February 27, 2020

Permobil AB
Ivan Fernandez
Director of Regulatory Compliance
Box 120 S-861 23
Timra, Sweden

Re: K190682
Trade/Device Name: Explorer Mini
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup Wheelchair
Regulatory Class: Class II
Product Code: IPL
Dated: January 28, 2020
Received: January 28, 2020

Dear Ivan Fernandez:

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,

Heather Dean, Ph.D.
Acting Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190682

Device Name

Explorer Mini

Indications for Use *(Describe)*

The Explorer Mini is a pediatric powered wheelchair with the intention to provide mobility to pediatric users weighing up to 35 pounds and maximum length of up to 39 inches tall, between 12-36 months of age, who position themselves in a sitting position in the wheelchair and have the capacity to operate a joy stick hand control.

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 - **K190682**

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Date Prepared: February, 2020

Trade Name: Explorer Mini

Common/
Classification Name: Wheelchair, Standup,
Standup Wheelchair

Product Code: IPL
21CFR 380.3900

Predicate Device: WHEELCHAIR MODEL STS
Innovative Products Inc
071390
Product code: IPL
21CFR 380.3900

Description of the Explorer Mini

This submission covers the Explorer Mini device.

Indication for use:

The Explorer Mini is a pediatric powered wheelchair with the intention to provide mobility to pediatric users weighing up to 35 pounds and maximum length of up to 39 inches tall, between 12-36 months of age, who position themselves in a sitting position in the wheelchair and have the capacity to operate a joy stick hand control.

ORIGINAL, TRADITIONAL 510(K) NOTIFICATION
PERMOBIL POWERED WHEELCHAIR: **Explorer Mini**

General Description:

The Explorer Mini is designed for children with mobility impairments that will never walk, inefficient mobility or lose the ability to walk or to walk efficiently, need mobility assistance in early childhood.

The Explorer Mini is intended for children weighing up to 35 pounds versus the Wheelchair Model STS (K071390) which is intended for users weighing up to 150 pounds. The Explorer Mini is designed specifically for the pediatric users. This is a limit in indications for use to the larger population of the predicate device that includes children and young adults. Clinical and non-clinical performance testing has demonstrated this difference does not affect safety and effectiveness of the device when used as labeled.

Use environment:

Explorer Mini is intended to be used in everyday life, in safe environments where the child is. Typical environments are at the clinical training site, at home, at preschool, at friends and extended family. The design of the device is small and compact, making it possible for the child to drive the device in these environments.

Like any other infant or toddler at play, Explorer Mini is intended to be used under supervision by an adult, and it is the care-givers responsibility to ensure that the surrounding environment is safe and appropriate for the child to drive.

Principle of operation:

Explorer Mini includes a base to which the wheels and casters are attached. An adjustable height, vertical column is attached to the base. The driver control (joystick) is integrated at the top of the column and the seating system is attached to the column.

The Explorer Mini speed and direction are controlled via a control system comprising a power module and joystick.

The Explorer Mini has the appearance of a “ride on toy” and weighs between 60% and 90% less than typical power chairs available to this population today. Both appearance and weight are factors critical to acceptance by the intended user population.

Explorer Mini seat is configured with a permanent 360degree support assembly positioned around the upper torso for added user safety and stability. This assembly supports both sitting and standing. An adjustable-position saddle shaped seat is used for sitting. The saddle shape allows for ‘straddle’ standing or alternately the seat can be removed to open the area for full active standing. The 360degree support assembly adjusts to accommodate and support standing while driving.

The Explorer Mini is powered by two 5 Amp. batteries providing an approximate driving range up to 4.6 miles.

The base provides the propulsion which is derived from two (left and right) front mounted gear-motor wheel assemblies supported by two rear mounted 360degree swiveling casters. Also incorporated in the base are the batteries and control module.

When the user activates the joystick, the controller receives a signal to move the device in the direction the joystick is pointed. Simultaneously, the controller directs the gear-motors to respond appropriately. When the user releases the joystick, the chair decelerates to a stop. The inherent gear ratio holds the device in place like a park brake.

Predicate comparison of major technical features:

The Explorer Mini is substantially equivalent to **WHEELCHAIR MODEL STS (Innovative Products Inc., K071390, product code: IPL)**. The Explorer Mini has similar intended use and indications, technological characteristics, and principles of operation. The differences between the Explorer Mini and the predicate device are:

- The total weight of the of the device is considerably less at 40 pounds. This make the Explorer Mini easier to handle for secondary users.
- The speed of the Explorer Mini is 1.5mph while the Wheelchair Model STS (K071390) has a speed of up to 5mph. The speed is set to correlate to the speed a child within the intended age has when or running slowly. The low speed also ensures that the caregiver can keep up with child. This ensures that Explorer Mini has a safer speed for the pediatric end user as well as care giver.

The minor technological differences between Explorer Mini and its Predicate device Wheelchair Model STS raise no new issues of safety or effectiveness. Performance data demonstrates that the Explorer Mini is as safe and effective as the Wheelchair Model STS. Thus, the Explorer Mini is substantially equivalent.

Table 1 provides a comparison of the predicate device (Wheelchair Model STS) and the Explorer Mini in order to demonstrate substantial equivalence.

Table 1 Comparison to predicate device

Feature	**Predicate Device:** **Wheelchair Model STS**	**Subject Device:** **Explorer Mini**	**Comparison**
510(k) number	K071390	K190682	N/A
Intended Use	The intended use of the model STS pediatric powered wheelchair is to provide mobility to children and young adults, weighting up to 150 pounds, with the ability to place themselves in a sitting position in the wheelchair and have the capacity to operate a standard joy stick hand control.	The Explorer Mini is a pediatric powered wheelchair with the intention to provide mobility to pediatric users weighing up to 35 pounds and maximum length of up to 39 inches tall, between 12-36 months of age, who position themselves in a sitting position in the wheelchair and have the capacity to operate a joy stick hand control.	Permobil has designed the Explorer Mini specifically for the **pediatric users weighing up to 35 pounds and maximum length of up to 39 inches tall, between 12-36 months of age,** which is a narrower scope of the predicate device. The predicate device has a broader target group **"…provide mobility to children and young adults,**

			weighting up to 150 pounds…". Several of the functions in the Explorer Mini are designed to be appropriate for the young target group, such as the lower speed, seating area, table area, etc.
Product code	IPL 890.3900	IPL 890.3900	Identical
User age ranges and maximum weight capacities	Children or young adults weight up to 150 lbs.	12-36 months -35lbs (16kg) or 39″ (100cm)	Differences is that STS does specify upper weight limit but does not specify intended user age population. The intended user of Explorer Mini is described by a lower age limit and a maximum weight and physical size limit. Regardless of user weight or age, no new or increased risks are identified. The Explorer Mini has been subjected to all applicable ISO 7176 series tests
Device description	STS includes a base to which the wheels and casters are attached with the option of attaching a seat or standing frame.	Explorer Mini powered wheelchair includes a base to which wheels and casters are attached with the option of utilizing the seat or configuring the system for standing	Functionally Equivalent
	When the joystick is activated a signal is directed through the power module to the gear motors which propel the chair	When the joystick is activated a signal is directed through the power module to the gear motors which propel the chair &	Identical

	& control both speed and direction	control both speed and direction	
	STS uses a motor lock system for park brakes. A park brake for safety is attached to each gear-motor which is activated when the chair comes to a stop	A park brake is provided by the gear ratio which is designed to prevent movement when no signal is detected.	Functionally Equivalent
Total width	24”	19”	Functionally Equivalent
Total length	32”	25”	Functionally Equivalent
Total height	35” (to backrest)	Minimum: 28.7” Maximum 36.6”	Functionally Equivalent
Turning diameter	50”	42.5”	Functionally Equivalent
Speed Range	0-5 mph	0-1.5 mph	Appropriate for the intended user group
Driving range	25 miles	3.4 miles	Appropriate for the intended user group
Brake distance-Normal operation (Horizontal-Forward-Max speed)	Information regarding the braking distance for the STS is not available in the labeling	Minimum braking distance from maximum speed 11.8″	The lower speed of the Explorer Mini and the gear ratio which is designed to prevent movement when no signal is detected, and thereby ensuring that the Explorer Mini stops immediately make the Explorer Mini safer than the STS in regard to braking distance
Time to brake	Information regarding the braking distance for the STS has not been found. The STS User Manual states: The STS is equipped with two powerful brake systems. ● Regenerative – uses electricity to rapidly slow the vehicle when the joystick returns to the center/stop position. ● Disc park brake – activates mechanically after regenerative braking slows the vehicle to a near stop,	A park brake is provided by the gear ratio which is designed to prevent movement when no signal is detected. When the user releases the joystick, the chair immediately decelerates to a stop.	

	or when power is removed from the system for any reason The STS uses a motor lock system for park brakes. A park brake for safety is attached to each gear-motor which is activated when the chair comes to a stop.		
Operating surface & environment	The STS is designed to operate both indoors and outdoors. It maneuvers on all terrains except soft sand.	Explorer Mini is designed for indoor use and limited outdoor use on firm, flat and dry surfaces	Explorer Mini is intended to be used on safer surfaces/surroundings. Even though the Explorer Mini is designed for limited outdoor use it has been subjected to the same stability test requirements as an outdoor chair.
Manageable gradient	5°	6°	Functionally Equivalent
Max. curb height Obstacle Climbing Ability	2.5”	1.0”	Appropriate for the intended use environment
Max. chair weight	160 lbs.	52 lbs.	Appropriate for the intended user group
Frame material, frame tube size	The STS is constructed primarily of steel tubing. The base has a steel frame with a molded Plastic Overlay. The seat and standing frame are constructed of steel tubing. A version of the standing system uses a wooden backboard.	The Explorer Mini base is constructed with a steel frame with molded Plastic Overlays. The tower is constructed with aluminum extrusions while the seat and table are a combination of aluminum and steel components with molded plastic overlays. The back and lateral arms are molded plastic	There are differences in the materials used but both products are appropriately constructed for the intended user and the intended use environment and has been tested according to the requirements and to ensure safety of the device. The Explorer Mini has been tested per ISO 7176 test requirements. No new risk identified. Both STS and Explorer

			Mini are appropriately constructed for the intended use
Controller	Controller 24V PG	Controller 24V PG nVR2	Functionally Equivalent
Joystick mounting	Left or right mounted	Central mounted	Functionally Equivalent
Batteries	2 x 28 AH Gel cell batteries	2 x 12 V AGM lead-acid batteries in series	Functionally Equivalent
Stand-up feature	Power to go from sit to stand	Manual adjustment to go from sit to stand	Functionally Equivalent

Non-Clinical Testing:

The Explorer Mini has been tested according to ISO 7176 series. ISO 7176 evaluates the strength, stability (static and dynamic), and durability of the powered wheelchair. Tests are performed on the whole wheelchair to determine the performance, safety, and effectiveness of the device. All performed testing revealed that the Explorer Mini successfully passed all requirements and was found to be substantially equivalent to the predicate device mentioned in this submission.

The predicate device, the STS device, was tested according to FDA Recognized standards. The Explorer Mini was tested to the current recognized standards; ISO 7176 Series.

Table 2 List of recognized standards to which the Explorer Mini complies

Recognized standard	Standard name	Outcome
ISO 7176-1:2014 [ANSI/RESNA WC-1/1]	Wheelchairs - Part 1: Determination of static stability	Pass
ISO 7176-2:2001 [ANSI/RESNA WC-1/1]	Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs	Pass
ISO 7176-3:2012 [ANSI/RESNA WC-2/3]	Wheelchairs - Part 3: Determination of effectiveness of brakes	Pass
ISO 7176-4:2008 [ANSI/RESNA WC-2/4]	Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range	Pass
ISO 7176-5:2008 [ANSI/RESNA WC-1/5]	Wheelchairs - Part 5: Determination of overall dimensions, mass and maneuvering space	Pass
ISO 7176-6:2001 [ANSI/RESNA WC-2/6]	Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs	Pass

ISO 7176-7:1998 [ANSI/RESNA WC-1/7]	Wheelchairs - Part 7: Measurement of seating and wheel dimensions	Pass
ISO 7176-8:2014 [ANSI/RESNA WC-1/8]	Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths	Partial conformance provided alternative evidence to fulfill requirement
ISO 7176-9:2009 [ANSI/RESNA WC-2/9]	Wheelchairs - Part 9: Climatic tests for electric wheelchairs	Pass
ISO 7176-11:2012	Wheelchairs - Part 11: Test dummies	N/A – This standard sets requirements for testing
ISO 7176-10:2008 [ANSI/RESNA WC-2/10]	Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs	Pass
ISO 7176-13:1989	Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces	N/A – This standard sets requirements for testing
ISO 7176-14:2008 [ANSI/RESNA WC-2/14]	Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods	Pass
ISO 7176-15:1996 [ANSI/RESNA WC-1/15]	Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling	Pass
ISO 7176-16:2012 [ANSI/RESNA WC-1/16]	Wheelchairs - Part 16: Resistance to ignition of postural support devices	Pass
ISO 7176-21:2009 [ANSI/RESNA WC-2/21]	Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers	Pass
ISO 7176-25:2013	Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs	Partial conformance provided alternative evidence to fulfill requirement
RESNA WC-1:2009 Section 20	Determination of the Performance of Stand-up Type Wheelchairs	Pass
ISO 10993-1	Biological evaluation of medical devices	Pass

Clinical Testing:

The device is designed to provide the compensatory motor skills that work in concert with the sensory skills to bring about postural control, upper extremity stability and mobility in this young population where several developmental milestones remain to be met. A usability study was performed on 33 children with mobility impairments justifying a need for a device as the Explorer Mini. A label comprehension study of the User's manual was performed on 15 physiotherapists/occupational therapists and 15 parents. The human factor validation testing revealed that the Explorer Mini is a safe and effective medical device for the intended user, and all studied use-related risks were deemed acceptable.

Conclusions:

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as the legally marketed device. The Explorer Mini and Predicate device, Wheelchair Model STS are substantially equivalent. Explorer Mini has the same general intended use and similar indications, principles of operation, and similar technological characteristics as the previously cleared WHEELCHAIR MODEL STS; Innovative Products Inc

- K071390
- Product code: IPL
- 21CFR 380.3900