January 10, 2025

Bowhead Design Corp.
% Roshana Ahmed
Principal Consultant
Quaras, LLC
2101 Camino Rey
Fullerton, California 92833

Re: K243111
Trade/Device Name: Bowhead ERA Wheelchairs
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: December 10, 2024
Received: December 10, 2024

Dear Roshana Ahmed:

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)*

K243111

Device Name

Bowhead ERA Wheelchairs

Indications for Use *(Describe)*

The Bowhead ERA Wheelchairs are manually operated wheelchairs intended to be used as a means of mobility for individuals restricted to a sitting 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

I. Submitter

Bowhead Design Corp.
6919 32 Ave NW
Calgary, AB T3B 0K6
Canada

Contact Person: Tatiana Place
Contact Phone: 825-437-2141
Date Prepared: January 10, 2025

II. Device

Device Proprietary Name:	Bowhead ERA Wheelchairs
Common or Usual Name:	Mechanical Wheelchair
Classification Name:	Wheelchair, Mechanical
Regulation Number:	890.3850
Product Code:	IOR
Device Classification	1

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Product Name	**510(k)**	**Applicant**
APEX Manual Wheelchair (primary predicate)	K161425	Motion Composites
Panthera X	K220698	Panthera

IV. Device Description

The Bowhead ERA Wheelchairs are composite based mechanical, manually operated, wheelchairs intended to be used as a means of mobility for adults restricted to a sitting position. Using the push ring on the rear wheels, users can self-propel themselves forward or backwards. The chairs are designed for riding over various indoor and outdoor surfaces.

The Bowhead ERA Wheelchairs include four (4) mechanical wheelchair models with each model containing slightly different design features. Each wheelchair is provided assembled with a sling backrest, seat, seat post, brakes, frame, rear wheels, and casters. The overall length, width and height, backrest angle, COG, wheelbase, and seat width and height are adjustable ensuring comfort for the patient.

V. Indications for Use

The Bowhead ERA Wheelchairs are manually operated wheelchairs intended to be used as a means of mobility for individuals restricted to a sitting position.

VI. Comparison of Technological Characteristics

The subject device has the same intended use as the predicate devices. All of the devices are intended to be used as a means of mobility for persons (adults) restricted to a sitting position.

A comparison of the subject and predicate devices indications for use statements and technological characteristics is provided in the table below.

	Bowhead ERA Wheelchairs	**Primary Predicate: APEX Manual Wheelchair (K161425)**	**Panthera X (K220698)**	**Analysis**
Manufacturer	Bowhead Design Corp.	Motion Composites	Panthera	-
Indications for Use	The Bowhead ERA wheelchairs are manually operated wheelchairs intended to be used as a means of mobility for individuals restricted to a sitting position.	The indications for use of the APEX Manual wheelchair are to provide mobility to persons limited to a sitting position.	Panthera mechanical wheelchairs are manually operated multifunctional wheelchairs designed for indoor / outdoor use and intended to provide mobility to persons that have the capability of operating a mechanical wheelchair.	Different
Intended User	Adults	Adults	Adults	Identical
Rx/OTC	OTC	OTC	Rx	Identical to K161425
Operation Environment	Indoor/Outdoor	Indoor/Outdoor	Indoor/Outdoor	Identical
Control Mode	Self/user propelled, manual mechanical wheelchair	Self/user propelled, manual mechanical wheelchair	Self/user propelled, manual mechanical wheelchair	Identical
Folding Method	Rigid	Rigid	Rigid	Identical
Weight of Devices	2.5 – 6 kg w/out wheels & dependent on configuration with or without removeable seat.	9.2 – 10.7 lbs w/o wheels	4.4 – 4.6 kg	Different
Weight Capacity	110 kg (~242.5 lbs)	250 lbs	100 kg	Different
Seat Width	Adjustable: Small: 12” – 15” Medium: 14.5” – 17” Large: 17’’ – 19.5’’	12’’ – 20’’	33 – 45 cm (12.99” – 17.7”)	Different
Seat Height	Adjustable: 16’’ – 21’’	14’’ – 20’’	Rear: 43 cm Front: 47 cm	Different
Seat Depth	14” 16”	12’’ – 20’’	35 – 46 cm	Different

	Bowhead ERA Wheelchairs	**Primary Predicate: APEX Manual Wheelchair (K161425)**	**Panthera X (K220698)**	**Analysis**
	18”		(13.78’’ – 18.11”)	
Back Rest Type	Angle Adjustable Sling with or without Push Handle Folding Lock-Down Angle Adjustable with or without Push Handle	Folding Lock-Down Angle Adjustable straight with or with-out push handle Ultralight Folding without push Handle	Angle Adjustable, Folding	Different
Back Height	8-25in (dependent backrest selected)	9’’ – 21’’	22’’ – 35’’	Different
Push Handle	Yes, optional	Yes, optional	Yes, optional	Identical
Wheels (Size)	540, 559, 584 (24’’, 25’’, 27.5’’)	20’’ – 26’’	24’’	Different
Castors	3”, 4’’, 5”, 6’’	3”, 4’’, 5’’, 6”	87 mm	Identical to K161425
Arm Rest	Arm rest with integrated Padding, removeable, height adjustable.	T-Shaped armrest, removable, height adjustable (by user, no tool required) Tubular Swing-away	N/A No arm rests	Different
Foot rest	Integrated to frame	Integrated to frame	Height Adjustable, integrated to frame.	Identical to K161425
Frame material	Carbon fiber	Aluminum or Carbon Fiber	Carbon Fiber Reinforced Plastics	Different
Safety feature (manual wheel lock)	Yes, push to lock style.	Yes, push to lock style.	Yes, locks both wheels at once, push to lock style.	Identical to K161425
Brakes	One hand operation	One hand operation, Scissor lock option	High brakes or one-hand brake	Different
Anti-Tip	Yes - optional	Yes	No	Identical to K161425

There are slight differences between the subject and predicate devices with respect to device weight, weight capacity, wheelchair dimensions and ranges of adjustability, and materials of construction; however, these differences do not raise different questions of safety and effectiveness. The results of non-clinical testing demonstrate that the subject device is as safe and effective as the predicate devices:

VII. Performance Data

The following non-clinical tests were performed to support substantial equivalence:

- RESNA WC-1:2019, Section 1: Determination of static stability
- RESNA WC-1:2019, Section 3: Determination of effectiveness of brakes
- RESNA WC-1:2019, Section 5: Determination of overall dimensions, mass and maneuvering space
- RESNA WC-1:2019, Section 7: Measurement of seating and wheel dimensions
- RESNA WC-1:2019, Section 8: Requirements and test methods for static, impact and fatigue strengths
- RESNA WC-1:2019, Section 13: Determination of coefficient of friction of test surfaces
- Flammability testing

VIII. Conclusion

The Bowhead ERA Wheelchairs have the same intended use and principle of operation as the predicate devices. Non-clinical testing demonstrates that slight differences in design do not alter the safety, efficacy, or performance of the subject device when compared to the predicate devices.

The technological differences between the subject and predicate devices do not raise different questions of safety and effectiveness when compared to the predicate devices. The data presented within this submission support substantial equivalence of the Bowhead ERA Wheelchairs to the identified predicate devices.