechanical brake<br>- Electronic brake<br>- Throttle release brake<br>**Front mounted without handlebar:**<br>- Electronic brake<br>**Rear mounted:**<br>- No braking effect, only freewheeling mode. The brake effect is given by the user acting on the wheel rims | No braking effect, only freewheeling mode. The brake effect is given by the user acting on the wheel rims | **For subject device front mounted:**<br>The Subject device level of safety is higher because the user is always able to completely stop the device in any situation.<br>**For subject device rear mounted:**<br>The safety level is considered the same for both devices |
| **Speed limit in downhill** | **Front mounted:**<br>The device limits the speed when riding down a slope according with the speed level selected or with the speed fixed with the cruise control function<br>**Rear mounted:**<br>The system stops pushing (freewheel available) when the maximum speed is reached. There is no speed limit when riding down a slope. | The system stops pushing when the maximum speed is reached. There is no speed limit when riding down a slope. | **For subject device front mounted:**<br>The subject device's level of safety is improved because there is no risk to overcome the desired/fixed speed when riding down a slope.<br><br>**For subject device rear mounted:**<br>The safety level is considered the same for both devices |
| | **Front mounting:**<br>Mounted on the front of the wheelchair, the castor wheels are lifted off the ground 25mm to 40mm | Mounted on the rear of the wheelchair. The castor wheels are always in contact with the ground | **For subject device front mounted:**<br>The subject device's level of safety is improved due to the minimum risk of tip over in case of ground |

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| **Mounting Position** | (0.98 inch to 1.58 inch)<br>**Rear mounting:**<br>Mounted on the rear of the wheelchair. The castor wheels are always in contact with the ground | | unevenness, curbs, obstacles (this risk is likely high on the predicate device). Moreover, the subject device can limit the speed and effectively brake when riding down a slope, due to the front mounting.<br>**For subject device rear mounted:**<br>The safety level is considered the same for both devices |

## 4 NON CLINICAL TESTING TO SUPPORT SUBSTANTIAL EQUIVALENCE

| Standard | Name | Recognition# |
| --- | --- | --- |
| 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 7176-6:2018 | Wheelchairs - Part 6: Determination of maximum speed of electrically powered 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 7176-22:2014 | Wheelchairs - Part 22: Set-up procedures | 16-198 |
| ANSI USEMCSC C63.27-2021 | American National Standard for Evaluation of Wireless Coexistence | 19-48 |
| TIR69:2017/(R2020) | Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems. | 19-22 |
| EN 1041:2008 | Information supplied by the manufacturer of medical devices | |
| ISO 14971:2019 | Medical devices - Application of risk management to medical devices | 5-125 |
| EN 60335-2-29:2016 | Household and similar electrical appliances - Safety - Part 2-29: Particular requirements for battery chargers | |
| UL 62133-2:2020 | 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 - Part 2: Lithium systems | |
| IEC 62133-2:2017 | 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 - Part 2: Lithium systems | 19-33 |
| IEC 62304:2015 | Medical device software - Software life cycle processes (ed. 2006 as required by EN 12184:2014 Standard, Including Amendment 1-2015) | 13-79 |
| UN 38.3 | Recommendations of the TRANSPORT OF DANGEROUS GOODS, Manual of Test and Criteria, Part III, Lithium metal and lithium ion batteries | |
| ETSI EN 301 489-17 V3.2.4 | Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonized Standard for Electromagnetic Compatibility | |

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| ETSI EN 301 489-1 V2.2.3 | Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonized Standard for Electromagnetic Compatibility | |
| ETSI EN 300 328 V2.2.2 | Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonized Standard for access to radio spectrum | |
| EN 62479:2010 | Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz) | |
| IEC 60601-1-2:2014+AMD1:2020 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests | 19-36 |
| ISO 10993-1:2018 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process | 2-258 |
| ISO 10993-5:2009 | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity | 2-245 |
| ISO 10993-10:2021 | Biological evaluation of medical devices - Part 10: Tests for skin sensitization | 2-296 |
| ISO 10993-23:2021 | Biological evaluation of medical devices - Part 23: Tests for irritation | 2-291 |
| EN 12184:2014 | Electrically poweredwheelchairs, scooters and theirchargers — Requirements andtest methods | |
| 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 | | |
| USE OF INTERNATIONAL STANDARD ISO 10993-1, "BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 1: EVALUATION AND TESTING WITHIN A RISK MANAGEMENT PROCESS | | |
| The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] - July 28, 2014 | | |

### *4.1 CONCLUSION OF NON-CLINICAL TESTING*

Both the predicate device SMOOV O10 and the subject TWIST and TWIST R devices have been subjected to the same testing requirements, therefore Klaxon Mobility's subject device is substantially equivalent to the predicate, based on the results and demonstrated acceptable safety and performance.