November 12, 2024

Soul Mobility
℅ John Ziobro
Principal Consultant
SpectraMedEx, LLC
3215 Golf Road, #149
Delafield, Wisconsin 53018

Re: K242430
Trade/Device Name: Power-Flex (PFX1214); Power-Flex (PFX1517); Power-Flex (PFX1820)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 15, 2024
Received: August 15, 2024

Dear John Ziobro:

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)*

K242430

Device Name

Power-Flex (PFX1214);
Power-Flex (PFX1517);
Power-Flex (PFX1820)

Indications for Use *(Describe)*

The Power-Flex by Soul Mobility is intended to provide enhanced mobility to disabled persons who are capable of operating a powered and manual wheelchair, by providing powered mobility to manual wheelchairs.

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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K242430 510(k) Summary

1. Summary Date: August 16, 2024

2. Applicant Name: Soul Mobility
659 River Bluff Circle
Oconomowoc, WI 53066
Website: www.soul-mobility.com
Owner/Operator Number: Pending

3. Submission Correspondent: On behalf of Soul Mobility, the following consultant is assigned the responsibility of submission correspondence:
Troy Tesmer
CEO & Founding Partner
Soul Mobility, Inc
Ph: 920-691-6700
email:troy@soul-mobility.com

4. Authorized Correspondent: On behalf of Soul Mobility, the following consultant is authorized to correspond with the agency in regard to this submission:
John F. Ziobro, Principal Consultant
SpectraMedEx, LLC
3215 Golf Drive, #149
Delafield, WI 53018
Ph: 262-719-8922
email: jfz@spectramedex.com

5. Trade Name: Power-Flex

6. Common Name: Powered Wheelchair

7. Model Numbers PFX1214 / PFX1517 / PFX1820)

8. Description: Power-Flex is a power-assist drive that can be attached to a manual wheelchair frame, which enables a manual wheelchair to perform like an electrical wheelchair. The power-flex drive system includes two drive wheels, two caster wheels for stability, batteries, a control unit, a power supply and a manual tilt mechanism which also acts as an anti-tip preventative. The Power-Flex connects via the manual chair frame standard axle receivers and the rear manual tilt clamp which attaches to the rear rigidizer bar of the manual wheelchair. The manual wheelchair and frame are not part of the drive system and is provided by the customer. The control unit is the steering device of the system

9. Manufacturing Site: Lake Air Products
1380 Co Rd E East
Vadnais Heights, MN 55110
Ph: (763) 785-2429
Establishment Registration Number: Pending

10. Sterilization Site: N/A. The device is not provided sterile, nor does it need to be sterilized.

11. Suggested Classification Regulation, Class, Product Code, Description & Panel:

Regulation #	Class	Product Code	Description	Review Panel
21 CFR 890.3860	II	ITI	Powered Wheelchair	Physical medicine

12. Reason for Traditional 510(k): New Submission (No previous submissions)
13. Predicate Device(s): AMP
14. 510(k) Number: K231032
15. Manufacturer: Method Mobility
    2562 N Fordham Avenue
    Fresno, CA 93727
    Ph: (888) 882-6788
    Website: methodmobility.com
    Owner/Operator Number: 10088920
    Trade Name: AMP, AMP+
    Predicate Classification Regulation, Class, Product Code, Description & Panel

Regulation #	Class	Product Code	Description	Review Panel
21 CFR 890.3860	II	ITI	Powered Wheelchair	Physical medicine

16. Proposed Indication for Use:
    The Power-Flex by Soul Mobility is intended to provide enhanced mobility to disabled persons who are capable of operating a powered and manual wheelchair, by providing powered mobility to manual wheelchairs.
17. Compliance to Special Controls / Performance Standards
    The recognized ANSI RESNA consensus standards under ITI which are applicable to the proposed device are as follows:
    - 16-207 ANSI RESNA WC-1:2019 Section 1, American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 1: Determination of static stability.
    - 16-208 ANSI RESNA WC-2:2019 Section 2, American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 2: Determination of dynamic stability of electrically powered wheelchairs.
    - 16-209 ANSI RESNA WC-1:2019 Section 3, American National Standard for Wheelchairs - Volume 1: Additional Requirements for Wheelchairs (including Scooters) Section 3: Determination of effectiveness of brakes.
    - 16-210 ANSI RESNA WC-2:2019 Section 4, American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 4: Energy consumption of electrically powered wheelchairs and scooters for determination of theoretical distance range.
    - 16-211 ANSI RESNA WC-1:2019 Section 5, American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 5: Determination of dimensions, mass and maneuvering space.
    - 16-212 ANSI RESNA WC-2:2019 Section 6, American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 6: Determination of maximum speed of electrically powered wheelchairs.
    - 16-213 ANSI RESNA WC-1:2019 Section 7, American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 7: Method of measurement of seating and wheel dimensions.
    - 16-214 ANSI RESNA WC-1:2019 Section 8, American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 8: Requirements and test methods for static, Impact and fatigue strengths.
    - 16-215 ANSI RESNA WC-2:2019 Section 9, American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 9: Climatic tests for Electrically powered wheelchairs.

- 16-216 ANSI RESNA WC-2:2019 Section 10, American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 10: Determination of obstacle-climbing ability of electrically powered wheelchairs.
- 16-217 ANSI RESNA WC-1:2019 Section 11, American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 11: Test mannequins.
- 16-218 ANSI RESNA WC-1:2019 Section 13, American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 13: Determination of Coefficient of Friction of Test Surfaces.
- 16-219 ANSI RESNA WC-2:2019 Section 14, American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 14: Power and Control Systems for Electrically Powered Wheelchairs Requirements and Test Methods.
- 16-220 ANSI RESNA WC-1:2019 Section 15, American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 15: Requirements for Information Disclosure, Documentation and Labeling.
- 16-223 ANSI RESNA WC-1:2019 Section 22, American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheels chairs (including Scooters) Section 22: Set-up Procedures.
- 16-224 ANSI RESNA WC-2:2019 Section 21, American National Standard for Wheelchairs - Volume 2, Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters.
- 16-225 ANSI RESNA WC-1:2019 Section 26, American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 26: Vocabulary
  Note: This standard pertains to vocabulary and as such, is not "applied.
- 16-230 ANSI RESNA WC-2:2019 Section 25 , American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 25: Batteries and Chargers for Powered Wheelchairs.
- 16-234 ISO 7176-14 Third Edition 2022, Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
- 16-235 ISO 7176-25 Second Edition 2022, Wheelchairs - Part 25: Lead-acid batteries and chargers for powered wheelchairs - Requirements and test methods

Other applied standards are as follows

- ISTA 3A Packaged products for parcel delivery system shipment 70kg (150lb) or Less

	Proposed Device		Predicate Device		Comments
Design Variants / Family Members	Soul Mobility - Power-Flex PFX1214 / PFX1517 / PFX1820		Method Mobility AMP (14"-16") / AMP (16"-18") / AMP (18"-20") Cleared under K231032		For visual comparison only
	Indications for Use				
Device Description	Power-Flex is a power-assist drive that can be attached to a manual wheelchair frame, which enables a manual wheelchair to perform like an electrical wheelchair. The Power-Flex drive system includes two drive wheels, two caster wheels for stability, batteries, a control unit, a power supply and a manual tilt mechanism which also acts as an anti-tip preventative. The Power-Flex connects via the manual chair frame standard axle receivers and the rear manual tilt clamp which attaches to the rear rigidizer bar of the manual wheelchair. The manual wheelchair and frame are not part of the drive system and is provided by the customer. The control unit is the steering device of the system		The AMP is a groundbreaking power add-on that transforms standard wheelchairs into electric mobility devices. Developed with user feedback in mind, the AMP offers an intuitive, user-friendly solution that enhances independence and mobility for people with disabilities. The AMP is designed to be easily installed on most manual wheelchairs, allowing users to convert their existing chair into a powerful electric mobility device. With its compact design and lightweight construction, the AMP can be easily transported and attached to a wheelchair in a matter of seconds		Both devices provide powered mobility to a manual wheelchair. The main difference is how the physically attach to the wheelchair. The proposed device requires the removal of the rear wheels of the wheelchair while the predicate does not. Both comply with the applicable standards which indicate that this difference does not raise any questions of safety or effectiveness.
Indication for Use / Intended Use	The Power-Flex by Soul Mobility is intended to provide enhanced mobility to disabled persons who are capable of operating a powered and manual wheelchair, by providing powered mobility to manual wheelchairs.		The AMP by Method Mobility is intended to provide enhanced mobility to disabled persons who are capable of operating a powered and manual wheelchair, by providing powered mobility to manual wheelchairs.		Except for branding, Identical to the predicate
Intended Use Environment	Suitable for: Use indoors or outdoors on ADA specified/compliant surfaces		Suitable for: Use indoors or outdoors on ADA specified/compliant surfaces		Identical to the predicate
Targeted Population	Adolescent children and adults utilizing a manual wheelchair with seat widths ranging from 12" to 20" in width and having the capability to utilize and maneuver a power chair both physically and cognitively as assessed by a qualified clinician.		Given their 3 models able to accommodate manual chair seat widths from 14" to 20" it is assumed their target population is the same: Children and adults utilizing a manual wheelchair ranging from 14" to 20" and having the capability to utilize and maneuver a power chair both physically and cognitively as assessed by a qualified clinician.		Both devices provide three variants to accommodate different sizes of manual wheelchairs. The proposed device ranges from 12-20" while the predicate ranges from 14-20." The targeted patient population is assumed to be identical. Offering a slightly wider range in wheelchair sizes does not raise any new questions of safety or effectiveness.
Intended User	Disabled persons who are capable of operating a powered and manual wheelchair		Disabled persons who are capable of operating a powered and manual wheelchair		Identical to the predicate
	General Similarities				
Overview	The Power-Flex is a power base device intended to be attached to an existing manual wheelchair		The AMP is a power base device intended to be attached to an existing manual wheelchair		Identical to the predicate
Major Components	Major Components of the Power-Flex are wheels, frame, motors, motor controller, joystick, rechargeable batteries, anti-tip mechanism		Major Components of the AMP are wheels, frame, motors, motor controller, joystick, rechargeable batteries, anti-tip mechanism		Identical to the predicate
Component Materials	Standard components produced with commonly available mfg materials and processes, i.e. - Plastics, Aluminum, Stainless Steel, Powder Coating, Anodized surfaces, rubber tires		Standard components produced with commonly available mfg materials and processes, i.e. - Plastics, Aluminum, Stainless Steel, Powder Coating, Anodized surfaces, rubber tires		Identical to the predicate
Free Wheel / Motor Disengagement	Free Wheel Mode which disables the drive motors allow the device to be attendant propelled when attached to a manual wheelchair frame		Free Wheel Mode which disables the drive motors allow the device to be attendant propelled when attached to a manual wheelchair frame		Identical to the predicate
Modularity	The Power-Flex may be removed and the host wheelchair restored to its manual wheelchair configuration		The AMP may be removed and the host wheelchair restored to its manual wheelchair configuration		Identical to the predicate
Operator	Power wheelchair operation is carried out by the user and not by an attendant		Power wheelchair operation is carried out by the user and not by an attendant		Identical to the predicate
Operation	Power wheelchair operation is controlled by a joystick input		Power wheelchair operation is controlled by a joystick input		Identical to the predicate

	Features / Specifications				
Weight Limit	Weight Limit is 275lbs		Weight Limit is 265lbs		Minor difference of 10lbs(<4% of weight) is netlabel. Power-Flex tested to 275lb weight per standards. As such, having different weight limits does not raise any new questions of safety or effectiveness.
Maximum Speed	Maximum Speed is 4.8mph		Maximum speed is 4mph		Speeds in excess of 4.5mph are common amongst power wheelchair applications. Group 3 power wheelchairs have a minimum top end speed of 4.5mph. The Power-Flex was tested and passed applicable standards with the 4.8mph top speed. As such, having different top speeds does not raise any new questions of safety or effectiveness.
Range of Travel on single charge	Range of the unit is up to 12 miles on a single charge		Range of the unit is up to 11 miles on a single charge		Minor difference is maximum range does not raise any new questions of safety or effectiveness
Operating Voltage	Operating Voltage is 24VDC		Operating Voltage is 25.7VDC		Minor differences in DC voltages does not raise any new questions of safety or effectiveness
Horn	Hand-Operated Horn via push button on joystick controller		Hand-Operated Horn via push button on joystick controller		Identical to the predicate
Battery Level Indication	Battery Level Indicator via LED lights on joystick controller		Battery Level Indicator via LED lights on joystick controller		Identical to the predicate
Speed Level Indication	Speed Level Setting indicator via LED lights on the joystick controller		Speed Level Setting indicator via LED lights on the joystick controller		Identical to the predicate
Power On/Off	On/Off Switch via push button on joystick controller		On/Off Switch via push button on joystick controller		Identical to the predicate
Operating Environment	Indoor and outdoor environment. Avoid extreme cold and/or wet conditions. Do not drive into water or submerge the power base, parts are not water tight		Indoor and outdoor environment. Avoid extreme cold and/or wet conditions. Do not drive into water or submerge the power base, parts are not water tight		Identical to the predicate
Storage Environment	Room Temperature		Room Temperature		Identical to the predicate
Standards	ANSI/RESNA WC-1 / WC-2 (ISO 7176 per FDA website listing)		ANSI/RESNA WC-1 / WC-2 (ISO 7176 per FDA website listing)		Identical to the predicate

	Operating Principles / Technology				
Motor Drives	Basic electro-mechanical drive technology consisting of two drive motors and basic gear reduction		Basic electro-mechanical drive technology consisting of two drive motors and basic gear reduction		Identical to the predicate
Braking	Braking is controlled via the microprocessor and based on the user input at the joystick		Braking is controlled via the microprocessor and based on the user input at the joystick		Identical to the predicate
Park Brake	The park brake is electro-mechanical and is removed electronically when the joystick is actuated to move the chair. The default is Park Brake ON when there is no power or input signal to move the chair		The park brake is electro-mechanical and is removed electronically when the joystick is actuated to move the chair. The default is Park Brake ON when there is no power or input signal to move the chair		Identical to the predicate
Free Wheel Mode (Park Brake Off)	Free Wheel Mode - Moving the chair without power or removing the parking brake is done via levers on top of the motor which are rotated to release the mechanical brake		Free Wheel Mode - Moving the chair without power or removing the parking brake is done via levers at the back of the motor which are pushed down to release the mechanical brake		Identical to the predicate
Wheel Configuration	4 wheels: 2 (10") drive wheels located substantially under the manual frame when installed and 2 (5") rear caster wheels for base stability		4 wheels: 2 (8") drive wheels located substantially under the manual frame when installed and 2 (4") casters - 1 each located fore and aft of the drive wheels in the center for base stability		Both devices utilize centrally located drive wheels and maintain usage of the host manual wheelchair's front casters. Therefore, they are substantially equivalent in this respect
Mechanism to attach/detach to wheelchair	The Power-Flex is attached by removing the quick release large drive wheels of the manual chair and then connecting the manual chair frame to the base via right and left axle pins that insert into the manual frame axle receivers. An anti-tip clamp is then attached to the rear of the frame. There are (3) connection points that require no tools. To detach - you reverse the steps and disconnect the rear anti-tip, retract the axle pins and then remove the frame and replace the manual chair drive wheels.		The AMP attaches to the power base by rolling the manual chair backwards onto Wheel Catches that cradle the manual chair drive wheels, locking the manual chair wheels via wheel locks on the manual chair, and then plugging the manual chair into the power base with a power lead mounted on the manual chair during initial set-up. To detach you pull the wheel catch release handle in the rear of the unit, disconnect the power lead, release the manual chair wheel locks, and roll forward out of the wheel catches.		While the systems of attachment are different, both provide a safe and secure means of attaching a manual wheelchair to a power base for enhanced mobility. The 3 attachment points of the Power-Flex utilizing axle pins in the manual chair axle receivers and a secure anti-tip clamp mechanism provides a safe and effective means for attachment.
Host Wheelchair Requirements - Type	Used only with a Rigid frame manual wheelchair. Cannot be used with a folding frame manual wheelchair		Adapts to both rigid and folding frame manual wheelchairs as long as there is 8.5" of ground clearance under the frame to avoid interference with the base.		This has no effect on safety or effectiveness. It only limits the type of wheelchair with which the Power-Flex can be used. The Power-Flex manual clearly states that it cannot be used with a folding frame manual wheelchair. Both comply with the applicable standards which indicate that this difference does not raise any questions of safety or effectiveness.
Host Wheelchair Requirements - Seat Height (Front to Rear)	The Power-Flex has no special requirements for fitment to the power base and maintains the manual chair configuration		The manual chair must have a minimum of 1/2" front to rear seat difference because the base lifts the chair when docked changing the user position		This difference has no effect on safety or effectiveness of the Power-flex as the power base does not require specific front to rear seat differences of the manual frame for the safe configuration when installed.
Software	Software is not controlled or owned by Soul Mobility and is part of the joystick/power module package purchased from the vendor utilized on numerous industry power chair applications		Software is not controlled or owned by AMP Mobility and is part of the joystick/power module package purchased from the vendor utilized on numerous industry power chair applications		Identical to the predicate
Motor Control	Motors are controlled using a microprocessor based motor controller		Motors are controlled using a microprocessor based motor controller		Identical to the predicate
Speed Control	Preselected max-speed, microprocessor controlled speed, acceleration, and deceleration. The user controls these parameters with the joystick		Preselected max-speed, microprocessor controlled speed, acceleration, and deceleration. The user controls these parameters with the joystick		Identical to the predicate
User interface	The user interface is a Joystick and push buttons		The user interface is a Joystick and push buttons		Identical to the predicate
Power	The power source is a rechargeable battery		The power source is a rechargeable battery		Identical to the predicate
Directional Control	Joystick control is used to engage motion in the forward or rearward direction and to steer the chair		Joystick control is used to engage motion in the forward or rearward direction and to steer the chair		Identical to the predicate
Charging	Charging is completed via the provided off-board battery charger and the system is charged via a 3 pin XLR type plug connection under the base of the joystick which is connected to the power base.		Charging is completed via the provided off-board battery charger and the system is charged via a 3 pin XLR type plug connection under the base of the joystick which is connected to the manual wheelchair when the manual chair is connected to the power base electrically. The power base can also be charged independently via a connection under the battery cover if the manual chair is not connected.		Both devices use rechargeable batteries. Offering different recharging methods does not does not raise any new questions of safety or effectiveness.
Battery	(2) 12V lead-acid wired in series for a 24VDC system - Rechargeable		25.7 VDC Lithium Iron Phosphate System - Rechargeable		Both devices use rechargeable batteries. Offering different battery chemistries does not does not raise any new questions of safety or effectiveness.
Battery Mount	The battery is stored under a cover and can be removed by disconnecting the battery cables from the (4) battery terminals and lifting them out		The battery is stored under a cover and can be removed by disconnecting the primary battery connection to the battery and lifting it out		Both devices use rechargeable batteries, offering different methods to access/recharge the batteries does not does not raise any new questions of safety or effectiveness..
Battery Charging	The batteries are charged via a 3 pin connector plugged into the bottom of the joystick connected to the Power-Flex base.		The batteries can be charged via (2) methods. The first is via a 3 pin connector plugged into the bottom of the joystick connected to the manual chair when docked onto AMP base. The second is directly via a connector at the battery when the manual chair is not docked.		The first method of the AMP is substantially equivalent to how the Power-Flex unit charges the batteries and the addition of a second method for when the manual chair is not docked to the AMP has no effect on safety or effectiveness as the Power-Flex does not require the manual chair to be docked to the base for charging as the joystick is mounted to the power base and not the Manual chair like the AMP. Offering different charging methods does not does not raise any new questions of safety or effectiveness.
Anti-Tip Mechanism	The Power-Flex utilizes a rear clamping mechanism which attaches to the back of the manual frame to provide both a manual tilt and an anti-tip mechanism to the manual frame when installed		The AMP relies on the user to lock his manual chair drive wheels to help prevent tipping and provides an anti-tip bar behind the unit, however, this bar only works if the manual chair is equipped with its own anti-tip bars.		Both devices offer anti-tipping mechanisms and have passed the applicable tests, as such, having a different method does not does not raise any new questions of safety or effectiveness.
Manual Wheelchair width compatibility	Power-Flex is compatible with manual chair seat widths ranging from 12" to 20"		AMP is compatible with manual chair seat widths ranging from 14" to 20"		Both units are adjustable and can adapt to a range of seat widths. The minor difference of 12" vs 14" on the low end has no effect on the safety or effectiveness of the Power-Flex base. The Power-Flex is simply able to adapt to a larger cross section of manual chair seat widths does not does not raise any new questions of safety or effectiveness.
Manual Wheelchair wheel size compatibility	Power-Flex is compatible with Manual Wheelchair wheel size ranging from 22" to 26" in diameter		Power-Flex is compatible with Manual Wheelchair wheel size ranging from 24" to 26" in diameter		Both units are adjustable and can adapt to a range of manual chair wheel diameters. The minor difference of 22" vs 24" on the low end has no effect on the safety or effectiveness of the Power-Flex base. The Power-Flex is simply able to adapt to a larger cross section of manual chair wheel diameters does not does not raise any new questions of safety or effectiveness.
Power Base Weight	Power-Flex has a weight of the unit with batteries and no manual frame attached of 118lbs		The AMP has a weight of the unit with batteries and no manual frame attached of 42lbs		The Power-Flex is heavier due to the battery type utilized, larger wheels, and motor sizes. However, it has no negative effect on the safety or effectiveness of the Power-Flex.

18. Differences between the Proposed Device and the Predicate Device:
The main differences between the Soul Mobility Power-Flex System and the predicate device Method Mobility AMP System cleared under K231032 are as follows:
- Both devices provide powered mobility to a manual wheelchair. The main difference is how they physically attach to the wheelchair. The proposed device requires the removal of the rear wheels of the wheelchair while the predicate does not. Both devices utilize centrally located drive wheels and maintain usage of the host manual wheelchair's front casters.
- The proposed device can be used only with a rigid frame manual wheelchair, while the predicate can be used with either a rigid or folding frame manual wheelchair.
- Both devices comply with the applicable standards which indicate that these differences do not raise any questions of safety or effectiveness.

The Minor differences between the Soul Mobility Power-Flex System and the predicate device Method Mobility AMP System cleared under K231032 are as follows:
- The proposed device ranges from 12-20" while the predicate ranges from 14-20."
- The proposed device uses a rechargeable lead acid battery while the predicate uses a rechargeable lithium iron phosphate battery and have DC voltages and different access ports for the recharger itself.
- The proposed device and the predicate device have different anti-tip mechanisms.
- The proposed device has a maximum weight limit of 275lbs while the predicate device has a maximum weight limit of 265lbs.
- The proposed device has a maximum speed of 4.8 mph while the predicate device has a maximum speed of 4.0 mph.
- The proposed device has a maximum range of 12 miles while the predicate device has a maximum range of 11 miles.

The minor differences are a result of customer preferences and both devices comply with the applicable standards which indicate that these differences do not raise any questions of safety or effectiveness

19. Comparison Summary / Conclusions
Soul Mobility believes the proposed device under review and the predicate device cleared under K231032 are substantially equivalent in their intended use, intended users, intended use environment and indications for use. Furthermore, both devices have the same/equivalent technological characteristics, physical characteristics and safety standards. The differences that exist between the devices, relating to their features do not affect the relative safety and/or effectiveness.