December 16, 2022

KLAXON Mobility GmbH
Riccardo Colomba
Bme
Industriesrasse, 1
Arnoldstein, Villach Land 9601
Austria

Re: K222502
Trade/Device Name: Klick (variants: Power, Race, Monster)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 18, 2022
Received: August 18, 2022

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 (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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222770

Device Name
Conductive Gel

Indications for Use *(Describe)*
Intended for use with electric stimulation therapy devices, such as TENS and EMS. Conductive Gel is used with external electrodes to reduce the impedance of the contact between the electrode and the skin.

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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"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."

Table Of Contents

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

1.1 SUBMITTER'S DATA

a. **Name**: Klaxon-Mobility GmbH
b. **Address**: Industriestrasse, 1
ZIP 9601, Arnoldstein
Austria
c. **Telephone Nr**: +43 (0)6644681294
d. **Contact Person**: Mr Riccardo Colomba (r.colomba@klaxon-klick.com; 0043(0)6763213105)

e. **Issue date**: 2022, July the 7th

1.2 SUBJECT DEVICE'S DATA

a. **510(k) Number:** **K222502**
b. **Name**: Klick (variants: Power, Race, Monster)
c. **Classification regulation**: Powered Wheelchairs
d. **Regulatory Class**: Class II 21 CFR 890.3860
e. **Classification Panel**: Physical Medicine
f. **Product code**: ITI

1.3 PREDICATE DEVICE'S DATA

Klaxon claims substantial equivalence for the subject device Klick (in the variants Power, Race and Monster) to the predicate device SMOOV O10 by Alber GmbH.

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

a. **510(k) Number**: K192016
b. **Trade/Device Name**: SMOOV O10
c. **Regulation Number**: 21 CFR 890.3860
d. **Regulation Name**: Powered Wheelchair
e. **Regulatory Class**: Class II
f. **Product Code**: ITI
g. **Classification Panel**: Physical Medicine
h. **Dated**: February 14, 2020
i. **Received**: February 19, 2020

1.4 SUBJECT DEVICE DESCRIPTION

The KLICK 2021 device is a "TRACTION UNIT" (also called DRIVE UNIT or HUB) which is connected to the wheelchair (via a LINK SYSTEM) to provide electric propulsion to the three wheels resultant vehicle.

The motor is in the front wheel (traction unit).

The handlebar contains all the interfaces with which the user can drive the vehicle.

The front castors rise off the ground and a single wheel, in the "traction unit", is used for steering.

Klick can be used both with rigid or foldable wheelchairs.

The main parts of the drive unit are as follows:

- HUB (drive or traction unit): is the aluminium frame with brushless motor, steering set and aluminium fork, for both the steering and the traction functions
- Motor: is a brushless unit with 250W nominal power for the Power variant and 1000W power for the Race and Monster variants
- Wheel: aluminium rim, 14inch diameter for Power and Race, 20inch for Monster
- Removable battery (available in 3 capacity versions: 11.6Ah, 5.8Ah, 2.9Ah)
- Handlebar with user interfaces:
    i. Throttle
    ii. Cruise control, front/reverse selection switch

iii. Electronic brake
iv. Left hand mechanical brake
v. Right hand mechanical brake
vi. Display command for ON/OFF, level selection, on/off lights (optional), on/off usb charger

- Display with driving informations, main parameters adjust.
- Stand for support the device when disconnected from the vehicle
- Battery charger is an external carriable unit (54,6V - 2A) supplied by Klaxon-Mobility GmbH.

The main parts of the connection system are:

- Clamps: are always connected to the wheelchair, assembled by a Klaxon's trained specialist
- Crossbeam: is connected to the clamps and supports the connector; the crossbeam is removable for installation on foldable wheelchairs. The connector is adjusted for each application by a Klaxon's trained specialist
- Connector: it includes the front hook and connects the HUB to the crossbeam

1.5 STATEMENT OF THE INTENDED USE OF THE DEVICE

1.5.1 Indication for use:

KLICK is not intended for specific clinical use, but as a support to the mobility of active manual wheelchairs' users. It is designed to add auxiliary power to the manual wheelchair, increasing the mobility for the wheelchair's user. Therefore, bearing in mind the operating precautions described in this document, there is no need for professional, technical or aptitude requirements to operate or use a KLICK device.

KLICK devices are intended as add-on devices for wheelchairs, thus the intended user is a person with motor disability who needs of the wheelchair support for movement.

1.5.2 Intended use

KLICK devices are medical devices designed for active, disabled wheelchair users with max 120 kg of weight. KLICK devices are designed to add an auxiliary power assist system to manual wheelchairs, quickly and easily.

The intended user is a person with motor disability who needs of the wheelchair's support for movement.
Coupling the KLICK device to the wheelchair raises the front castors off the ground. The single wheel of the "traction unit" is then used for steering. The resultant 3 wheeler vehicle increase the mobility of the patient and allows him to cover up to 50km of travel range both indoor and outdoor. The system
is easy to connect and disconnect.

The first set up is provided by Klaxon's trained specialists.

2 SUBSTANTIAL EQUIVALENCE DISCUSSION BETWEEN SUBJECT AND PREDICATE DEVICES

The predicate and subject devices have the following similar characteristics:

1. Electric brushless motor for traction
2. Powered by Lithium battery
3. The device works only when connected with a manual wheelchair

In the following discussion, the SE aspects will be detailed and compared to demonstrate the substantial equivalence in terms of:

- INDICATIONS FOR USE
- TECHNOLOGY
- PERFORMANCE SPECIFICATION

2.1 INDICATIONS FOR USE COMPARISON BETWEEN PREDICATE AND SUBJECT DEVICES

Indications For Use	KLICK is not intended for specific clinical use, but as a **support to the mobility of active manual wheelchairs' users**. It is designed to **add auxiliary power to the manual wheelchair**, increasing the mobility for the wheelchair's user. Therefore, bearing in mind the operating precautions described in this document, there is no need for professional, technical or aptitude requirements to operate or use a KLICK device. KLICK devices are intended as add-on devices for wheelchairs, thus **the intended user is a person with motor disability who needs of the wheelchair support for movement.**	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.

2.2 TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICE

2.2.1 GENERAL

Item	Predicate device	Subject device	Safety Remarks
Motor	Brushless motor	Brushless motor	Same technology
Battery	Lithium-Ion	Lithium-Ion	Same technology
Display	Only leds for battery levels, device's status information and BT connection	Display with complete driving information and device status information (see 10.5.1 USER INTERFACE FUNCION)	The more complete information about driving that are available on Subject device increases the

			level of safety (e.g. the user is always aware about the speed).

2.2.2 MOUNTING POSITION

Predicate device	Subject device	Safety Remarks
Mounted on the rear of the wheelchair. The castor wheels are always in contact with the ground	Mounted on the front of the wheelchair, the castor wheels are lifted from the ground 25mm to 40mm	The Subject device does not present a new safety risk of tip over in case of ground unevenness, curbs, obstacles (this risk is very high on the predicate device). Moreover the Subject device can limit the speed and effectively brake in downhill due to the front mounting.

2.2.3 BRAKING/SPEED LIMIT

	Predicate device	Subject device	Safety Remarks
Brake means	No braking effect, only freewheeling mode. The brake effect is given by the user acting on the wheel rims	3 braking modes available: 1.double caliper's mechanical brake with double lever command. Each caliper is strong enough to completely stop the motor while is pushing at the maximum power 2.EBS (electronic brake system) is an electronic brake which is operated both by a button and by the first movement of the brake lever	The Subject device does not present a new safety risk because the user is always able to completely stop the device in any situation.
Speed limit	The system stops pushing when the maximum speed is reached. There is no speed limit in downhill.	The device limits the speed in downhill according with the speed level selected or with the speed fixed with the cruise control function	The Subject device does not present a new safety risk because there is no risk to overcome the desired/fixed speed in downhill

2.2.4 COMMANDS

Predicate device	Subject device	Safety Remarks
Wireless command	Wired commands	For subject device there is no risk connection fault

2.3 PERFORMANCE SPECIFICATION

	Predicate device	Subject device	Safety Remarks
Maximum speed	10 km/h	15 km/h	The level of safety of the predicate device could be considered higher. Taking into consideration the two aspects: 1.brakes 2.mounting position The level of safety is still deemed the same as the Subject device

Travel Range	20km	45-50km	No safety remarks
System voltage	36V	48V	No safety remarks
Motor Nominal Power	250W	250W (Power) 1000W (Race-Monster)	No safety remarks

2.4 SUBSTANTIAL EQUIVALENCE CONCLUSIONS

2.4.1 INDICATIONS FOR USE

From the **indications for use** point of view, referring to the labeling, the two devices are deemed substantially equivalent:

a. Both are intended as ADD ON to manual wheelchairs.
b. Both the devices are designed to add electrical power to the manual wheelchair in order to reduce or eliminate (in the case of Klick) the efforts of the user.
c. Both are meant to be used by active wheelchair users

The Predicate device is meant to be mounted on the rear of the wheelchair, while the Subject device is meant to be mounted on the front. This different layout of the two devices doesn't affect the neither indications for use nor the intended use, which, for both, is to be added to a manual wheelchair in order to turn it into an electrical powered device.

2.4.2 TECHNOLOGY

The main technical differences between the predicate device and the subject device are:

The mounting position: the predicate device is mounted on the rear and the castor wheels are on the ground, which leads to a high risk of roll over in case of ground unevenness; the subject device is mounted on the front of the wheelchair and the castor wheels are risen off the ground (25mm to 40mm). The safety level is higher on the subject device because of the very low risk of roll over in presence of ground uneveness.

The braking means: there are no brakes on the predicate device, whilst the subject device has double-caliper mechanical brakes and electronic brakes. Moreover in downhill there is no mean to reduce the speed of the predicate device, whilst the subject has an automatic speed control which maintains the selected speed also in downhill.

2.4.3 PERFORMANCE

The higher performance of the subject device (15 km/h instead of 10km/h) do not affect the safety. The subject device is deemed to be safer than the predicate due to the presence of both double-caliper mechanical brakes and electronic brakes. The predicate device has no braking means.

2.4.4 CONCLUSION

Under all points of view (indications for use, technology, performance) the subject device's level of safety is not negatively affected by the differences against the predicate device.

The analysis of the indications for use, technology and performance leads to deem the subject device as safe and effective as the predicate.