March 7, 2025

Batec Mobility, S.L.
Jordi Clapés Donadeu
Quality Manager
C/ Illa de Buda 2
Sant Quirze del Vallès, Barcelona 08192
Spain

Re: K241159
Trade/Device Name: Handbike Batec Electric
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: March 4, 2025
Received: March 4, 2025

Dear Jordi Clapés Donadeu:

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.

510(k) Number *(if known)*
K241159

Device Name
Handbike Batec Electric

Indications for Use *(Describe)*
Batec 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 Batec device.
Batec 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.

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.

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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."

510(k) Summary

DATE PREPARED: March 7, 2025
SUBMITTER NAME: Batec Mobility S.L.
SUBMITTER ADDRESS: C/ Illa de Buda 2
08192, Sant Quirze del Vallès, Barcelona
SPAIN

CONTACT: Jordi Clapés
TELEPHONE: +34 93 544 2003

e-mail: jclapes@batec-mobility.com

DEVICE TRADE NAME: Handbike Batec Electric
COMMON NAME: Powered wheelchair
REGULATION DESCRIPTION: Physical Medicine
REGULATION NUMBER: 21 CFR 890.3860
PRODUCT CODE: ITI

PREDICATE DEVICE(S): Klick (variants: Power, Race, Monster) (K222502)

DEVICE DESCRIPTION:

The Handbike Batec Electric is a handcycle mechanism that adapts to a manual wheelchair, forming a three-wheeled chair, allowing the user to move with the help of an electric motor located in the front wheel, optimizing the user's capabilities and increasing their autonomy.

Handbike Batec Electric aims to convert a manual wheelchair into an electrically propelled tricycle that allows the disabled collective to make larger and more complex movements and routes than those that can be made only with the manual wheelchair, increasing their independence and autonomy in daily life by performing recreational and sporting activities.

The operation of the Handbike Batec Electric is the same in all models, changing only the wheel size, maximum speed, and equipment. First the handbike must be coupled to the wheelchair. Once the two parts are attached, we will have a set consisting of three wheels: the wheelchair seat, the transmission and traction on the front wheel. To operate the handbike, the transmission of the handbike must be operated by pedaling with the controls or by pressing the accelerator. In this way we will drive the front wheel with the manufactured product.

The device has two independent mechanical brakes (right and left) and a parking brake. In addition, there is an automatic speed-limiting motor brake managed by software, which prevents exceeding 120% of the speed limit setting in each mode.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of substantial equivalence, Handibike Batec Electric are compared with the following previously cleared devices:

- K222502 Klick (variants: Power, Race, Monster)

510(k) Summary

Comparison of the proposed devices with the predicate devices is summarized in the following table:

	SUBJECT DEVICE	PREDICATE	EQUIVALENCE DISCUSSION
510(k)	K241159	K222502	-
Product Code	ITI	ITI	Same
Class	Class II	Class II	Same
Regulation Number	21 CFR 890.3860	21 CFR 890.3860	Same
Device	Handbike Batec electric	Handbike klaxon Klick	Equivalent
Indication for Use	Batec 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 Batec device. Batec 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.	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.	Same
Intended Use	Batec devices are medical devices designed for active, disabled wheelchair users with max 110 kg of weight. Batec devices are designed to add auxiliary power to the manual wheelchair, quickly and easily. The intended user is a person with motor disability who needs of the wheelchair's support for movement. Coupling the Batec 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 50km of travel range both indoor and outdoor. The system	KLICK devices are medical devices designed for active, disabled wheelchair users with max 120 kg of weight. KLICK devices are designed to add auxiliary power to the manual wheelchair, 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 50km of travel range both indoor and outdoor. The system is easy to connect and disconnect.	Same

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	SUBJECT DEVICE	PREDICATE	EQUIVALENCE DISCUSSION
	is easy to connect and disconnect. The first set up is provided by Batec's trained specialist.	The first set up is provided by Klaxon's trained specialist.	
Use condition	Indoor and outdoor.	Indoor and outdoor.	Same
Number of wheels	**1**	**1**	Same
Function of wheels	Front wheel: driven wheel suitable for rotation, acceleration and brake	Front wheel: driven wheel suitable for rotation, acceleration and brake.	Same
Movement control method	Electronic and mechanic system	Electronic and mechanic system	Same
Driving System	Direct drive, steering bar, handlebar and twist throttle	Direct drive, steering bar, handlebar and twist throttle	Same
Display	LCD display	LCD display	Same
Brake system	Two mechanical brake levers, two callipers, one disc brake Ø140 mm in Mini 2 and Ø200 mm in Scrambler 2 Automatic electronic brake limits max speed to ≤ 120% of set limit	Electronic brake, left and right mechanical brake	Similar, there are no safety or effectiveness concerns.
Braking distance	< 1.5 meters at 15 km/h in dry conditions	Not publicly available	Similarly, no safety or effectiveness concerns.
Maximum Safe operational incline degree	10°	6°/ 10%	Similar
Battery charger	Mini 2: 36 V Scrambler 2: 48 V	48 V	Same
Main frame material	Aluminium 7005-T6 Aluminium 6061-T6	Aluminium	Similar, no safety or effectiveness concerns raised.
Seat cushion	No	No	Same
Overall Dimension (length*width*height)	Mini 2: W=570 ,H=856, L=870 Scrambler 2: L=1070, W=580, H=1020	Power: W 50 cm x H 90 cm x D 40 cm Monster: W 50 cm x H 90 cm x D 50 cm	Similar
Folded Dimension (length*width*height)	Mini 2: W=369, H=719, L=736 Scrambler 2: W=310, H=825, L=925	Not publicly available	n/a
Front wheel size/type	Mini 2: 12" Aluminium rim, 12.5 x 2.75" Tyre Scrambler 2: 19" Aluminium rim, 20 x 2.5" Tyre	Aluminium rim, 14" diameter for Power and race, 20" for Monster	Similar, no safety or effectiveness concerns raised.
Analysis Rear wheel size/type	No	No	Same
Max forward speed	15km/h	15km/h	Same
Max reverse speed	5 km/h	Not publicly available	n/a
Max loading weight	110 kg	120 kg	Similar

510(k) Summary

	SUBJECT DEVICE	PREDICATE	EQUIVALENCE DISCUSSION
Battery	Li-ion battery: 36 V 280 Wh, 36 V 576 Wh, 48 V 748 Wh	3 versions of Lithium-Ion battery 48V: 2.9 Ah (140Wh), 5.8 Ah (280Wh), 11.6 Ah (528Wh),	Similar
Maximum distance of travel on the fully charged battery	Mini 2: 21.5 km using 280 Wh battery 44 km using 576 Wh battery Scrambler 2: 57.5 km using 748 Wh battery	45-50 km	Similar
Motor	Mini 2: Brushless motor nominal 350 W, peak 600 W Scrambler 2: Brushless motor nominal 1440 W, peak 1620 W	is a brushless unit with 250W nominal power for Power variant and 1000W power for the Race and Monster variants	Similar, no safety or effectiveness concerns raised.
Electronic controller	20 A nominal rate - 30 A max rate	Not publicly available	n/a
Turning Radius	1.2 meters	Not publicly available	n/a
Maximum obstacle climbing	Climbing forwards without a run-up 50 mm Climbing forwards with a run-up of 500 mm 75 mm Climbing rearwards without a run-up 25 mm Climbing rearwards with a run-up of 500 mm 25 mm Descending forwards 100 mm Descending rearwards 100 mm	To go over steps higher than 50 mm, both uphill and downhill.	Similar

None of the differences presented above impact the substantial equivalence of the subject device when compared to the predicate devices.

INTENDED USE:
As established in the Indications for Use Statement:

> Batec 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 Batec device.
> Batec 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.

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SUMMARY DISCUSSION OF NON-CLINICAL DATA:
The subject device has been tested to determine conformance to performance specifications and requirements taking account of its intended use as a mobility device. Non-clinical testing performed as specified in the following standards and in foreseeable operating conditions showed correct performance of the device as per its intended use:

- ISO 7176-1:2014, ISO 7176-2:2017, ISO 7176-3:2012, ISO 7176-4:2008, ISO 7176-5:2008, ISO 7176-6:2018, ISO 7176-8:2014, ISO 7176-9:2009, ISO 7176-10:2014, ISO 7176-11:2012, ISO 7176-13:1989, ISO 7176-14:2008, ISO 7176-15:2014, ISO 7176-21:2009 (Wheelchairs), IEC 60601-1-2:2014 + A1:2020 and IEC 62133-2 Edition 1.0 2017-02 (Lithium batteries)

SUMMARY DISCUSSION OF CLINICAL DATA:

Non-clinical test data are submitted to support this premarket notification and to establish substantial equivalence. No clinical studies are submitted.

CONCLUSIONS

We believe the intended use, the indications for use and principle of operation Handbike Batec Electric are the same as the intended use, indications for use and performance of the predicate devices.
We did not use any new technology in this system, so those differences between our new system and its predicate do not affect safety and effectiveness (SE).

- General information of both devices is the same
- Intended use and indications/principle of operations of both devices are the same.
- There are minimum differences in the technological characteristic/performance data of the proposed device and those of the predicate devices, nevertheless, all of them comply with ISO 7176 Wheelchairs. Thus, the SE is not affected.

Based on the information provided in this premarket notification, Batec Mobility S.L. concludes that Handbike Batec Electric devices are substantially equivalent to the predicate device with regard to safety and effectiveness.