January 24, 2023

Stryker Medical
Rachel Stallworth
Staff Regulatory Affairs Specialist
3800 E. Centre Ave.
Portage, Michigan 49002

Re: K222818
Trade/Device Name: Xpedition ™ Powered Stair Chair (625700000000)
Regulation Number: 21 CFR 890.5150
Regulation Name: Powered Patient Transport
Regulatory Class: Class II
Product Code: ILK
Dated: December 23, 2022
Received: December 23, 2022

Dear Ms. Stallworth:

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,

Tushar Bansal -S

for Heather Dean, PhD
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222818

Device Name
Xpedition ™ Powered Stair Chair (625700000000)

Indications for Use *(Describe)*
Xpedition transports a patient with a mobility-limiting medical condition or injury, who is physically able to maintain a seated position while restrained, up or down a set of stairs. Xpedition is intended for use in residential and commercial environments, including pre-hospital and hospital environments, emergency, and non-emergency applications. All operators, including healthcare professionals such as emergency medical service personnel and medical first responders, must be trained by a qualified trainer before product use.

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."

510(k) Summary

I. SUBMITTER

Stryker Medical
3800 E. Centre Ave
Portage, MI 49002

Phone: (269) 213-6493
Email: rachel.stallworth@stryker.com

Contact: Rachel Stallworth
Date Prepared: December 11, 2022

II. DEVICE

K222818
Name of Device: Xpedition ™ Powered Stair Chair (625700000000)
Common or Usual Name: Powered patient transport
Classification Name: Transport, Patient, Powered (21 CFR 890.5150)
Regulatory Class: II
Product Code: ILK

III. PREDICATE DEVICE

C-Max +, K130864
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Stryker Xpedition™ Powered Stair Chair is a seated patient transport device with handles and a powered belt and track system. The chair is designed to support and transport a maximum weight of 500 lb (227kg) up and down stairs. The chair is intended for patients who weigh 50 lb (23 kg) or more and can remain seated in the chair while secured by patient restraint straps. Handles at the head and foot ends allow operators to control the chair during powered or manual ascent or descent on stairs. Operators can push and maneuver the chair over various types of terrain expected in commercial and residential environments, as well as lift patients over obstacles. The chair has a removable patient containment system with attachment points for the chest and waist to secure a patient during transport. A fold-out footrest can be deployed for secure feet placement. A removable, rechargeable battery powers electrical functions including the motorized drive system for traversing stairs,

speed selection, direction selection, ground lighting activation, battery capacity feedback, drive activation buttons, and LED visual feedback networks. User interfaces at the back of the chair and the top handle allow for drive system control. The chair has several mechanical activations including wheel locks to prevent unintended motion on ground, a latch to fold or unfold the chair, a track deployment mechanism to deploy the stair driving track system, and top and bottom handle length adjustment activations. Options include the footrest and head end flip-up carry handles.

V. INDICATIONS FOR USE

Xpedition™ transports a patient with a mobility-limiting medical condition or injury, who is physically able to maintain a seated position while restrained, up or down a set of stairs. Xpedition™ is intended for use in residential and commercial environments including pre-hospital and hospital environments, emergency, and non-emergency applications. All operators, including healthcare professionals such as emergency medical service personnel and medical first responders, must be trained by a qualified trainer before product use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Xpedition™ Powered Stair Chair and C-Max + (plus) have the same general operating principle, frame construction, and type of power source. The specific areas where the subject device and predicate device have similar or different technological characteristics are described in more detail in the sections below.

Primary Climbing Method (Different)

The subject device can traverse stairways using two belts driven on a continuous loop. The predicate device uses an electro-mechanical piston mechanism to climb and descend stairs.

Manual Backup Option (Different)

In the event of power loss, the subject device can be used manually. The predicate device cannot be used manually.

Stairway Configuration (Similar)

The stairway configuration that the subject device and predicate can traverse in power mode is identical. The subject device can also be used on winding stairs if operators use the lift handles to manually carry the device on winding stairs.

Maximum Load (Similar)

The subject device can support a maximum load of 500 pounds, compared to the predicate device maximum load of 661 pounds.

Steps on a full charge (Different)
The subject device covers a minimum of 180 steps on a single charge, whereas the predicate device covers approximately 300 steps on a single charge.

User Interface (Similar)
The head end operator of the subject device presses buttons at the head end of the chair to ascend and descend stairs at their chosen speed. The predicate device uses a combination of an up/down switch, on/off switch, and a speed control button to ascend and descend stairs.

Speed (Different)
The subject device speed ranges from 51-71 steps per minute. The predicate device speed ranges from 3-8 steps per minute.

Height, Width, and Weight (Different)
The subject device has a height of 38 inches, width of 20.375 inches, and weight of 57.4 lbs. The predicate device has a height of 58.6-69.8 inches, width of 20.748 inches, and weight of 174.8 lbs.

Number of Operators Required (Different)
The subject device requires a minimum of two operators, whereas the predicate device instructs one operator and an optional second operator.

Storage Configuration (Similar)
The subject device is collapsible, by pulling a latch at the back of the device that folds and unfolds the chair. The predicate device can be disassembled into three parts.

Climbing Brake (Similar)
The subject device has an electric motor brake that will stop motion on stairs when the operator releases the "Go" button(s) on the user interface. The predicate device has an automatic safety brake.

Wheel Lock (Different)
The subject device has a manual foot-activated wheel lock, and the predicate device does not.

Accessories/Components/Options
The subject device has a patient containment system, head end flip-up carry handles, grooved tracks, a footrest, and a charging system. The predicate device has a head rest, seat belts, different footrests, a power charger for a vehicle, and a magnetic charging system.

VII. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination.

Non-clinical tests were conducted to demonstrate the performance (safety and effectiveness) of the Xpedition™ Powered Stair Chair and demonstrate substantial equivalence to the predicate. The following performance testing for Xpedition™ was conducted:

- To demonstrate the device's mechanical and functional safety, we performed testing according to BS ISO 7176-28:2012 Wheelchairs- Part 28: Requirements and test methods for stair-climbing devices.

- To demonstrate safe functionality under different climates, we performed tests according to ISO 7176-9:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs, Sections 8.2 – 8.5 and Section 8.8.

- To demonstrate general safety of the device, we evaluated testing according to ISO 7176-14:2022 Wheelchairs – Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods.

- To demonstrate the device's static and fatigue strength, we evaluated testing according to ISO 7176-8:2014 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths.

- To demonstrate the device's brake fatigue strength, we performed testing according to ISO 7176-3:2012 Wheelchairs – Part 3: Determination of effectiveness of brakes.

- Biocompatibility testing was performed to the following standards:

    - ISO-10993-10:2010 – Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

    - ISO 10993-5 Third edition 2009-06-01 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

    - ISO-10993-23:2021 – Biological evaluation of medical devices – Part 23: Tests for irritation

- To demonstrate the device's EMC and electrical safety, we performed testing according to the following testing methods:

    - ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R)2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

- IEC 60601-1-2:2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

- IEC 60601-1-12 Edition 1.0 2014-06- Medical electrical equipment -Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

- IEC 60601-1-6 Edition 3.1 2013-10 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- IEC TR 60601-4-2 Edition 1.0 2016-05 - Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

- AIM 7351731, Rev. 2.00, 2017-02-23 - Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

- To ensure the device can be cleaned and disinfected, testing was performed according to the following standards:

  - AAMI TIR12:2020 and AAMI TIR30:2011

- Additional simulated use testing to demonstrate mechanical and electrical performance

  - Life cycle testing (including powered stair climb performance)

  - Static and dynamic overload testing

  - Power-wash exposure

  - Shipping verification

  - Manual stair climb performance

  - Continuous stair climb performance

- Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

- Usability testing was conducted to ensure the users of the device could operate the device safely and effectively.

The following additional standards were applied to the design and development process of Xpedition™:

- ISO 14971, 3rd Edition:2019 - Medical devices – Application of risk management to medical devices
- IEC 62304-1 Edition 1.1 2015-06 Consolidated Version - Medical device software – Software lifecycle processes
- IEC 62366-1 Edition 1.0:2015 - Medical devices - Part 1: Application of usability engineering to medical devices

Clinical Studies were not required to demonstrate substantial equivalence to the predicate device.

The above software, mechanical, electrical, electromagnetic compatibility, biocompatibility, functionality, and usability testing demonstrate that the Stryker Xpedition™ Powered Stair Chair meets its functional, performance, safety and efficacy specifications and requirements and is as safe and effective as the predicate device. Based on this testing, the Stryker Xpedition™ Powered Stair Chair was demonstrated to be substantially equivalent to the predicate device

VIII. CONCLUSIONS

The subject device, Xpedition™ Powered Stair Chair is substantially equivalent to the legally marketed predicate device, C-Max +, as the differences in the technological characteristics do not raise new questions of safety and effectiveness. Non-clinical performance data demonstrates that the subject device is substantially equivalent to the predicate.