October 25, 2019

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

Re: K191874
Trade/Device Name: F5 Corpus VS
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup Wheelchair
Regulatory Class: Class II
Product Codes: IPL, ITI
Dated: September 26, 2019
Received: September 26, 2019

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,

For: Vivek J. Pinto, PhD
Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191874

Device Name
F5 Corpus VS

Indications for Use *(Describe)*
The F5 Corpus VS powered wheelchair is to provide indoor and outdoor mobility, including stand-up feature, to persons limited to a seating position that are capable of operating a powered 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Section 5. 510(k) Summary

Submitter Permobil AB
Box 120
S-861 23 Timrå
Sweden

Phone: +46 60 595900
Facsimile: +46 60 575250

Contact Person: Ivan Fernandez, Director of Regulatory Compliance

E-mail address: Ivan.Fernandez@permobil.com

Telephone number: 800-736-0925

Date Prepared: June, 2019

Trade name: F5 Corpus VS

Common or Usual Name: Powered wheelchair, Standup

Classification Name: Standup Wheelchair

Primary Product Code (*Standup feature*): IPL

Secondary Product Code: ITI

Predicate Device:

Primary:
Quickie® Q700-UP M (K172384) manufactured by Sunrise Medical (US) LLC
Secondary:
F5 (K143014) manufactured by Permobil AB.

Description of the F5 Corpus VS:

This submission covers the F5 Corpus VS device.

Indications for use:

The F5 Corpus VS powered wheelchair is to provide indoor and outdoor mobility, including stand-up feature, to persons limited to a seating position that are capable of operating a powered wheelchair.

Environment of Use:

This wheelchair has been designed to accommodate both indoor and outdoor use at care facilities and private residences. The chair is capable of handling different surfaces but performs optimally on firm even surfaces such as concrete, asphalt and indoor flooring. The Chair is designed to

-overcome a maximum obstacle height of 3" (not in standing mode),
-operate at a maximum incline angle for safe operation of 9°,

-Travel a maximum distance of 16 miles on fully charged battery.

Principles of Operation:

F5 Corpus VS Powered Wheelchair is battery powered, front wheel motor driven and is controlled by the R-net 120 amp controller. The user interface is a joystick.

The F5 Corpus VS is powered by two 12VDC, Group M24, approximate driving range on fully charged batteries is up to 25km (15.5 miles), depending on use and the terrain the chair is driven on. The chair frame is a steel construction and includes two front drive wheels with drive units (motor, gear and brake), two batteries and two rear pivoting casters. Depending on the user's needs, the joystick motor control is mounted to the left or right armrest.

When the user activates the joystick, the controller receives a signal to release the brakes. With the brakes released, the chair is allowed to move in the direction the joystick is actuated. When the user releases the joystick, the chair slows to a stop and the brakes are automatically re-engaged. The solenoid electromechanical brakes allow the user to stop by letting go of the joystick.

F5 Corpus VS will enable the user to stand up, completely or partially, to facilitate reaching, working eye to eye with colleagues.
The standing sequence is controlled by the joystick and gives the user the possibility to come to a standing position. The seating, chest support and knee stop stabilize the user during the stand-up or sit-down operation.

Comparison to Predicate Devices:

The following tables provides a comparison of the predicate device Q700-UP M and the F5 Corpus VS to demonstrate substantial equivalence. F5 Corpus VS has the same general intended use and similar indications, principles of operation, and similar technological characteristics as the previously cleared predicate Quickie® Q700-UP M. The functional difference is small and do not present any new issues of safety or effectiveness because both wheelchairs pass the requirements in ISO 7176. Thus, the F5 Corpus VS is substantially equivalent to the Q700-UP M.

Use/functions/ characteristics	**Primary Predicate device** Quickie® Q700-UP M (K172384)(Data collected from 510(k) summary)	**Submitted device** F5 Corpus VS
Intended use	The Sunrise Medical Quickie® Q700-UP M power wheelchairs are battery operated devices, that are indicated for medical purposes to provide mobility and repositioning of the user, including a stand-up feature.	The F5 Corpus VS powered wheelchair is to provide indoor and outdoor mobility, including stand-up feature, to persons limited to a seating position that are capable of operating a powered wheelchair
Type of base	Mid wheel driven	Front wheel driven
Type of motors	6.0 mph Motor Package Output Speed: 163 rpm Gear Ratio: 26:1 Peak Power:1026W @120A 8.0 mph Motor Package: Output speed: 220 rpm	LINIX 24V PM 500W

	Gear Ratio: 26:1 Peak Power: 1293W @120A	
Electronics	PG R-Net 120Amp	PG R-Net PM 120 120Amp
Battery	2 X 12V Group 24 – 73Ahr 2 X 12V Group 34 -50 Ahr	2 x 12V 73 Ah gel Group M24
Drive wheel dimension	14" diameter	3.00"-8"
Rear wheel dimension	6" diameter	210x65 (8"x2,5")
Adjustable Support Wheels	Mid wheel driven	Support Wheels mounted in the front, R100x32(4"x0.1,26")
Over all dimension, l/w/h in mm	36"/25"/not stated"	1140/790/1170(45"/31"/46")
Weight incl. batteries	375 lbs	191 kg (421 lbs)(incl. Corpus VS Seat and elevator, seat tilt)
Weight bearing capacity	265 Ibs	136 kg (300 lbs)
Maximum speed	6 or 8 mph	Up to 12 km/h (7,5 mph)
Turning Radius	43" (Turning circle)	762,5 mm (30")
Driving range	21 miles (55 Ahr Batteries)	Up to 25 km (16 miles)

Comparison to Secondary Predicate Device:

The F5 Corpus VS is substantially equivalent to the F5 (#K143014). The F5 Corpus VS has the same intended uses and similar indications, technological characteristics and principles of operation. F5 Corpus VS has the same option in tilt, recline and elevation functions as the reference device, see table below. These functions working in the same technological characteristics as the F5.

Use/functions/ characteristics	**Secondary Predicate device** F5 (K143014)	**Submitted device** F5 Corpus VS
Intended use	To provide indoor and outdoor mobility to persons restricted to a sitting position that are capable of operating a powered wheelchair	To provide indoor and outdoor mobility, including a Stand-up feature, to persons restricted to a sitting position that are capable of operating a powered wheelchair
Type of base	Front wheel driven	Front wheel driven
Type of motors	LINIX 24V PM 230W	LINIX 24V PM 500W
Electronics	PG R-Net PM 120 120 Amp	Electronics PG R-Net PM 120 120 Amp
Type of brakes	Electronic braking by drive motor. Magnetic parking brakes	Electronic braking by drive motor. Magnetic parking brakes
Battery	2 x 12V 73 Ah gel Group M24	2 x 12V 73 Ah gel Group M24
Drive wheel dimension	3.00"- 8"	3.00"- 8"
Rear wheel dimension	210 x 65 mm (8.3" x 3")	210 x 65 (8" x 2.5")
Adjustable Support Wheels	Support Wheels mounted in the front, R100x24 (4" x 0.9")	Support Wheels mounted in the front, R100x32 (4" x 0.9")
Over all dimension, length/width/height in mm	1140/680/820	1980/820/875
Weight incl. batteries	186 kg (410 lbs)(with M24 batteries)	191 kg (421 lbs)(incl. Corpus VS Seat and elevator, seat tilt)
Weight bearing capacity	136 kg (300 lbs)	136 kg (300 lbs)
Maximum speed	12 km/hr (7.6 mph)	Up to 12 km/h (7,5 mph)

	4.4 km/hr (3 mph)-rev	
Brake system	Multiple brake system: 1. Electronic braking by drive motors. 2. Magnetic parking brakes that automatically stops the chair in case of power failure.	Multiple brake system: 1. Electronic braking by drive motors. 2. Magnetic parking brakes that automatically stops the chair in case of power failure.
Ground clearance/Obstacle-climbing	76 mm/75 mm (3"/3")	76 mm/75 mm (3"/3")
Turning Radius	762,5 mm (30")	762,5 mm (30")
Driving range	Up to 25 km (15.5 miles)	Up to 25 km (16 miles)
EMI (Electromagnetic Interference)	20V/m modulated 80% AM	20V/m modulated 80% AM
Seat width	480 mm	470 mm
Total width	620 mm (24.5")	25.5-31"
Total length	1256 mm (49.5")	44.8"
Seat plate depth	Not provided	14-22"
Armrest height	235 mm	180 mm
Turning circle	762.5 mm	1470 mm
Speed	Up to 12 km/hr (7.5 mph)	12.20 km/hr (7.5 mph fwd) 4.4 km/hr (3 mph rev)
Range	23.79 km	16 miles (25 km)
Manageable gradient	6º	9º
Max curb height	60 mm	3"
Max user weight	150 kg	300 lbs. (136 kg)
Transport volume max	655-790 mm (w) x 825-930 mm (l) x 825 mm (h)	36.5" x 31" x 32.5"
Joystick Mounting	Not provided	Not provided
Attendant Controls	N/A	N/A
Light kit option	Not provided	Not provided

The minor technological differences between the F5 Corpus VS and its Reference device F5 raise no new issues of safety or effectiveness. Performance data demonstrates that the F5 Corpus VS is as safe and effective as the F5. Thus, the F5 Corpus VS is substantially equivalent.

Non-Clinical Testing:

The F5 Corpus VS complies to the below standards:

Standard # as tested	**Title**
ISO 7176-1:1999	Determination of static stability
ISO 7176-2:2001	Determination of dynamic stability of electric wheelchairs
ISO 7176-3:2003	Determination of effectiveness of brakes

ISO 7176-4:2008	Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
ISO 7176-5:2008	Determination of overall dimensions, mass and maneuvering space
ISO 7176-6:2001	Determination of maximum speed, acceleration and deceleration of electric wheelchairs
ISO 7176-7:1998	Measurement of seating and wheel dimensions
ISO 7176-8:1998	Requirements and test methods for static, impact and fatigue strengths
ISO 7176-9:2009	Climatic tests for electric wheelchairs
ISO 7176-10:2008	Determination of obstacle-climbing ability of electrically powered wheelchairs
ISO 7176-11:2012	Test dummies
ISO 7176-13:1989	Determination of coefficient of friction of test surfaces
ISO 7176-14:2008	Power and control systems for electrically powered wheelchairs and scooters – requirements and test methods
ISO 7176-15:1996	Requirements for information disclosure, documentation and labelling
ISO 7176-16:2012	Resistance to ignition of postural support devices
ISO 7176-19:2008	Wheeled mobility devices for use as seats in motor vehicles
ISO 7176-21:2009	Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
ISO 7176-22:2014	Set-up procedures
ISO 7176-25:2013	Batteries and chargers for powered wheelchairs
ISO 7176-26:2007	Vocabulary
RESNA WC-1:2009 Section 20	Determination of the Performance of Stand-up Type Wheelchairs

Clinical Testing:

Clinical testing is not applicable.

Conclusions:

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device. The F5 Corpus VS and Predicate device Q700-UP M are substantially equivalent. The F5 Corpus VS and Secondary predicate device F5 are substantially equivalent. F5 Corpus VS has the same general intended use and similar indications, principles of operation, and similar technological characteristics as the previously cleared Q700-UP M and F5 (K143014).