April 11, 2025

KLAXON-MOBILITY GmbH
Riccardo Colomba
Quality Manager
Industriestrasse 1
Arnoldstein, KT 9601
Austria

Re: K250748
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: March 12, 2025
Received: March 12, 2025

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)*

K250748

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.

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
PRAStaff@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) #:

510(k) Summary

Prepared on: 2025-03-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	KLAXON-MOBILITY GmbH
Applicant Address	Industriestrasse 1 Arnoldstein KT 9601 Austria
Applicant Contact Telephone	+436763213105
Applicant Contact	Mr. RICCARDO COLOMBA
Applicant Contact Email	riccardo.colomba@etac.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	KLAXON (TWIST); KLAXON (TWIST R)
Common Name	Powered wheelchair
Classification Name	Wheelchair, Powered
Regulation Number	890.3860
Product Code(s)	ITI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K240267	TWIST and variant TWIST R	ITI

Device Description Summary

21 CFR 807.92(a)(4)

The device is an add on accessory for manual wheelchairs.

1. TWIST

TWIST device is meant to be added to the wheelchair in 5 different combinations of position and control:
1. Front mounted without handlebar, driven by the wheelchair occupant
2. Front mounted without handlebar, driven by the attendant
3. Front mounted position with handlebar, driven by the wheelchair occupant
4. Rear mounted without handlebar, driven by the wheelchair occupant
5. Rear mounted without handlebar, driven by the attendant

Coupling the TWIST device in front position to the wheelchair raises the front castors off the ground. The single wheel of the “traction unit” is then used for steering.

2. VARIATION TWIST R

VARIATION TWIST R device is meant to be added to the wheelchair in 1 only position (rear) and 2 ways of control
1. Rear mounted without handlebar, driven by the wheelchair occupant
2. Rear mounted without handlebar, driven by the attendant

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

INTENDED USE:

The TWIST and TWIST R are medical devices for active wheelchair users with a user weight of 120/140 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.

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

There are no differences in the Indications for Use between the subject devices and the devices cleared under K240267.

Technological Comparison

21 CFR 807.92(a)(6)

The TWIST (and TWIST R variation) has been cleared with 510(k) K240267.

The present request is for substantial equivalence between the device cleared with 510(k) K240267 and the changed device.

The changes do not affect intended use and indications for use.

Changes to the predicate devices are:
• Max speed in the configuration with handlebar changed from 10 km/h to 15 km/h. This change affects the TWIST device.
• Max user weight for configuration without handlebar, rear installed, changed from 120kg to 140kg. This change affects the TWIST and variation TWIST R devices.

The changes satisfy the requirements for the Special 510(k) process.

1. The changes are to the manufacturer's own device.
2. To validate the changes, evaluation of performances are needed. Static stability, dynamic stability, stopping distance and structural resistance have been evaluated throughout the application of consensus standards.
3. There are well-established methods to evaluate the change. Recognized consensus standards have been used to validate the changes.
4. The data can be reviewed in a summary or risk analysis format. Change Control Activities description and Risk analysis (in a matrix form) have been used for data review.

Device & Predicate Device(s):	K250748	K240267
General Device Characteristics	**Subject**	**Predicate**
Device Name/Model	TWIST / TWIST R	TWIST / TWIST R
Sponsor Company	Klaxon Mobility GmbH	Klaxon Mobility GmbH
Primary Device Regulation	890.3860	890.3860
Pro Code	ITI	ITI
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.	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.
Use Environment	Indoor/Outdoor	Indoor/Outdoor
Wheelchair Compatibility	Broad compatibility across majority of legally marketed wheelchairs	Broad compatibility across majority of legally marketed wheelchairs
Materials	Aluminum, Polyvinyl chloride, Polyurethane, Polyamide, Polyester	Aluminum, Polyvinyl chloride, Polyurethane, Polyamide, Polyester
Device Dimensions (inches)	10	10
Accomodates Wheel Dimensions (inches)	22 – 26 front mount 24 – 26 rear mount	22 – 26 front mount 24 – 26 rear mount
Max User Weight	120 kg ; 265 lbs 140 kg; 309 lbs when rear mounted	120 kg; 265 lbs
Device Weight	Weight without battery TWIST with handlebar: 9.8 (21.6 lbs) TWIST w/out handlebar: 7.4 (16.3 lbs) TWIST R: 6.5 (14.3 lbs) Battery weight: 1.4 (3 lbs)	Weight without battery TWIST with handlebar: 9.8 (21.6 lbs) TWIST w/out handlebar: 7.4 (16,3 lbs) TWIST R: 6.5 (14.3 lbs) Battery weight: 1.4 (3 lbs)
Controller	Joystick (Electronic, brushless dual-drive rocker)	Joystick (Electronic, brushless dual-drive rocker)
Motor Type	Brushless	Brushless
Motor Output	Brushless Motor, 24V, 150 W, 2 pieces	Brushless Motor, 24V, 150 W, 2 pieces
Location	Front or Rear wheels	Front or Rear wheels
Battery	Rechargeable Li-ion	Rechargeable Li-ion
User Interface	LEDs for battery levels, device's	LEDs for battery levels, device's

Device & Predicate Device(s):	K250748	K240267
General Device Characteristics	**Subject**	**Predicate**
Device Name/Model	TWIST / TWIST R	TWIST / TWIST R
	Status information and BT connection	Status information and BT connection
Power	250 W, 36 V, 4 Ah	250 W, 36 V, 4 Ah
Charging Time	Approx. 2 h	Approx. 2 h
Range per charge	21 km (13 miles)	21 km (13 miles)
Maneuvering Range	10 km	10 km
Max Speed	TWIST front with handlebar: 15 km/h (9.3 mph) TWIST front without handlebar: 6 km/h (3.7 mph) TWIST and TWIST R rear: 6 km/h (3.7 mph); TWIST and TWIST R (optional): 10 km/h (6.2 mph)	TWIST front with handlebar: 10 km/h (6.2 mph) TWIST front without handlebar: 6 km/h (3.7 mph) TWIST and TWIST R rear: 6 km/h (3.7 mph); TWIST and TWIST R (optional): 10 km/h (6.2 mph)
Charger Type	Off-board	Off-board
Input Power	230 V	230 V
Output Power	48 Vdc, 2 A	48 Vdc, 2 A
Actuator	BLE remote controller for all versions without handlebar.	BLE remote controller for all versions without handlebar.
Brake	Mechanical and electronic electromagnetic brake system; No brake applied when in rear mount configuration.	Mechanical and electronic electromagnetic brake system; No brake applied when in rear mount configuration.
Minimum Breaking Distance and Time	With Handlebar 0.89 m Without Handlebar 0.97 m	With Handlebar 0.47 m Without Handlebar 0.97 m
Downhill Travel Speed Control	Front mounted: 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 Rear mounted: The system stops pushing (freewheel available) when the maximum speed is reached. There is no speed limit when riding down a slope.	Front mounted: 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 Rear mounted: The system stops pushing (freewheel available) when the maximum speed is reached. There is no speed limit when riding down a slope.
Curb Climbing (Max) Ability	30 mm	30 mm
Ground Clearance	30 mm	30 mm
Max Incline	6 °	6 °

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

NON CLINICAL TESTS USED TO VALIDATE CHANGES
The following consensus standards have been applied to validate the changes.

ISO 7176-1:2014 (Wheelchairs - Part 1: Determination of static stability), recognition 16-195

ISO 7176-2:2017 (Wheelchairs - Part 2: Determination of dynamic stability of electrically powered wheelchairs), recognition 16-202

ISO 7176-3:2012 (Wheelchairs - Part 3: Determination of effectiveness of brakes), recognition 16-192

ISO 7176-8:2014 (Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths), recognition 16-197

CONCLUSION OF NON CLINICAL TESTING
Both the TWIST, and variation TWIST R, devices as cleared in 510(k) K240267 and changed TWIST, and variation TWIST R, devices have been subjected to the same testing requirements to validate the changes. Therefore, Klaxon Mobility's changed device is substantially equivalent to the cleared one, based on the results and demonstrated acceptable safety and performance.