August 31, 2023

Ki Mobility LLC
Mark Murphy
Vice President of Operations
5201 Woodward Drive
Stevens Point, Wisconsin 54481

Re: K223533
Trade/Device Name: Little Wave Arc; Little Wave Flip
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: LBE
Dated: August 29, 2023
Received: August 30, 2023

Dear Mark Murphy:

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
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

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)*
K223533

Device Name
Little Wave Arc;
Little Wave Flip

Indications for Use *(Describe)*
The Ki Mobility Little Wave Arc and Little Wave Flip manual wheelchairs are intended to provide mobility to pediatrics limited to a seating 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.

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) #: K223533

510(k) Summary

Prepared on: 2023-01-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ki Mobility LLC
Applicant Address	5201 Woodward Drive Stevens Point WI 54481 United States
Applicant Contact Telephone	(715) 303-6447
Applicant Contact	Mr. Mark Murphy
Applicant Contact Email	mmurphy@kimobility.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Little Wave Arc; Little Wave Flip
Common Name	Mechanical wheelchair
Classification Name	Stroller, Adaptive
Regulation Number	890.3850
Product Code	LBE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K151492	R82 Kudu	LBE

Device Description Summary

21 CFR 807.92(a)(4)

The Ki Mobility Little Wave Arc is used by pediatrics up to 165lb (75kg) in need of manual wheeled mobility offering an operator adjustable body support system. Angular repositioning of the occupant alters the seated pressure distribution to reduce potential of pressure ulcers, improve comfort, facilitate improved transfer and for improved daily activities such as eating, breathing and social interaction. The Little Wave Arc offers a tilting seat frame that tilts up to 45°, reclining backrest that reclines up to 60°, and elevating leg rest, all adjustable by an attendant.

Single pivot tilt systems provide the maximum horizontal and vertical translation of the occupant center of gravity. One of the goals of this device is to reduce the horizontal and vertical translation of the occupant center of gravity (CG) by utilizing a roller-link arm mechanism, where the roller is guided by a curved path to allow the rear of the seat frame to move forward and downward while the front of the seat frame is guided upward by the link arm. This reduces the CG translation and thus allows for reduced tilting force, reduced wheelbase for better maneuverability and increased comfort during tilting as compared to a single pivot tilt. An upper roller is guided laterally by a spine on the roller guide to provide lateral stability to the backrest tubes. Different styles of stabilizer/rigidizer bars and handles can be utilized for added lateral backrest rigidity.

The Little Wave Arc side frames are constructed of high strength aluminum tubing with cast aluminum roller guides. There are 4 sizes of side frames for varying seat depth ranges. The chair folds using a set of aluminum X-brace style cross braces. There are 4 sizes of cross braces to accommodate varying seat width ranges. There are 4 sizes of aluminum seat tubes that match the 4 sizes of side frame. The backrest can be set to varying angles. The backrest folds down for stowage or transport. The reclining backrest is welded steel tubing, utilizing locking gas springs for recline angle recovery assistance as well as recline angle locking. An extended rear frame is utilized with the reclining backrest to move the rear wheels rearward by 4.5" for added stability.

The adjustable tubular aluminum seat and backrest frame assembly is made to adapt to planar seating systems which have hardware adapted to mount to tubes. A solid mounted and depth adjustable aluminum seat pan is available for use with wheelchair seat cushions and the backrest frame accepts contoured wheelchair backrests. The seating system is a separate medical device adapted for use to the

Little Wave Arc and is the primary contact surface to the occupant. Little Wave Arc components such as armrests and footrests will also have contact to the occupant.
The tilt angle is locked by using slide locking mechanisms (mechlocks) that utilize a torsion spring mounted in a fixed housing that binds around a telescoping shaft. These mechlocks are controlled by cables that are driven by a hand lever or a foot pedal. The hand actuated cables are either two levers that control two separate cables, or a single lever that controls a single cable that splits into two cables. The foot pedal controls two separate cables with a single pedal.
The chair may be used as a seat in a motor vehicle and conforms to ISO 7176-19 as well as ANSI/RESNA WC-4 Section 19 requirements.
The chair is intended to be pushed by an attendant or also may be self-propelled using larger wheels with handrims. The chair also offers a growing aluminum seat pan that allows up to 2" of growth in width and up to 3" of growth in depth. The size ranges of seat pan match the size ranges of the seat tubes.
The Little Wave Arc XP, Little Wave Arc XPe and Little Wave Arc TTL order forms are order form variations of the same device to meet different market configuration requirements for pricing and reimbursement. All can be configured identically.

The Ki Mobility Little Wave Flip is used by pediatrics up to 165lb (75kg) in need of manual wheeled mobility offering an operator adjustable body support system. Angular repositioning of the occupant alters the seated pressure distribution to reduce potential of pressure ulcers, improve comfort, facilitate improved transfer and for improved daily activities such as eating, breathing and social interaction. The Little Wave Flip offers a tilting seat frame that tilts up to 45°, reclining backrest that reclines up to 60°, and elevating leg rest, all adjustable by an attendant.
Single pivot tilt systems provide a simple system for repositioning the seat angle. One of the goals of this device is to provide tilting of the seat frame in a chair that folds horizontally, rather than laterally.

The Little Wave Flip base frame is constructed of high strength extruded aluminum, steel and aluminum sheet aluminum. There are 3 sizes of aluminum seat tubes to accommodate varying seat depth ranges. The backrest folds down, the seat frame tilts anterior, and the axle bar swings under the base frame to provide horizontal folding action rather than lateral folding. Different strut lengths accommodate specific chair widths with no adjustment. A pivoting yoke attaches to the seat frame, providing a single-pivot tilting paradigm. The high strength tubular aluminum seat frame utilizes telescoping members to allow adjustment of the depth of the seat frame. The Front frame and axle bar change angle relative to the side plates to provide height and wheelbase adjustment. The front frame also extends to provide additional height and wheelbase adjustment for varying seat depths.
The Little Wave Flip manual wheelchair has a folding backrest frame for ease of storage for transport. A non-folding backrest and a reclining backrest are options. The backrest can be set to varying angles. The optional reclining backrest is welded steel tubing, utilizing locking gas springs for recline angle recovery assistance as well as recline angle locking. An extended axle bar is utilized with the reclining backrest for added rearward stability.
The adjustable tubular aluminum seat and backrest frame assembly is made to adapt to planar seating systems which have hardware adapted to mount to tubes. A solid mounted and depth adjustable aluminum seat pan is available for use with wheelchair seat cushions and the backrest frame accepts contoured wheelchair backrests. The seating system is a separate medical device adapted for use to the Little Wave Flip and is the primary contact surface to the occupant. Little Wave Flip components such as armrests and footrests will also have contact to the occupant.
The tilt angle is locked by using slide locking mechanisms (mechlocks) that utilize a torsion spring mounted in a fixed housing that binds around a telescoping shaft. These mechlocks are controlled by cables that are driven by a hand lever or a foot pedal. Two separate hand actuated levers are attached to the push handles to control two separate cables. The foot pedal, attached to the axle tube, controls two separate cables with a single pedal.
The chair may be used as a seat in a motor vehicle and conforms to ISO 7176-19 as well as ANSI/RESNA WC-4 Section 19 requirements.
The chair is intended to be pushed by an attendant or also may be self-propelled using larger wheels with handrims. The chair also offers a growing aluminum seat pan that allows up to 2" of growth in width and up to 3" in depth.
The Little Wave Flip XP, Little Wave Flip XPe and Little Wave Flip TTL order forms are order form variations of the same device to meet different market configuration requirements for pricing and reimbursement. All can be configured identically.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Ki Mobility Little Wave Arc and Little Wave Flip manual wheelchairs are intended to provide mobility to pediatrics limited to a seating position.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Ki Mobility Little Wave Arc and Little Wave Flip manual wheelchairs are intended to provide mobility to persons limited to a sitting position. The primary use is by pediatrics in need of manual wheeled mobility offering an operator adjustable body support system. The Little Wave Arc and Little Wave Flip offer both seat tilt and an optional reclining backrest, with both adjustable by the attendant. This is consistent with the intended use of the R82 Kudu.

LBE PREDICATE COMPARISON TABLE

Device	Ki Mobility Little Wave Arc	Ki Mobility Little Wave Flip	R82 Kudu
510(k) Number	K223533	K223533	K151492
Intended Use	The Ki Mobility Little Wave Arc manual wheelchair is intended to provide mobility to persons limited to a sitting position.	The Ki Mobility Little Wave Flip manual wheelchair is intended to provide mobility to persons limited to a sitting position.	The device is a wheelchair for children and adults with disabilities.
Indications for Use	The Ki Mobility Little Wave Arc manual wheelchair is intended to provide mobility to pediatrics limited to a seating position.	The Ki Mobility Little Wave Flip manual wheelchair is intended to provide mobility to pediatrics limited to a seating position.	The Kudu is a wheelchair intended for medical purposes to provide mobility to children limited to a sitting position. It is designed for indoor and outdoor use over smooth surfaces.
Design	**Ki Mobility Little Wave Arc**	**Ki Mobility Little Wave Flip**	**R82 Kudu**
Weight Limit	165lb/75kg (with or without transit)	165lb/75kg (with or without transit)	88lb/40kg – 162lb/60kg. Transit 88lb/40-kg – 125.5lb/57kg
Frame Material	Aluminum	Aluminum, Steel	Aluminum
Seat Width	10” – 18”	10” – 18”	10” – 15”
Seat Depth	12” – 20”	12” – 20”	8.5” – 17.5”
Seat Height	14.5” – 19”	13.5” – 20”	14.5” – 18”
Stowage Width	14.4” (Folded Laterally)	24.0”	26.25”
Stowage Depth	31.7"	28.9”	34.5”
Stowage Height	20.1"	27.6”	24.5”
Transit approved?	Yes (optional)	Yes (optional)	Yes (optional)
Product weight	44lb	55lb	42lb – 55lb, depending on size
Turning Radius	33.5”	35”	32.5”
Tilt Range	0° - 45°	0° - 45°	-3° - 45°
Frame Options	Standard 1” Offset Extended Frame for Vent and Battery Tray	Standard 1” Offset Hanger	None
Tilt Action	Single hand tilt (left or right) Dual hand tilt Foot tilt (left or right)	Dual hand tilt Foot tilt	Single hand tilt Dual hand tilt
Back Angle Range	85° - 115°, 5° increments, adjustable w/tools	85° - 115°, 5° increments, adjustable w/tools	85° - 120° adjustable without tools
Backrest Styles	Height Adjustable Fixed Height 60° Reclining back Dynamic Rocker Back	Height Adjustable Fixed Height 60° Reclining back Dynamic Rocker Back	Fixed Height Height adjustable 30° Reclining back
Back Heights	Adjustable Height: 18”-25” or 20”-27” Fixed Height: 20”, 22”, 24”, 26” Reclining Back: 22”, 26”	Height Adjustable: 18”-25” or 20”-27” Fixed Height: 20”, 22”, 24”, 26” Reclining Back: 22”, 26”	14.5” – 24.5”
Push Handles	Fixed push handle on back canes Angle adjustable push handle Removable Stroller handle	Fixed Push handle on back canes Angle adjustable push handle Removable Stroller handle	Fixed push handles on back canes Angle adjustable push handle
Rigidizer bars	Folding height adj. rigidizer bar Height adj. rigidizer bar (non-folding)	Height adj. rigidizer bar (non-folding)	Non-folding rigidizer handle
Armrests	Height Adj. T-Arm (Std, tall, low, pediatric) Tubular Flip Back Armrest Angle Adj. Locking Extendable Flip Back armrest Desk and Full Arm Pad – Standard and Waterfall styles Foam Grip	Height Adj. T-Arm (Std, tall, low, pediatric) Tubular Flip Back Armrest Angle Adj. Locking Extendable Flip Back armrest Desk and Full Arm Pad – Standard and Waterfall styles Foam Grip	Armrest w/tray holders Angle Adjustable Armrest
Wheel Lock	Push to lock Pull to lock Attendant foot lock Drum brake Dual Drum brake w/push or pull Hemi wheel lock Wheel lock extension handles	Push to lock Pull to lock Attendant foot lock Drum brake Dual Drum brake w/push or pull Wheel lock extension handles	Push to lock (20, 22 and 24”) Drum Brake (12.5”)
Anti-Tips	Removable/swing-up rear Anti-tips	Fold-up rear Anti-tips (not removable)	Swing away rear Anti-tips/tipping levers
Rear Wheels	Mag: 12”, 16” and 20” Stainless Steel Spoke (18Ct.): 20”	Mag: 12”, 16”, 20”, 22 and 24” Stainless Steel Spoke (18Ct.): 20”, 22” and 24”	12.5” mag 20”, 22” and 24” spoke wheels
Tires	Pneumatic Pneumatic with Airless Insert Solid Polyurethane	Pneumatic Pneumatic with Airless Insert Solid Polyurethane	Pneumatic Solid Polyurethane
Handrims	Aluminum Anodized Aluminum with Plastic Coating	Aluminum Anodized Aluminum with Plastic Coating Aluminum with Non-Slip Tape	Aluminum

Handrims		Projection Knob with Plastic Coating Ergonomic Thumb Grip: Alum with Grip Coating	Aluminum
Camber	0°	0°	6° (20, 22 and 24" only)
Caster Wheels (W x Ø)	0.75" x 5" Lighted Roller Blade 1" x 5", 6", 7", 8" Polyurethane 1" x 5" Polyurethane Aluminum 1" x 6", 8" Pneumatic 1.5" x 5", 6" Polyurethane 1.5" x 5", 6" Soft Roll Aluminum 2" x 6" Polyurethane	0.75" x 5" - Lighted Roller Blade 1" x 5", 6", 7", 8" - Polyurethane 1" x 5" - Polyurethane Aluminum 1" x 6", 8" - Pneumatic 1.5" x 5", 6" - Polyurethane 1.5" x 5", 6" - Soft Roll Aluminum 2" x 6" - Polyurethane	6" Polyurethane 7" Polyurethane 7" Pneumatic
Caster Forks	Aluminum Fork	Aluminum Fork	Aluminum Fork
Footrests Hangers	Swing Away Footrest, Extension mount Swing Away Footrest, Front Mount Pro Elevating Leg rest (ext. and front mount) Contracture footrest (bilateral or center) Residual limb support Hanger release (Classic, 4-way)	Swing Away Footrest, Extension mount Swing Away Footrest, Front Mount Pro Elevating Leg rest (ext. and front mount) Contracture footrest (bilateral or center) Residual limb support Hanger Release (Classic, 4-Way)	Individual removable footplates Center mount
Footplates	Composite Composite Angle Adjustable Aluminum Angle Adjustable Aluminum Locking Multi-angle adjustable One-piece Flip-Up Angle Adj. Footplate	Composite Composite Angle Adjustable Aluminum Angle Adjustable Aluminum Locking Multi-angle adjustable One-piece Flip-Up Angle Adj. Footplate	Composite Angle adjustable One piece center mounted Formed footplates
Seating and positioning	Width/depth adjustable seat pan Seat Cushions Backrest Lumbar pads Shoulder guides Headrest Supports (Chest and Truck) Laterals Pelvic Positioning belts Calf straps Heel loops	Width/depth adjustable seat pan Seat Cushions Backrest Lumbar pads Shoulder guides Headrest Supports (Chest and Trunk) Laterals Pelvic Positioning belts Calf straps Heel loops	Depth adjustable seat pan Seat cushions Backrest Headrest Harnesses/vests Laterals Positioning belts Ankle straps Knee abductors Adductors Pommels Calf straps Heel loops
Accessories	**Ki Mobility Little Wave Arc**	**Ki Mobility Little Wave Flip**	**R82 Kudu**
Vent/Battery tray	Ventilator Tray w/Battery box holder	No	Ventilator tray
Sideguards	Composite Side guards (adult and pediatric)	Composite Side guards (adult and pediatric)	Composite Side guards
Backpack/Pouch	Yes	Yes	Yes
Spoke Guards	Yes	Yes	Yes
ELR Gel Pads	Yes	Yes	No
IV Pole	Yes	Yes	No
O2 tank holder	Yes	No	Yes
Impact guards	Yes	Yes	No
Canopy	Yes	Yes	Yes
Tilt Stop	Yes	Yes	No
Tool Kit	Yes	Yes	Yes

Technological Comparison 21 CFR 807.92(a)(6)

The Ki Mobility Little Wave Arc manual wheelchair in comparison to predicate device shares intended use, similarity of configuration of components, wheels, and accessories.
The seat tilt function shares similar tilt angles, with the seat frame tilting relative to a stationary base frame supported by rear wheels and front caster wheels. The variation in the Little Wave Arc tilt design using a roller/linkage mechanism provides a simpler tilting mechanism while still minimizing the translation of the occupant center of gravity. This contrasts the Kudu which uses a constant radius motion control rail moving through a set of rollers.
The Little Wave Arc aluminum base frame does not present a significant change to the safety or effectiveness of the wheelchair function and has been qualified through fatigue testing per the applicable standards.
The Little Wave Arc components and accessories do not pose new risks, being as safe and effective as the predicate device.
The Little Wave Arc is substantially equivalent to the predicate device in intended use, design, materials, and operating principles with no new issues of safety or effectiveness.

The Ki Mobility Little Wave Flip manual wheelchair in comparison to predicate device shares intended use, similarity of configuration of components, wheels, and accessories.
The seat tilt function shares similar tilt angles, with the seat frame tilting relative to a stationary base frame supported by rear wheels and front caster wheels. The Little Wave Flip tilt design varies from the Kudu in that is uses slide locking mechanism for a simpler tilting mechanism. This contrasts the Kudu which uses a constant radius motion control rail moving through a set of rollers.
The Little Wave Flip aluminum base frame does not present a significant change to the safety or effectiveness of the wheelchair function and has been qualified through fatigue testing per the applicable standards.
The Little Wave Flip components and accessories do not pose new risks, being as safe and effective as the predicate device.
The Little Wave Flip is substantially equivalent to the predicate device in intended use, design, materials, and operating principles with no new issues of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The Little Wave Arc and Little Wave Flip have been tested to meet recognized consensus standards including:
ANSI/RESNA WC-4:2017 Section 19: Wheelchairs used as seats in motor vehicles
ISO-7176-1:2014 Determination of static stability
ISO 7176-5:2008 Determination of dimensions, mass, and maneuvering space
ISO 7176-7:1998 Measurement of seating and wheel dimensions
ISO 7176-8:2014 Requirements and test methods for static, impact, and fatigue strengths
ISO 7176-11:2012 Test Dummies
ISO 7176-13:1989 Determination of coefficient of friction of test surfaces
ISO 7176-15:1996 Requirements for information disclosure documentation and labeling
ISO 7176-16:2012 Resistance to ignition of postural support devices
ISO 7176-19:2022 Wheeled mobility devices for use as seats in motor vehicles
ISO 7176-22:2014 Set-up procedures
Design testing of Little Wave Arc and Little Wave Flip met or passed the recognized test standard requirements for manual wheelchairs, and which would apply to predicate devices.

Not Applicable

The Little Wave Arc and Little Wave Flip manual wheelchairs have the same intended use and similar technological characteristics as the predicate devices. The non-clinical testing to recognized standards exhibits that the device will perform as intended and risk analysis has documented risk reduction and identified requirements for labeling for safe and effective use of the device. The Little Wave Arc and Little Wave Flip are substantially equivalent to the predicate devices as shown in the product design comparison.

The conclusion from testing and comparison to predicate devices demonstrates that the Little Wave Arc and Little Wave Flip are as safe, as effective, and performs as well as the legally marketed devices identified as predicate.