February 16, 2023

Panthera AB
℅ Stuart Goldman
Sr. Consultant RA/QA
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K220698
Trade/Device Name: Bambino 3, S3 and S3 Swing, U3 and U3 Light, X
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: July 7, 2022
Received: July 11, 2022

Dear Stuart Goldman:

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,

Julia E. Slocomb -S

Julia E. Slocomb -S
2023.02.16 15:08:16
-05'00'

for Tushar Bansal, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K220698

Device Name
Bambino 3, S3, S3 Swing, U3, U3 Light and X

Indications for Use *(Describe)*
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.

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.

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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
Panthera Mechanical Wheelchairs
(Bambino 3, S3, S3 Swing, U3, U3 Light and X)

1. Submission Sponsor

Panthera AB
Gunnebogatan 26
SE-163 53 Spanga
Stockholm, Sweden
+46-8-7615040-73869
Fredrik Skantz, VP/General Manager

2. Submission Correspondent

Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, TX 78746, USA
+1.512.327.9997
Stuart R. Goldman, Sr. Consultant, RA/QA

3. Date Prepared

February 15, 2023

4. Device Identification

Trade/Proprietary Name:	Bambino 3, S3, S3 Swing, U3, U3 Light and X
Common/Usual Name:	Wheelchair
Classification Name:	Mechanical wheelchair
Regulation Number:	890.3850
Product Code:	IOR
Class:	1
Classification Panel:	Physical Medicine

5. Legally Marketed Predicate Device

Device name:	Bambino, S2, S2 Swing, U2, U2 Light
510(k) number:	K083231
Manufacturer:	Panthera AB

The subject devices are modified versions of the predicate devices. The predicate devices have not been subject to a design related recall. The following reference device is also included in this submission:

Trade Name: APEX Manual Wheelchair
510(k) No.: K161425
Manufacturer: Motion Composites

6. Indication for Use

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.

7. Device Description

Panthera mechanical wheelchairs are of a spoke and hub design and made of chrome-molly steel to construct the chassis (frame and back rest), except for the X model which uses carbon fiber reinforced composite (CFRC) instead of chrome-molly steel. All Panthera mechanical wheelchairs have rubber tires, while the casters are of a semi-solid polymer-based design. The seat cushions and backs are made from flame retardant polyurethane coated polyester fabric, over a foam core. The primary differences in the models of wheelchairs are in their dimensions, gross weights, weight carrying capacities, adjustability features, wheels, accessories and hardware options.

8. Device Modifications

The minor modifications made to the predicate Bambino, S2, S2 Swing, U2 and U2 Light model wheelchairs to create the subject Bambino 3, S3, S3 Swing, U3 and U3 Light model wheelchairs are primarily related to dimensional changes, as well as minor modifications to some of the components and accessories used on the wheelchairs. These modifications were undertaken in order to make these devices more modular in their design, construction and features than the predicate devices. In addition, the X model wheelchair was added as a product line extension of the U2 Light model, as the X model uses CFRC instead of chrome-molly steel to construct the frame chassis.

9. Substantial Equivalence Discussion

The following tables compare the modified subject devices to the unmodified predicate devices with respect to their intended uses, indications for use and technological characteristics and forms the basis for the determination of substantial equivalence. The subject devices do not raise any new questions of safety or effectiveness compared to the predicate devices.

Table 5-1 – Comparison of Characteristics of Panthera Subject and Predicate Devices

Attributes	Predicate Devices (K083231)	Subject Devices	Comparison
Manufacturer	Panthera AB	Panthera AB	Same
Models	Bambino, S2, S2 Swing, U2, U2 Light	Bambino 3, S3, S3 Swing, U3, U3 Light and X	Equivalent. Model X is a product line extension of the U2 light model.

Attributes	Predicate Devices (K083231)	Subject Devices	Comparison
Intended Use	Provide mobility to persons restricted to a sitting position.	Provide mobility to persons restricted to a sitting position.	Same
Indications for Use	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.	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.	Same
Mode of Operation	User propelled, manual, mechanical wheelchair.	User propelled, manual, mechanical wheelchair.	Same
Models Bambino (G356) vs. Bambino 3 (G517)			
Frame Width (cm)	52-61	55-64	Similar
Seat Depth (cm)	23-30	25-30	Similar
Back Rest Angle (°)	12-(-7.7)	11.5-(-7.5)	Similar
Back Rest Height (cm)	17-25 (standard) 27-35 (optional)	20-28 (standard) 27-35 (optional)	Similar Same
Footrest Angle (°)	103	100	Similar
Footrest Width (cm)	29.5-38.5	32.5-38.5	Similar
Total Weight (kg)	8.1-8.8	9.8-10.4	Similar
Castors (inches)	5	4.73	Similar
Models S2 (G348) vs. S3 (G548)			
Back Rest Angle (°)	11.5-(-7.3)	17.3-(-5)	Similar
Footrest Width (cm)	46-64	46-63	Similar
Total Weight (kg)	8.3-8.8	8.2-8.8	Similar

Attributes	Predicate Devices (K083231)	Subject Devices	Comparison
Castors (inches)	5	4.73	Similar
Models S2 Swing (G347) vs. S3 Swing (G547)			
Total Height (cm)	64-84	93	Similar
Back Rest Angle (°)	7-(8.5)	13.3-(-12)	Similar
Frame Width (cm)	57/60/63/66	57/60/63/66/71	Similar
Seat Width (cm)	36/39/42/45	36/39/42/45/50	Similar
Footrest Width (cm)	49-59	49-63	Similar
Total Weight (kg)	9.6-10.0	9.4-10.3	Similar
Castors (inches)	5	4.73	Similar
Models U2 (G351) vs. U3 (G551)			
Total Length (cm)	84.5	84	Similar
Back Rest Angle (°)	11.5-(-7.3)	17.3-(-5)	Similar
Total Weight (kg)	8.2-8.7	8.0-8.5	Similar
Castors (inches)	3	3.54	Similar
Models U2 Light (G346) vs. U3 Light (G557)			
Back Rest Height (cm)	22-35	25-35	Similar
Footrest Angle (°)	100	100	Same
Total Weight (kg)	6.8-7.2	6.0-6.2	Similar
Castors (inches)	3	2.95	Similar

Attributes	Predicate Devices (K083231)	Subject Devices	Comparison
Models U2 Light (G346) vs. X (G350)			
Frame Material	Chrome-molly chassis	CFRC	Different. CFRC is also used to construct the frame of the reference device (K161425).
Total Weight (kg)	6.8-7.2	4.4-4.6	Different. The reference device (K161425) has a similar weight (4.9 kg with wheels and 4.2 kg without wheels) to the X model subject device as a result of its CFRC chassis.
Safety and Performance Testing	• Biocompatibility per ISO 10993-1. • Requirements and Test Methods of Manual Wheelchairs per EN 12183. • Resistance to Ignition of Postural Support Devices per ISO 7176-16.	• Biocompatibility per ISO 10993-1. • Requirements and Test Methods of Manual Wheelchairs per EN 12183. • Resistance to Ignition of Postural Support Devices per ISO 7176-16.	Same

10. Non-Clinical Performance Data

To demonstrate substantial equivalence of the subject Bambino 3, S3, S3 Swing, U3, U3 Light and X model wheelchairs to the predicate Bambino, S2, S2 Swing, U2 and U2 wheelchairs, Panthera submitted their devices for the following non-clinical tests. Results confirm that the design inputs and performance specifications for the modified subject devices have been met.

- Biocompatibility testing per:
  - ISO 10993-1
- Cytotoxicity testing per:
  - ISO 10993-5
- Chemical Characterization testing per:
  - ISO 10993-18
- Toxicological Risk Assessment per:
  - ISO 10993-17
- Wheelchair Performance Testing per:

- ISO 7176-16, *Resistance to Ignition of Postural Support Devices*
- EN 12183, *Manual Wheelchairs. Requirements and Test Methods* (equivalent to):
  - ISO 7176-1 (static stability)
  - ISO 7176-3 (brakes)
  - ISO 7176-8 (static, impact and fatigue strengths)
  - ISO 7176-11 (test dummies)
  - ISO 7176-15 (information, documentation and labeling)
  - ISO 7176-19 (crash)
  - ISO 7176-22 (Set-up procedures)

Panthera also performed the following internal quality assurance and quality control measures during the design, development and manufacturing of their Bambino 3, S3, S3 Swing, U3, U3 Light and X wheelchairs:

- Compliance with the following FDA guidance document:
  - *Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles*
- Compliance with 21 CFR Part 820 Quality System Regulation
  - (including Design Controls)
- Compliance with 21 CFR Part 801 Labeling
- Compliance with 21 CFR Part 830 Unique Device Identification
- Dimensional Verification per:
  - Panther internal specifications
- Risk Analysis (FMEA) per:
  - ISO 14971, *Medical Devices — Application of Risk Management to Medical Devices*

In conclusion, the performance of the subject devices met the requirements of the non-clinical bench testing and demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate devices, and therefore support substantial equivalence to them.

11. Clinical Performance Data

Clinical testing on the subject devices have not been performed.

12. Substantial Equivalence Conclusion

The Bambino 3, S3, S3 Swing, U3, U3 Light and X wheelchairs have the same intended use and indications for use as the Bambino, S2, S2 Swing, U2 and U2 wheelchairs, and the same or similar technological characteristics. The differences in technological characteristics between the subject and predicate devices do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated that the subject devices are as safe and effective as the predicate devices and substantially equivalent to them.