March 30, 2022

Sunrise Medical (US) LLC
Devin Mcelroy
Senior Director Quality Assurance and Regulatory Affairs
2842 N Business Park Ave.
Fresno, California 93727

Re: K220213
Trade/Device Name: Empulse R90
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: January 21, 2022
Received: January 26, 2022

Dear Devin Mcelroy:

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,

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)*
K220213

Device Name
Empulse R90

Indications for Use *(Describe)*
The Empulse R90 is intended to be used to provide power assistance to manual wheelchair users. It is designed to augment the manual propulsion provided by the user, reducing the effort required by the user to propel the wheelchair.

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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510(k) Summary

DATE PREPARED
January 10, 2021

MANUFACTURER AND 510(K) OWNER
Sunrise Medical (US) LLC
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Empulse R90
Common Name:	Power Assist Device
Regulation Number:	21 CFR 890.3860
Class:	II
Product Code:	ITI: Powered Wheelchair
Premarket Review:	Neurological and Physical Medicine Devices (OHT5) Neuromodulation and Physical Medicine Devices (DHT5B)
Review Panel:	Physical Medicine

PREDICATE DEVICE IDENTIFICATION
The Empulse R90 is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K151199	Smart Drive MX2 / Max Mobility (Permobil)	✓
K140204	JWX-2 (Navione) / Yamaha	

DEVICE DESCRIPTION

The Empulse R90 is an auxiliary power module to provide augmented power to manual wheelchair users. The device utilizes a single electric drive wheel to provide the augmented power. The device mounts to a camber tube (rigid wheelchair) or a compressible axle (folding wheelchair) to provide the assisted power. On-board sensors, including an inclinometer, accelerometer and motor current sensing to determine when the user wishes to move forward and if the system is on an incline or decline.

The removable Lithium Ion battery pack is easily switched out to an alternate battery pack if additional range is required. The battery can also be removed if the user wishes to reduce the overall weight.

The actuator is used to automatically engage and disengage the locking latch as well as compress the pre-load traction spring when the user wishes to disconnect the EMPULSE R90 from the wheelchair. In the extended position, the actuator allows the pre-load spring to provide sufficient pre-load to the drive wheel to ensure sufficient traction.

INTENDED USE

The EMPULSE R90 is designed to be used on both indoor and outdoor environments, smooth flat surfaces, inclined surfaces up to 6 degrees and lightly rough surfaces such as asphalt. It is not designed to be used on highly rough surfaces such as grass or loose soil.

INDICATIONS FOR USE

The Empulse R90 is intended to be used to provide power assistance to manual wheelchair users. It is designed to augment the manual propulsion provided by the user, reducing the effort required by the user to propel the wheelchair.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Sunrise Medical (US) LLC believes that the Empulse R90 Power Assist Device is substantially equivalent to the predicate devices based on the information summarized here and in **Table 5.1**:

The subject device has a similar design and dimensions to the device cleared in K151199 and uses similar or identical materials as the devices cleared in K140204. The subject device has the same intended use and similar technological characteristics to the devices cleared in K151199 and K140204. The subject device has the same intended use environment as the devices cleared in K151199 and K140204. The subject device uses similar software to the devices cleared in K151199 and K140204. The Empulse R90 Power Assist Device has undergone testing to ensure that any differences in technological characteristics (e.g., battery, controls, and power assistance) do not negatively affect safety and effectiveness when compared to the predicate devices.

Table 5.1: Table of Technological Comparison

	Primary Predicate Permobil (Max Mobility) Smart Drive MX2	**Secondary Predicate Yamaha JWX-2 (Navione)**	**Subject Device Empulse R90**	**Statement of Equivalence**
	K151199 ITI 890.3860 30-Jul-15	K140204 ITI 890.3860 28-Aug-14	K220213 ITI 890.3860	
1 Intended Use				
1.1 Intended Use	Not provided.	The device JWX-2 (Navione) is a Power Assist Wheelchair Conversion Kit and suitable for the manual wheelchair users who are limited in their field of activities because of their physical conditions. The device can expand their field of activities by assisting their wheelchair operating force.	The Empulse R90 is intended to be used to provide power assistance to manual wheelchair users. It is designed to augment the manual propulsion provided by the user, reducing the effort required by the user to propel the wheelchair.	Substantially equivalent to Secondary Predicate. No new issues of safety or effectiveness.
1.2 Indications for Use	The SmartDrive MX2 Wheelchair Power Assist is intended to provide auxiliary power to manual wheelchairs to reduce the pushing power needed by their users, including pediatrics. It is intended to be used by users capable of operating and maneuvering a powered and manual wheelchair	The Yamaha JWX-2 is a Power Assist Wheelchair Conversion Kit and suitable for the manual wheelchair users who are limited in their field of activities because of their physical conditions. The device can expand their field of activities by assisting their wheelchair operating force.	The Empulse R90 is intended to be used to provide power assistance to manual wheelchair users. It is designed to augment the manual propulsion provided by the user, reducing the effort required by the user to propel the wheelchair.	Substantially Equivalent to Predicates. No new issues of safety or effectiveness.

	Primary Predicate Permobil (Max Mobility) Smart Drive MX2	Secondary Predicate Yamaha JWX-2 (Navione)	Subject Device Empulse R90	Statement of Equivalence
1.3 Where Used	Indoors and outdoors; care facilities and private residences.	Indoors and outdoors; care facilities and private residences.	Indoors and outdoors; care facilities and private residences.	Identical to Predicates. No new issues of safety or effectiveness
2 Safety				
2.1 Mechanical Safety	Subject to ANSI/RESNA or ISO 7176 Requirements for Power Wheelchairs, where applicable.	Subject to ANSI/RESNA or ISO 7176 Requirements for Power Wheelchairs, where applicable.	Subject to ANSI/RESNA or ISO 7176 Requirements for Power Wheelchairs, where applicable.	Identical to Predicates. No new issues of safety or effectiveness.
2.2 Electrical Safety	Subject to ANSI/RESNA or ISO 7176 Requirements for Power Wheelchairs, where applicable.	Subject to ANSI/RESNA or ISO 7176 Requirements for Power Wheelchairs, where applicable.	Subject to ANSI/RESNA or ISO 7176 Requirements for Power Wheelchairs, where applicable.	Identical to Predicates. No new issues of safety or effectiveness.
2.3 Biocompatibility	No indications of compliance	Compliant to ISO 10993-1, -5	Compliant to ISO 10993-1, -5 (See Section 15 of this submission for details).	Identical to Secondary Predicate. No new issues of safety or effectiveness.
3 Overall System				
3.1 Weight Capacity	14 kg to 150 kg	130 kg	136 kg	Substantially equivalent to Primary Predicate. No new issues of safety or effectiveness.
3.2 Expected Product Life	5 years	Not provided	5 years	Identical to Primary Predicate. No new issues of safety or effectiveness.
4 Mechanical Enclosure and Mounting				
4.1 Structural Materials	Aluminum and Steel	Aluminum and steel	Aluminum and steel	Identical to Predicates. No new issues of safety or effectiveness.
4.2 Width	141 mm	91mm (both left and right wheels)	150mm	Substantially equivalent to Primary Predicate. No new issues of safety or effectiveness. Slightly

	Primary Predicate Permobil (Max Mobility) Smart Drive MX2	Secondary Predicate Yamaha JWX-2 (Navione)	Subject Device Empulse R90	Statement of Equivalence
				wider width does not interfere with safe operation of manual wheelchairs.
4.3 Depth	389mm	Same as height	310mm	Substantially equivalent to Primary Predicate. No new issues of safety or effectiveness.
4.4 Height	242mm	609 mm (24”) 559 mm (22”)	377mm – 428mm	Substantially equivalent to Predicates. No new issues of safety or effectiveness.
4.5 Overall Mass	5.7 kg	17 kg (Ni-MH) 17.7 kg (Li-Ion)	5.5 kg + 1.1 kg (battery)	Substantially equivalent to Primary Predicate. No new issues of safety or effectiveness.
4.6 Manual Wheelchair Mount	**Rigid:** Clamp mount to the camber tube. Drive assembly pivotally mount onto clamp. **Folding:** Same as rigid but with the addition of a cross member that extends horizontally between the two axle plates, thus simulating a camber tube.	Quick Release axle mount. One wheel per side.	**Rigid:** Receiver fixed mounted to the camber tube. Drive assembly free to move vertically relative to mount. **Folding:** Same as rigid but with the addition of a cross member that extends horizontally between the two axle plates, thus simulating a camber tube.	Substantially equivalent to Primary Predicate. No new issues of safety or effectiveness.
4.7 Housing Material	Plastic	Aluminum	Plastic	Identical to Primary Predicate. No new issues of safety or effectiveness.
5 Performance				

	Primary Predicate Permobil (Max Mobility) Smart Drive MX2	Secondary Predicate Yamaha JWX-2 (Navione)	Subject Device Empulse R90	Statement of Equivalence
5.1 Max Speed (fwd)	5.5 mph	Not Specified	5.5 mph	Identical to Primary Predicate. No new issues of safety or effectiveness.
5.2 Max Speed (rev)	N/A	Not Specified	N/A	Identical to Predicates. No new issues of safety or effectiveness.
5.3 Max Safe Slope	As specified by manual wheelchair manufacturer	6°	6°	Identical to Secondary Predicate. No new issues of safety or effectiveness.
5.4 Maximum Range on Full Charge	19.8 km	20 km (NiMH) 40 km (Li-ion)	19 ± 1.5 km	Substantially equivalent to Primary Predicate. No new issues of safety or effectiveness.
5.5 Bluetooth	Bluetooth LE	Not Available	Bluetooth LE 5.2	Identical to Primary Predicate. No new issues of safety or effectiveness.
6 Power System				
6.1 Motor Power	250 W	2x 110 W	250 W	Identical to Primary Predicate. No new issues of safety or effectiveness.
6.2 Battery Type	Li-Ion	Ni-MH or Li-Ion	Li-Ion	Identical to Primary Predicate. No new issues of safety or effectiveness.
6.3 Battery Capacity	122 Whr	160 Whr (Ni-MH) 283 Whr (Li-ion)	100 Whr – 160 Whr	Substantially equivalent to Predicates. No new issues of safety or effectiveness.
6.4 Battery Charger Input	100-240 Vac, 50/60Hz	100-240 Vac, 50/60Hz	100-240 Vac, 50/60Hz	Identical to Predicates. No new issues of safety or effectiveness.
6.5 Battery Charger Output	2.0 A	2.6 A	2.0 A	Identical to Primary Predicate. No new issues

	Primary Predicate Permobil (Max Mobility) Smart Drive MX2	Secondary Predicate Yamaha JWX-2 (Navione)	Subject Device Empulse R90	Statement of Equivalence
				of safety or effectiveness.
6.6 Operating Voltage	36 Vdc	24 Vdc	36 Vdc	Identical to Primary Predicate. No new issues of safety or effectiveness.
7 Control System				
7.1Control Type	Constant power on. Stop and start of power assist is controlled by wrist strap sensor with Bluetooth communication to the drive unit.	Torque sensing handrim applies proportional power based on torque applied to the handrim. Power is pulsed on for specified duration. Gain of applied power is adjustable.	The device will sense acceleration (torque) and apply a power pulse to the drive motor for a specified duration. Gain of applied power is adjustable.	Substantially equivalent to Predicates. No new issues of safety or effectiveness.
7.2Operating Voltage	36 Vdc	24 Vdc	36 Vdc	Identical to Primary Predicate. No new issues of safety or effectiveness.
7.3 Moisture Resistance	ISO 7176-9	ISO 7176-9	ISO 7176-9	Identical to Predicates. No new issues of safety or effectiveness
7.4 Operating Temperature	-25°C to +50°C	-25°C to +50°C	-25°C to +50°C	Identical to Predicates. No new issues of safety or effectiveness.
7.5 Storage Temperature	-40°C to +65°C	-40°C to +65°C	-40°C to +65°C	Identical to Predicates. No new issues of safety or effectiveness.
8 EMC				
8.1 EMC – Immunity	Compliant to ANSI/RESNA WC2-21 or ISO 7176-21	Compliant to ANSI/RESNA WC2-21 or ISO 7176-21	Compliant to ANSI/RESNA WC2-21 or ISO 7176-21	Identical to Predicates. No new issues of safety or effectiveness.
8.2 EMC – Radiated Emissions	Compliant to ANSI/RESNA WC2-21 or ISO 7176-21	Compliant to ANSI/RESNA WC2-21 or ISO 7176-21	Compliant to ANSI/RESNA WC2-21 or ISO 7176-21	Identical to Predicates. No new issues of safety or

	Primary Predicate Permobil (Max Mobility) Smart Drive MX2	Secondary Predicate Yamaha JWX-2 (Navione)	Subject Device Empulse R90	Statement of Equivalence
				effectiveness.
8.3 EMC - ESD	Compliant to ANSI/RESNA WC2-21 or ISO 7176-21	Compliant to ANSI/RESNA WC2-21 or ISO 7176-21	Compliant to ANSI/RESNA WC2-21 or ISO 7176-21	Identical to Predicates. No new issues of safety or effectiveness.
8.4 Power Frequency Magnetic Field Immunity	Compliant to ANSI/RESNA WC2-21 or ISO 7176-21	Compliant to ANSI/RESNA WC2-21 or ISO 7176-21	Compliant to ANSI/RESNA WC2-21 or ISO 7176-21	Identical to Predicates. No new issues of safety or effectiveness.
9 User Input Controls				
9.1 On/Off Button	Located on the drive unit	Located on the drive unit	Located on the drive unit	Identical to Predicates. No new issues of safety or effectiveness.
9.3 Speed Up/Speed Down	Available by tapping on the wrist control. Maximum speed adjustable through App.	Maximum speed adjustable on the drive unit.	Speed adjustable by applying an acceleration/retardation torque to the manual wheelchair handrims.	Substantially equivalent to Predicates. No new issues of safety or effectiveness.
9.4 Battery state of charge indication	LED Indicator	LED Indicator	LED Indicator	Identical to Predicates. No new issues of safety or effectiveness.
9.5 Programming Tool	Smart phone app	Not programmable	Smart phone app	Identical to Primary Predicate. No new issues of safety or effectiveness.
9.6 Bluetooth functionality	Parameter setting Over the air firmware updates Distance, pushes and time tracker Route Tracking	Not available	The Control Box connects with the primary drive unit through a wireless Bluetooth connection. The Control Box provides secondary speed increase, speed decrease and motor de-energization through the control box. The	Substantially equivalent to the Primary Predicate. No new issues of safety or effectiveness.

	Primary Predicate Permobil (Max Mobility) Smart Drive MX2	Secondary Predicate Yamaha JWX-2 (Navione)	Subject Device Empulse R90	Statement of Equivalence
			Control Box also provides a means to toggle between lifting and deploying the drive wheel actuator.	

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate substantial equivalence based on current industry and FDA recognized standards.

- Energy consumption (per ISO 7176-4)
- Maximum speed, acceleration, and deceleration (per ISO 7176-6)
- Static, impact, and fatigue (per ISO 7176-8)
- Climatic test (per ISO 7176-9)
- Obstacle climbing (per ISO 7176-10)
- Power and control systems for power wheelchairs (per ISO 7176-14)
- Documentation and labeling (per ISO 7176-15)
- EMC testing (per ISO 7176-21)
- Vocabulary (per ISO 7176-26)
- Alkaline or other non-acid electrolyte batteries safety testing (IEC 62133-2)
- Evaluation and testing within a risk management process (per ISO 10993-1)
- Software life cycle process (per IEC 62304)

CONCLUSION

Based on the testing performed, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed Empulse R90 Power Assist Device is assessed to be substantially equivalent to the predicate devices.