January 12, 2024

Velox Manufacturing Inc
% Sarah Mundim
Regulatory Affairs Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, 2500 Bee Cave Road
Austin, Texas 78746

Re: K231315
Trade/Device Name: Velox Power Chair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: January 8, 2024
Received: January 8, 2024

Dear Sarah Mundim:

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.

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 Rehabilitation 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231315

Device Name
Velox Power Chair

Indications for Use *(Describe)*
The Velox power wheelchair is a battery operated device that is intended to provide mobility to individuals who lack mobility and who have the capability to operate a power wheelchair while being restricted to the seated position.

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.

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510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

Submitter Information

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Date Summary Updated: January 11, 2024

Device Information

Trade Name:	Velox Power Chair
Common Name:	Powered wheelchair
Classification Name:	wheelchair, powered (21 CFR 890.3860)
Review Panel:	Physical Medicine (PM)
Regulation:	890.3860
Device Class:	II
Product Code:	ITI

Equivalence Claimed to Predicate Device

The Velox Power Chair is equivalent to the Quickie, Zippie (K142457), manufactured by Sunrise Medical (US) LLC.

Device Description

The Velox Power Chair is designed for everyday use for both indoor and outdoor environments including care facilities and private residences. The subject device is intended to provide mobility to persons that are restricted or limited to a sitting position.

The Velox Power Chair is a battery powered, electric motor driven device that can be used on both indoor and outdoor surfaces, on soft/rough terrain. The user controls the speed and direction of the wheelchair using the joystick and hand control buttons mounted on the chair. The brakes of the wheelchair are electromagnetic.

Substantial Equivalence Comparison

The following table compares the subject device to the predicate, with additional description provided below.

Substantial Equivalence Table

Characteristic	Proposed Device: Velox Power Chair (K231315)	Predicate Device: Quickie, Zippie (K142457)	Comparison
Indication for Use	The Velox Power Wheelchair is a battery-operated device that is intended to provide mobility to individuals who lack mobility and who have the capability to operate a power wheelchair while being restricted to the seated position.	Quickie® and Zippie® power wheelchairs are battery-operated devices with wheels that are intended for medical purposes to provide mobility to persons restricted to a sitting position. The Zippie® power wheelchairs are specifically for people who are slightly smaller in stature— including children.	Equivalent; the difference is that the predicate device has a different model for people who are slightly smaller in stature, whereas Velox has only one model.
Intended Use	Provide mobility to persons restricted to a sitting position.	Provide mobility to persons restricted to a sitting position.	Same.
Device Materials	Steel and aluminum.	Steel and aluminum.	Same.
Dimensions	25" x 35" (length by width)	24"x 34" (length by width)	Equivalent; difference in dimension is small and does not affect the safety or effectiveness.
Maximum User Weight	300 lbs	300 lbs	Same.
Regulation Description	Powered Wheelchair	Powered Wheelchair	Same.
Location for Use	Indoors, outdoors, soft/rough terrain.	Indoors, outdoors.	Equivalent; the difference in location for use does not affect the safety or effectiveness.
Maximum Speed	5.64 mph	6 mph	Equivalent; the slight difference in maximum speed does not affect the use of the device. No impact on safety and effectiveness.
Rolling Base Weight (lbs)	145	130	Equivalent; difference in weight does not affect the use of the device. No impact on safety and effectiveness.
Power Source	Batteries	Batteries	Same.

Range (miles)	15.38	Not publicly available	No impact on safety and effectiveness. The difference in range, if any, would come down to the way the drive range is calculated based on various factors. Also, difference in range of miles has many factors, such as weight of

Characteristic	**Proposed Device: Velox Power Chair**	**Predicate Device: Quickie, Zippie (K142457)**	**Comparison**
			the user, terrain, extra bags being carried etc.
Climbing Ability	1.5" - 2"	Not publicly available	No impact on safety and effectiveness. The difference in climbing ability does not affect the use of the device.
Software / Controls	R-Net or VR2 from Curtiss Wright	VR2 from PGDT	Equivalent: Both use the same controller module (VR2). Velox powerchairs may be equipped with the alternative program R-Net from the same supplier, but both controllers are equivalent in functions and this difference does not affect safety or effectiveness of the device.
Pivot Radius	25.50"	Not publicly available	No impact on safety and effectiveness if there is any difference. The difference in pivot radius does not affect the use of the device.
Battery Details	8G22NF Gel Cell or 8G24SS Gel Cell, Sealed lead acid or gel batteries	22 NF, sealed lead acid or gel cell	Same.
Drive Wheel Diameter (inches)	13.5	13	Equivalent. The slight difference in inches does not affect safety or effectiveness of the device.
Lift Range (inches)	0-15" (from the top of the plastic to the top of the rehab seat) / 0-12" (the lift platform by itself)	0-12"	Same.
Tilt Range	0-50°	0-50°	Same.

Suspension	Cloud suspension which reduces vibration with shock absorbers	Standard all wheel suspension with shock absorbers	Equivalent, suspension reduces vibration.
Folding mechanism	Yes (fold down backrest)	Yes (fold down backrest)	Same.
Armrest	Height adjustable, removable, flip up option, depth adjustable	Height adjustable and flip up option	Equivalent. Additional options do not affect the safety or effectiveness.
Footrest	Fixed, flip up, swing away, angle adjustable, rigid footplates or footboard	Swing away footrests with heel loops	Equivalent: Additional options do not affect the safety or effectiveness.

Characteristic	**Proposed Device: Velox Power Chair**	**Predicate Device: Quickie, Zippie (K142457)**	**Comparison**
Anti-pitch Mechanism for Climbing	Six wheels provide pitch stabilization	Anti-pitch lock-out	Equivalent: Pitch is controlled to ensure appropriate stability. No impact on safety and effectiveness.
Speed settings	Proportional. The braking settings are set according to the guidance of the therapist involved in setting up the chair with the client.	Not publicly available	No impact on safety and effectiveness if there is any difference. The difference in speed settings does not affect the use of the device.
Minimum braking distance from maximum speed	Programmable. The minimum braking distance for a wheelchair depends on various factors, including the speed of the chair, road conditions, the reaction time of the braking, and the reaction time of the person operating the chair. Just like the speed settings the braking settings are set according to the guidance of the therapist involved in setting up the chair with the client.	Not publicly available	No impact on safety and effectiveness if there is any difference. The difference in minimum braking distance from maximum speed does not affect the use of the device.
Recline range	0-170°	Not publicly available	No impact on safety and effectiveness if there is any difference. The difference in recline range does not affect the use of the device.

Summary of Non-Clinical Testing

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

- Static stability (per ISO 7176-1 / RESNA Section 1)
- Dynamic stability (per ISO 7176-2 / RESNA Section 2)
- Effectiveness of brakes (per ISO 7176-3 / RESNA Section 3)
- Energy consumption (per ISO 7176-4 / RESNA Section 4)
- Dimensions, mass, and maneuvering space (per ISO 7176-5 / RESNA Section 5)
- Maximum speed, acceleration, and deceleration (per ISO 7176-6 / RESNA Section 6)
- Measurement of seat and wheel dimensions (per ISO 7176-7 / RESNA Section 7)
- Static, impact, and fatigue (per ISO 7176-8 / RESNA Section 8)
- Climatic test (per ISO 7176-9 / RESNA Section 9)
- Obstacle climbing ability (per ISO 7176-10 / RESNA Section 10)
- Test dummies (per ISO 7176-11 / RESNA Section 11)
- Determination of coefficient of friction of test surfaces (per ISO 7176-13 / RESNA Section 13)
- Power and control systems for power wheelchairs (per ISO 7176-14 / RESNA Section 14)
- Documentation and labeling (per ISO 7176-15 / RESNA Section 15)
- EMC testing (per ISO 7176-21 / RESNA Section 21)
- Changing occupant posture (per ISO 7176-30 / RESNA Section 30)

Substantial Equivalence Comparison

Velox Power Chair has some minor differences in technological characteristics to the predicate device, which are detailed and addressed in the Substantial Equivalence Table. The differences are such as in dimensions, weight, battery capacity, suspension and anti-pitch mechanism, whose values are different but similar to the predicate device and do not affect the use of the device and do not impact the safety or effectiveness of the device. Also, Velox Power wheelchair has additional armrest and footrest options to accommodate user preference; these do not affect safety or effectiveness of the device. The results of the above tests indicate that the Velox Power Chair is substantially equivalent to the predicate device.

Conclusion

Velox Power Chair has the same intended use as the predicate device, and the same or similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated the Velox Power wheelchair is as safe and effective as the predicate device. Therefore, the Velox Power Chair is substantially equivalent to the predicate device.