November 4, 2025

Karma Mobility Co Ltd
Anoohya Pulipaka
Regulatory Affairs
30 Moo 7 Tambol Khamtaleso Amphur (KORAT)
Khamthleso, Nakhonratchasima 30280
Thailand

Re: K250576
Trade/Device Name: Flexx Junior (FLX-J00, FLX-J50)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR, LBE
Dated: September 9, 2025
Received: September 18, 2025

Dear Anoohya Pulipaka:

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

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

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)*

K250576

Device Name

Flexx Junior
Models: FLX-J00 and FLX-J50

Indications for Use *(Describe)*

Flexx Junior manual wheelchair is 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.

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510(K) Summary - Flexx Junior (K250576)

510(K) Summary	
Applicant Contact Details	**21CFR807.92(a)(1)**
Applicant Name	**KARMA MOBILITY., CO LTD**
Applicant Address	**30 Moo 7 Tambol Khamtaleso Amphur Khamtaleso Nakhonratchasima (KORAT) 30280 THAILAND**
Applicant Telephone number	**+886-5-206-6688**
Applicant Contact Name	**Pulipaka Anoohya**
Applicant Contact Email	**eva@karma.com.tw**

Device Information	**21CFR807.92(a)(2)**
Name of the device/ Trade Name	**Flexx Junior**
Common name	**Mechanical Wheelchair**
Classification name	**Wheelchair, Mechanical**
Device Classification	**Class I**
Classification Product Code	**IOR**
Regulation number	**890.3850**

Legally Marketed Predicate Device	**21CFR807.92(a)(3)**
Predicate Device 510(K) Number	**K223527**
Name of the Device/ Trade Name	**Ki Mobility Spark**
Common Name	**Mechanical Wheelchair**
Classification Name	**Wheelchair, Mechanical**
Device Classification	**Class I**
Classification Product Code	**IOR**
Regulation Number	**890.3850**

Device Description: [21 CFR 807.92(a)(4)]

Designed for Comfort and Growth: The Flexx Junior is a pediatric manual wheelchair designed to provide mobility, comfort, and postural support for children with mobility limitations. Available in self-propelled (Model FLX-J00 with fixed backrest, Model FLX-J50 with foldable backrest) and transit configurations, it is primarily intended for indoor use with limited outdoor capability on smooth surfaces. The wheelchair offers both self-propulsion with 20" or 22" quick-release rear wheels and transit propulsion with 14" quick-release rear wheels. The device supports users weighing up to (165 lbs) 75 kg and is engineered for growth and incorporates adjustable features to accommodate growth.

Device Specifications:

The Flexx Junior is constructed with a lightweight aluminum folding frame, ensuring durability and ease of transport. Its compact folded dimensions facilitate storage and transport in vehicles. The device offers adjustable seat width, seat depth, and backrest height to ensure a customized fit as the child grows. The wheelchair's front caster wheel allows better maneuverability, while larger rear wheels improve stability and ease of movement, ensuring the device's structural integrity and safety. The wheelchair's compact design ensures maneuverability in tight spaces. The total width allows for easy navigation through doorways and confined spaces, and the overall height offers appropriate support and comfort. Easy to Transport and Its folding frame is built from aluminum, making it lightweight yet durable ensuring longevity. Despite its robust design, it remains lightweight and can be folded into a compact size for easy transport.

The handrim offers optimal leverage for self-propulsion. The wheelchair's turning radius ensures easy movement in confined spaces, with the pivot width supporting safe turning. Static stability defines the wheelchair’s ability to maintain balance on slopes, ensuring safety on inclines and uneven terrains. The angular ranges are consistent with predicate devices and do not raise new questions of safety or effectiveness

The seat and backrest angles provide ergonomic support, promoting good posture and comfort. Adjustable seat depth and width cater to various body types, while the seat surface height facilitates ease of transfer. The wheelchair includes adjustable footrest and armrest distances, enhancing user comfort and posture.

Ideal for Indoor and Outdoor Use - Primarily designed for indoor environments but is not suitable for rough terrains.

Stability and Safety - The Flexx Junior is tested and compliant with ISO 7176-19 standards, making it suitable as a seat in a motor vehicle. Safety features include push-to-lock brakes, standard anti-tippers, and optional accessories such as a table tray, IV pole holder, and oxygen tank holder. Flip-up, height-adjustable armrests and quick-release axles enhance usability. Engineered to support children throughout their formative years, it provides the perfect balance of flexibility, safety, and comfort as they grow.

Intended Use/Indications for Use: [21 CFR 807.92(a)(5)]

Flexx Junior manual wheelchair is intended to provide mobility to pediatrics limited to a seating position.

Indications for Use Comparison: 21CFR807.92(a)(5)

Flexx Junior manual wheelchair is intended to provide mobility to pediatrics limited to a seating position, aligning with the intended use of the predicate device. The Flexx Junior wheelchair is substantially equivalent to the predicate devices, Ki Mobility Spark (510(k) Number: K223527). The key specifications, intended use, indications for use, weight capacity, and core design principles align with the predicate devices, ensuring comparable safety and effectiveness.

Key Equivalences:

1. Intended Use & Indications for Use: Both devices are intended to provide mobility to pediatrics limited to a seating position. The Flexx Junior and the predicate device, the Ki Mobility Spark, share identical intended use and indications for use.

2. Weight Capacity: Both devices support a maximum user weight of (165 lbs) 75 kg, ensuring comparable structural integrity and performance for pediatric users.

3. Frame Materials: Both utilize aluminum frames with a folding X-brace mechanism that enhances rigidity and enables width adjustability.

4. Seat and Backrest Adjustability: Both devices feature adjustable seat width, depth, height, backrest angle, and armrest positioning via discrete holes, supporting pediatric growth and ergonomic positioning. The Spark offers a wider range of seat width and depth adjustments and additional backrest styles, but these differences do not affect safety or effectiveness, as the Flexx Junior's adjustment ranges meet the needs of the intended population.

5. Propulsion and Maneuverability: Both provide self-propulsion via handrims and attendant propulsion via push handles, with quick-release rear wheels and adjustable caster wheels. The Flexx Junior offers fewer rear wheel and caster options than the Spark, but both ensure equivalent maneuverability and stability for pediatric use, with adjustable center of gravity positioning.

6. Safety and Compliance: Both are crash-tested according to ISO 7176-19 standards, suitable for use as a seat in a motor vehicle and comply with equivalent performance standards ensuring comparable safety and effectiveness.

7. Accessories and Components: Both include comparable accessories, such as push-to-lock brakes, swing-away footrests, and height-adjustable armrests. The Flexx Junior offers unique accessories (e.g., IV pole holder, table tray), while the Spark includes options like spoke guards and backpacks. These differences do not introduce new risks, as both provide equivalent functionality and safety features.

The Flexx Junior complies with the same regulatory requirements and performance standards, demonstrating substantial equivalence to the legally marketed predicate devices.

Substantial Equivalence Comparison Table

PREDICATE COMPARISON TABLE		
	Subject Device	Predicate Device
510(k) Number	K250576	K223527
Name of the device	Flexx Junior	Ki Mobility Spark

Classification name	Wheelchair, Mechanical	Wheelchair, Mechanical
Manufacturer	Karma Mobility Co.,LTD	Ki Mobility LLC
Device Classification	Class 1	Class I
Classification Product Code	IOR	IOR
Regulation Number	890.3850	890.3850
Intended Use	Flexx Junior manual wheelchair is intended to provide mobility to pediatrics limited to seating position.	Ki Mobility Spark manual wheelchair is intended to provide mobility to pediatrics limited to seating position.
Indications for use	Flexx Junior manual wheelchair is intended to provide mobility to pediatrics limited to seating position.	Ki Mobility Spark manual wheelchair is intended to provide mobility to pediatrics limited to seating position.
User Weight Capacity	165lb/75kg	165lb/75kg
Frame Material	Aluminum	Aluminum
Frame Type	Fixed backrest (FLX-J00) Foldable backrest (FLX-J50)	Foldable backrest only
Transit approved	Yes	Yes
Seat Width	10" - 14"	10" - 16"
Seat Depth	11" -15"	12" - 18"
Seat Height	15.5" - 18"	Front Seat-to-Floor: 13" - 21" Rear Seat-to-Floor: 11" - 18.5"
Folded Width	12.8" - 14"	12.6"
Folded Length	31.9" - 34.3"	29.5"
Folded Height	28.5"	25.6"

Product Weight	31.5-33.7lb	28.7lb
Turning Radius	With user - 24"-30" Without user - 20.3"-25.6"	28.9"
Backrest Height	15"-17"	Stroller Handle: 20"-24" Height Adjustable: 13"-24"
Backrest Styles	Fixed Height, Rigid Canes Fixed Height, Foldable Canes Height-Adjustable, Rigid Canes	Stroller Handle Back Post Height Adjustable Straight with Push Handle Dynamic Rocker Back
Frame Options	Adjustable Seat Width Adjustable Seat Depth Adjustable Seat Height Adjustable Armrest Height Adjustable Backrest Angle Adjustable Center of Gravity Adjustable Footrest Length Adjustable Footrest Angle	Width Adjustable Folding Depth Adjustable Footrest Swing Away Footrest Super Low - Swing Away
Wheel Lock	Push to lock Pull to Lock Attendant Brakes	Push to lock Pull to Lock Push to Lock Flush Mount Hemi-Wheel Locks Extension handles (push and pull) Grade Aids
Anti-Tips	Standard anti-tippers	Removable/swing-up rear Anti-tips
Rear Wheels	14”, 20",22"	Stainless Steel Spoke (18Ct.): 18", 20", 22", 24" Mag: 20", 22", 24" Composite Fiber Spoke (18Ct.): 22" 24"
Caster Wheels	5/6”	.75" Roller Blade (3", 4") .75" Lighted Roller Blade (3",4",5") 1" Polyurethane (4", 5",6", 7",8") 1" Polyurethane Aluminum (4", 5") 1" Pneumatic (6",8") 1.5" Polyurethane (4", 5",6") 1.5" Soft Roll Aluminum (3", 4", 5", 6")

		2" Polyurethane (6") 2" Pneumatic w/ Foam Insert (8") Rear: 18"-24"; Casters: 3"-8", various materials
Seat to Backrest Angle	-4º to +16º (97-117)	85°-115°, 5° increments
Leg to seat angle	94°	-
Footrest to seat distance	6" - 9.8"	-
Armrest to seat distance	6" - 9.3"	-
Seat plane angle	2° - 5°	-
Static stability downhill	15°	-
Static stability uphill	14°	-
Static stability sideways	14°	-
Push Handle	Height-Adjustable Stroller Handle Push Handle	Std Push Handle fixed on back canes Removeable Stroller Back Handle
Armrest	Swing-away/ removable armrest and height-adjustable armrest	Single Post Height Adjustable Height Adjustable T-Arm (Std, Tall, Low) Angle Adjustable Locking Extendable Flip Up Pediatric Height Adjustable T-Arm Tubular Flip up Arm Pads (Std, Waterfall, Foam Grip)
Tires	Solid Tires (Standard) Pneumatic (optional)	Pneumatic Pneumatic with Airless Insert Pneumatic with puncture protection Solid Polyurethane
Handrims	Ergonomic handrim Aluminum handrim	Aluminum Anodized Aluminum with Plastic Coating Aluminum with Non-Slip Tape

		Projection Knob with Plastic Coating Ergonomic Thumb Grip: Flexible Polymer Ergonomic Thumb Grip: Alum with Grip Coating
Footrest	90º Swing away Detachable Footrests 80º Swing away Detachable Footrests Articulating Swing away Detachable Footrests	Swing Away, Footrest, Extension Mount Swing Away, Footrest, Front Mount Elevating Leg Rest (PRO, PRO Pediatric) Residual Limb Support Hanger Release (Classic, 4 Way In)
Footplate	Aluminum Footplate with 3D Angle Adjustment Aluminum Footplate with 4D Angle Adjustment	Composite Composite Angle Adjustable Aluminum Angle Adjustable Aluminum Locking Multi-Angle Adjustable One Piece Flip Up Adjustable Swing Away Extensions (Short, Med, Long) Front Mount Extension
Safety and Transportation Compliance	The Flexx Junior is crash-tested to ISO7176-19, making it suitable for use as a seat in adapted vehicles. It is recommended to use a four-point webbing system for secure restraint.	Ki Mobility Spark chair is used as seat in a motor vehicle and conforms to ISO 7176-19 Requirement.
Accessories	Pneumatic rear wheels Aluminum hand rim Attendant brake Swing away anti-tipper IV pole holder Transparent Table Tray Oxygen tank holder Cane holder Lap Belt 1" Metal Buckle Pelvic Belt.	Sideguards Composite Side guards (adult and pediatric) Backpack/Pouch Spoke Guards Cane/Crutch Holder ELR Gel Pads Impact guards Canopy Tool Kit One-Arm Drive
Performance compliance	ISO 7176-1: 2014 ISO 7176-3: 2012 ISO 7176-5:2008 ISO 7176-7:1998 ISO 7176-8: 2014 ISO 7176-11:2012 ISO 7176-13:1989	ISO-7176-1:2014 ISO-7176-3:2012 ISO 7176-5:2008 ISO 7176-7:1998 ISO 7176-8:2014 ISO 7176-11:2012 ISO 7176-13:1989

	ISO 7176-15: 1996 ISO 7176-19:2008 ISO 7176-22:2014 EN 1021-1 (Gap analysis) EN 1021-2	ISO 7176-15:1996 ISO 7176-16:2012 ISO 7176-19:2022 ISO 7176-22:2014

Technological Comparisons: [21CFR807.92(a)(6)]

Differences & Justification for Safety and Effectiveness: The Flexx Junior manual wheelchair and the predicate device, the Ki Mobility Spark are intended to provide mobility to pediatrics limited to a seating position. They share the same user weight capacity of (165 lbs) 75 kg.

1. Frame and Design Features: The Flexx Junior and Ki Mobility Spark share equivalent frame and design features, both using lightweight aluminum frames with an X-brace for rigidity. The Flexx Junior offers fixed or foldable backrests, while the Spark is foldable only. Both provide adjustable seat width, depth, height, backrest angle, armrests, and footrests via discrete holes, with the Spark offering more backrest styles and footrest/footplate options. Push handles and swing-away armrests are comparable. Differences in variety do not affect safety or effectiveness, as both ensure equivalent adjustability and stability, verified by ISO 7176 compliance.

2. Product Weight & Folding Dimensions: The Flexx Junior manual wheelchair and the predicate device, the Ki Mobility Spark, are equivalent in product weight and folding dimensions, ensuring ease of handling and transport for pediatric use. Both have comparable weights and folded dimensions, with the Flexx Junior's width aligning with the Ki Mobility Spark. Minor range variations in the Flexx Junior do not affect functionality, as both maintain a compact, lightweight profile suitable for pediatric use, with no implications for safety or structural integrity.

3. Turning Radius & Maneuverability: The Flexx Junior has a slightly smaller minimum turning radius compared to the predicate devices, improving maneuverability in tighter spaces without affecting overall stability. The Spark's additional wheel/tire/handrim options provide more variety, but differences do not raise safety concerns

4. Seat Height & Angle: Both devices offer similar seat height and angle adjustments for customization, with the Ki Mobility Spark wider ranges providing more flexibility. Both devices feature adjustable seat width via an X-brace mechanism, with the Flexx Junior providing a slightly narrower range than the Ki Mobility Spark, ensuring equivalent customization for growth. While the Spark offers wider adjustment ranges, these differences are minor and do not impact safety or effectiveness.

5. Accessories & Additional Features – The Flexx Junior offers comparable accessory options ensuring equivalent user positioning and support. Both provide essential safety and convenience items, with variations tailored to pediatric needs.

6. Performance Compliance: The Flexx Junior complies same standards and is substantial equivalence to the predicate device

7. Safety and Transportation Compliance: Both are crash-tested to ISO 7176-19, suitable for vehicle use with equivalent restraint recommendations.

Overall Equivalence: Accessories and features are equivalent in enhancing usability and safety, with differences reflecting optional customizations rather than core functionality. Both ensure compliance with overlapping standards, confirming no new risks and substantial equivalence in performance for pediatric mobility. Differences exist in the range of seat width, seat depth, and wheel options. The Spark offers a wider range of seat width and depth, as well as more rear wheel and caster options. However, these differences do not impact safety or effectiveness, as both devices provide sufficient adjustability for pediatric users and comply with ISO 7176-19 standard for use as a seat in a motor vehicle. Since the indications for use remain unchanged compared to the predicate devices, these differences do not constitute a new intended use. Both wheelchairs have been tested to equivalent performance and biocompatibility standards, ensuring no new safety or effectiveness concerns.

Bench testing performance tests summary and conclusions: [21 CFR 807.92(b)]

The Flexx Junior's bench testing confirms its safety, durability, and performance are equivalent to the Ki Mobility Spark. Compliance with ISO standards and biocompatibility standards verifies that the Flexx Junior performs reliably under expected use conditions, with no differences in design or adjustability raising safety or effectiveness concerns. The device is substantially equivalent to the predicate, ensuring safe and effective mobility for pediatric users.

Biocompatibility Tests and Flammability Tests: These tests ensure that the materials used in the wheelchair do not cause harm when they come into contact with the user's skin, evaluating the biological safety of medical device materials. These tests assess the fire resistance of upholstered furniture and safety-related components. Confirms components meets flammability requirements for safety aligning with the Ki Mobility Spark's compliance.

These tests collectively ensure that the materials used in the Flexx Junior wheelchair are biocompatible, safe for skin contact, and resistant to ignition, contributing to the overall safety and compliance of the device.

Standards and Test reports

Standards/ Regulations	Test Name	Result
ISO 7176-1: 2014	Static stability test	Pass
ISO 7176-3: 2012	Determination of effectiveness of brakes	Pass
ISO 7176-8: 2014	Multi drum, Drop test, Impact strength test, Manually operated parking brakes fatigue test, static strength test	Pass

ISO 7176-11:2012	Test Dummies	Pass
ISO 7176-13:1989	Determination of coefficient of friction	Pass
ISO 7176-15: 1996	Determination of dimensions mass report (Test report includes ISO 7176-7 (1998): Measurement of Seating and Wheel Dimensions and ISO 7176-5 (2008): Determination of Overall Dimensions, Mass, and Maneuvering Space)	Pass
ISO 7176-19:2008	Unwin front and rear tie down, Crash test	Pass
ISO 7176-22:2014	Set-up procedures	Pass

Test Standard	Tested Components & Test Report Number
ISO 10993-1, **ISO 10993-5,** **ISO 10993-10** **ISO 10993-23**	Fabric: EABML(E)1030421-140 GLP_SR_KL20250426-S Handle:EABML(E)1030421-138 Armrest: EABML(E)1030421-142
EN 1021-1, **EN 1021-2** Flammability test – Upholstery, Belt	Upholstery fabric - HL 90076/2020, HL 90077/2020 Seat belt or restraint system - HL10132/2015 Gap analysis Report

Conclusion:

The Flexx Junior manual wheelchair demonstrates substantial equivalence to the predicate device, the Ki Mobility Spark with no new risks to safety or effectiveness. Both devices share identical intended use, indications for use, weight capacity (165 lbs /75 kg), aluminum frame, and key adjustability features such as seat width, depth, height, backrest angle. Differences, such as the Flexx Junior's optional fixed backrest (FLX-J00), narrower seat width and depth ranges, and fewer wheel options, do not affect safety or effectiveness, as both provide comparable adjustability, stability, and maneuverability for pediatric users, verified through equivalent performance testing. Testing per ISO 7176 and biocompatibility standards confirms that the Flexx Junior performs as safely and effectively as the predicate device.