May 28, 2026

Motion Composites
Catherine Marquis
Regulatory Affairs & Quality Assurance Manager
160 Armand-Majeau Sud
Saint-Roch-Del'Achigan, QC JOK 3H0
Canada

Re: K260295
Trade/Device Name: Helio Kids; Apex P
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: April 28, 2026
Received: April 28, 2026

Dear Catherine Marquis:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260295

Please provide the device trade name(s).

Helio Kids ;
Apex P

Please provide your Indications for Use below.

Helio Kids:
The Helio Kids is indicated as a manual wheelchair to provide mobility for pediatric persons (23 kg to 75 kg) limited to a sitting position.

Apex P:
The Apex P is indicated as a manual wheelchair to provide mobility for pediatric persons (23 kg to 75 kg) limited to a sitting position.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
Devices: Helio Kids & Apex P

Applicant/Manufacturer: Motion Composites
Company Address: 160 Armand-Majeau Sud
Saint-Roch-de l'Achigan, Quebec
Canada JOK 3H0
Contact Person: Catherine Marquis
Date Summary Prepared: January 29, 2026
Trade Name: Helio Kids, Apex P
Classification Name: Manual Wheelchair
Product Code(s): IOR / wheelchair, mechanical
Device Class: Class I
Regulation Number: 21 CFR 890.3850

Predicate Devices:

Trade name	**Primary Predicate #1 Helio C2, Helio A7**	**Primary Predicate #2 Apex A, Apex C**	**Secondary Predicate Ki Mobility Spark**
510(k)	K120628, K143101	K161425	K223527
Manufacturer	Motion Composites	Motion Composites	Ki Mobility LLC
Class	I	I	I
Product Code / Name Classification Regulation / Name	IOR / wheelchair, mechanical 890.3850 / Manual Wheelchair	IOR / wheelchair, mechanical 890.3850 / Manual Wheelchair	IOR / wheelchair, mechanical 890.3850 / ManualWheelchair

Device Description

The Helio Kids and Apex P are mechanical non-powered wheelchairs respectively based on the current Helio and Apex families of wheelchairs. They are new pediatric sizes to extend the current adult sizes in each of the families. The Helio family are of the foldable type while the Apex type is non-foldable. They are provided in carbon or aluminum versions.

Comparison of intended use - indications for use

As compared in the table below to the primary and secondary predicates, the intended use as manual wheelchairs is unchanged. The indications in both the Helio Kids Apex P have been modified from that in the adult Helio and Apex adult versions to being for pediatric populations per their modified size. This indication is equivalent to the Ki Mobility Spark indication.

Intended Use / Indications			
K260295 Helio Kids, Apex P	**Primary Predicate #1 Helio C2, Helio A7**	**Primary Predicate #2 Apex A, Apex C**	**Secondary Predicate Ki Mobility Spark**
***Helio Kids**:* The Helio Kids is indicated as a manual wheelchair to provide mobility for pediatric persons (23 kg to 75 kg) limited to a sitting position. ***Apex P**:* The Apex P is indicated as a manual wheelchair to provide mobility for pediatric persons (23 kg to 75 kg) limited to a sitting position.	***Helio C2**:* The Helio wheelchair is a manually operated device intended to be used as a means of mobility for persons restricted to a sitting position. It is not indicated for the pediatric population. ***Helio A7**:* The indication for use of the Helio A7 manual wheelchair is to provide mobility to persons limited to a sitting position.	***Apex A & C:*** The indications for use of the APEX manual wheelchair are to provide mobility to persons limited to a sitting position.	***Ki Mobility Spark:*** The Ki Mobility Spark manual wheelchair is intended to provide mobility to pediatrics limited to a seating position.

Comparison of Technological Characteristics

As detailed in the comparison table shown below, the proposed pediatric Helio Kids and Apex P wheelchairs present the same main features as the predicates including: main frame upon which all components are assembled, seat with backrest, wheels with handrims and casters to each side, back canes / push handles, wheellocks, anti-tippers to the back, armrests, and footplates and leg rests.

As compared to each of their corresponding current Helio C2/A7 and Apex A/C adult predicate models, the base wheelchair components in the proposed pediatric Helio Kids and Apex P models are the same except that the frame/back width's and seat depth's ranges and weight limits have been reduced corresponding with compatible smaller pediatric users starting around 51 lbs (23 kg) up to 165 lbs (75kg).

As compared to the Ki Mobility Spark predicate for pediatric use, it presents the same main features with similar component and adjustment options. The differences are detailed engineering implementation differences or of a sizing nature without presenting any differences in the main technology or means of operation.

	APEX P	Apex A or C	Helio Kids	Helio A7 or C2	Ki Mobility Spark
Type	Non-foldable	Non-foldable	foldable	foldable	foldable
Weight Limit	165 lbs.	265 lbs	165 lbs.	265 lbs (also 350 lbs Heavy Duty option)	165 lbs.
Product Weight	24.8 lbs (standard configuration)	25.9 lbs (A) / 25.0 lbs (C) (standard configuration)	29.8 lbs (standard configuration)	31.2 lbs (A7) / 27.5 lbs (C2) (standard configuration)	28.7 lbs
Transit approved	yes	yes	yes	yes	yes
Primary Frame Materials	Aluminum (Upgrade of Carbon Fiber)	Aluminum (for A) / Carbon (for C)	Aluminum (Upgrade of Carbon Fiber)	Aluminum (for A7) / Hi-Modulus Carbon fiber + Epoxy Resin (for C2)	Aluminum
Frame Widths	10" to 15"	12" to 20"	12" to 16"	14” to 22”	10”-16”
Seat Depths	10" to 15"	12" to 20"	12" to 19"	14“ to 20”	12”-18”
Back Heights	9" to 21" (adjustable angle 80° to 101°)	9" to 21" (adjustable angle 80° to 101°)	9" to 21" (adjustable angle 90° to 105°)	9" to 21" (adjustable angle 85° to 110°)	13” to 24” (adjustable angle 85° to 115°)
Seat Height	14" to 21"	14" to 21"	13" to 21.5"	13" to 21.5""	(13”-21”) Front Seat-to-Floor (11”-18.5”) Rear Seat-to-Floor
Armrests: Type	Optional T-Shaped armrests, removable, height adjustable (by user, no tool required) or tubular swing away armrests or flip-up armrests	Optional T-Shaped armrests, removable, height adjustable (by user, no tool required) or tubular swing away armrests flip-up armrests	Optional T-Shaped or flip-back armrests, removable, height adjustable (by user, no tool required) or tubular swing away armrests or flip-up armrests	Optional T-Shaped or flip-back armrests, removable, height adjustable (by user, no tool required) or tubular swing away armrests or flip-up armrests	Single Post Height Adjustable Height Adjustable T-Arm Angle Adjustable Locking Extendable Flip Up Pediatric Height Adjustable T-Arm Tubular Flip up
Back Type	Angle adjustable, straight back canes with optional push handles. Optional height adjustable. Optional Depth adjustable.	Angle adjustable, straight back canes with optional push handles. Optional height adjustable. Optional Depth adjustable.	Height adjustable, straight or bended back canes with optional push handles. Optional angle adjustable. Optional Depth adjustable.	Height adjustable, straight or bended back canes with optional push handles. Optional angle adjustable. Optional Depth adjustable	Stroller Handle Back Post Height Adjustable Straight with Push Handle Dynamic Rocker Back Angle adjustable
Footrests/Legrest	Integrated to the frame Adjustable Height	Integrated to the frame Adjustable Height	Swing-in / Swing-out Flip in, flip out footrest; 60°, 70°,80°, 90°. Optional elevating legrest or residual limb support	Swing-in / Swing-out Flip in, flip out; 60°, 70°,80°, 90°. Optional elevating legrest or residual limb support	Swing Away Elevating Leg Rest PRO, PRO Pediatric) Residual Limb Support Adjustable Footplate angle adjustable
Footplates Type	Tubular or high mount platform Optional adjustable angle platform or Flip back platform	Tubular Optional adjustable angle platform or Flip back platform Optional high mount platform	Standard non angle adjustable Optional angle adjustable or one piece flip up platform or high mount footplates	Standard non angle adjustable Optional angle adjustable or one piece flip up platform or high mount footplates	
Wheel sizes	20”, 22”, 24”, 25”, 26 "	20”, 22”, 24”, 25”, 26 "	20”, 22”, 24”, 25”, 26 "	20”, 22”, 24”, 25”, 26 "	18”, 20”, 22”, 24”

	APEX P	Apex A or C	Helio Kids	Helio A7 or C2	Ki Mobility Spark
Handrims	Aluminum Anodized Optional Plastic Coated (regular or high friction) Optional Spinergy Flexrim Optional Natural Fit Handrim Optional Surge Handrim	Aluminum Anodized Optional Plastic Coated (regular or high friction) Optional Spinergy Flexrim Optional Natural Fit Handrim Optional Surge Handrim	Aluminum Anodized Optional Plastic Coated (regular or high friction) Optional Spinergy Flexrim Optional Natural Fit Handrim Optional Surge Handrim	Aluminum Anodized Optional Plastic Coated (regular or high friction) Optional Spinergy Flexrim Optional Natural Fit Handrim Optional Surge 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
Caster Sizes	3" to 6"	3" to 6"	3" to 8"	3" to 8"	3" to 8" (depending on configuration/options)
Wheel Locks	Push to lock, pull to lock	Push to lock, pull to lock,	Push to lock, pull to lock, one arm lock	Push to lock, pull to lock, one arm lock	Push to lock, Pull to lock Push to Lock Flush Mount Hemi-Wheel Locks
Anti-Tipper	Various sizes, with extension and contact wheels, removable	Various sizes, with extension and contact wheels, removable	Various sizes, with extension and contact wheels, removable	Various sizes, with extension and contact wheels, removable	Removable/swing-up

The Helio Kids and Apex P wheelchairs have been verified for their safety and effectiveness per the bench test and assessments as follows:

- **Biocompatibility:**

The materials that the user may contact and the applicable contact characteristics are the same and unchanged in the two proposed pediatric sizes as compared to the primary predicates (Helio C2 & A7, and Apex A & C). As such the proposed pediatric models present the same safe biocompatibility characteristics as is established in the current Helio and Apex adult models per their long history of safe use.

- **Performance Evaluation:**

As is detailed in the Performance Bench Test Section, the proposed pediatric sizes have been evaluated to meet the performance and safety requirements of the applicable parts of the ISO 7176 series of standards as well as RESNA WC-4 for manual wheelchairs. These include:

- ISO 7176-1 Wheelchairs - Part 1: Determination of static stability
- ISO 7176-3 Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-5 Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
- ISO 7176-7 Wheelchairs - Part 7: Measurement of seating and wheel dimensions
- ISO 7176-8 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
- ISO 7176-11 Wheelchairs - Part 11: Test dummies
- ISO 7176-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
- ISO 7176-19 Wheelchairs - Part 19: Wheeled mobility devices for use as seats in motor vehicles
- ISO 7176-22 Wheelchairs - Part 22: Set-up procedures
- RESNA WC-04 - Section 19: Wheelchairs used as seats in motor vehicles

Conclusion on Substantial Equivalence:

The pediatric Helio Kids and Apex P manual wheelchairs are of the same design as their base adult version predicates, the Helio C2/A7 and Apec A/C version, except for given sizing differences to accommodate pediatric users. They also present equivalent features to the Ki Mobility Spark predicate as is indicated for pediatric use. The differences do not raise any different questions of safety and effectiveness as compared to either of the Helio and Apex adult sized predicates, or to the Ki Mobility Spark pediatric predicate. Safety and performance evaluations and testing demonstrated that the proposed Helio Kids and Apex P can be expected to be safe and effective equivalently as the predicates. In conclusion, the Helio Kids and Apex P as indicated for pediatric use are substantially equivalent to the predicates.