



April 29, 2019

Leggero LLC  
% Mike Johnson  
Consultant  
Philosopher's River LLC  
P.O. Box 106  
Willow Creek, Montana 59760

Re: K182840  
Trade/Device Name: Element Pediatric Wheelchair  
Regulation Number: 21 CFR 890.3850  
Regulation Name: Mechanical Wheelchair  
Regulatory Class: Class I  
Product Code: IOR  
Dated: January 9, 2019  
Received: January 29, 2019

Dear Mike Johnson:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K182840

Device Name

Element Pediatric Wheelchair

Indications for Use (Describe)

The Element pediatric wheelchair is intended for medical purposes to provide mobility to persons 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.

**\*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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

# K182840

## 510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date 04-24-2019 [21 CFR 807.92(a)(1)].

**A. Applicant Name and Address [21 CFR 807.92(a)(1)]**

Leggero llc

P O Box 485

Burnet, Texas 78611

Tel: 406-551-9443

Fax: 406-551-9370

**B. Contact Information**

Philosopher's River llc

P O Box 106

Willow Creek, MT 59760

Tel: 406-209-3039

Fax: 406 209-3039

Contact person: Mike Johnson M.D.

mike@philosophersriver.com

**C. Device Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]**

Trade Name: *Element Pediatric Wheelchair*

Device Common Name: Wheelchair

Classification Name: Wheelchair, Mechanical 21 CFR 890.3850

Product Code: IOR

Device Classification: Class I

**D. Predicate Devices [21 CFR 807.92(a)(3)]**

The *Element Pediatric Wheelchair* uses similar technology and has a similar indication for use as the following predicate devices:

Primary predicate K973673 Zippy TS / TS SE

**E. Device Description [21 CFR 807.92(a)(4)]**

The *Element Pediatric Wheelchair* is designed for children who are limited to a seated position and require mobility and positioning assistance. It is intended for individuals less than 21 years old, who weigh less than 185 pounds.

The *Element Pediatric Wheelchair* consists of a frame and wheels (part number 3101-0000). The frame is powder-coated aluminum and the non-inflatable wheels are polyurethane plastic. The seat back, seat bottom, restraints and armrests are covered in flame retardant nylon fabric. The footrests are powder-coated aluminum. The seat back, seat bottom, armrests, footrests, and restraints are specified by a professional wheelchair fitter. Parameters such as seat width (18-28”) and depth (10-22”) are changeable over the course of use. This adds adjustability to the wheelchair to meet the needs of growth, postural changes, and level of disability.

Parameters adjustable by manufacturer or distributor include: seat width, seat depth, seat to floor height, wheel size, wheel base distance. Parameters adjustable by user include: back cane height, tilt of chair, foot rest height, and seat back angle (recline).

The *Element* has a “Transit Option” that is compliant with RESNA WC-19. The *Element* is foldable for storage or transport.

The *Element* was designed for firm and smooth surfaces, both indoors and outdoors. It is intended for surfaces with less than 5° slope. A back cane hand grip is provided for an attendant to push.

**Principle of Operation:** The Leggero Element Pediatric Wheelchair provides a stable seat and wheel chassis designed to provide mobility to persons restricted to a sitting position.

**F. Device Specifications and Comparison to Predicates [21 CFR 807.92(a)(6)]**

The Leggero Element Pediatric Wheelchair is compared to the predicate

- Primary predicate K973673 Zippy TS / TS SE

The indications for use and classification for the *Leggero Element Wheelchair* are equivalent to the predicate. Below is a comparison table.

|                                               |                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b><u>Characteristic</u></b>                  | <u>Leggero Element Pediatric Wheelchair</u><br><br>“Element”                                                                       | <u>Sunrise Medical Zippie TS/TS SE</u><br><br>“Zippie”                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b><u>Applicable 510(k)s</u></b>              | NA                                                                                                                                 | Primary predicate K973673 Zippie TS/TS SE                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b><u>Panel/</u></b>                          | Physical Medicine                                                                                                                  | Physical Medicine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b><u>Product Code/ Regulation Number</u></b> | IOR<br>21 CFR 890.3850                                                                                                             | IOR<br>21 CFR 890.3850                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b><u>Indications for Use Statement</u></b>   | The Element pediatric wheelchair is intended for medical purposes to provide mobility to persons restricted to a sitting position. | From K973673 (substantial equivalence is claimed for only first sentence): Quickie manual wheelchairs empower physically challenged persons by providing a means of mobility. This includes temporary and permanent conditions in all ages such as: Arthritis, Amputee, Paraplegic, Cerebral Palsy, Hemiplegic, Tetraplegic, Quadriplegic, Spina Bifida, Head Injury or Trauma, Muscular Dystrophy, Multiple Sclerosis, Polio, Geriatric Conditions and other Immobilizing or debilitating condition. |
| <b><u>Risk Classification</u></b>             | Class I                                                                                                                            | Class I                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b><u>Common Name</u></b>                     | Wheelchair, Mechanical                                                                                                             | Wheelchair, Mechanical                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b><u>Mechanism of Action</u></b>             | Adjustable seat on wheels, propelled by attendant.                                                                                 | Adjustable seat on wheels, propelled by attendant.                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

The specifications for the *Leggero Element Wheelchair* are equivalent to the predicate. Below is a comparison table.

|                                  |                                                              |                                                        |
|----------------------------------|--------------------------------------------------------------|--------------------------------------------------------|
| <b><u>Characteristic</u></b>     | <u>Leggero Element Pediatric Wheelchair</u><br><br>“Element” | <u>Sunrise Medical Zippie TS/TS SE</u><br><br>“Zippie” |
| <b><u>Applicable 510(k)s</u></b> | NA                                                           | Primary predicate K973673 Zippie TS/TS SE              |
| <b><u>Transit Option</u></b>     | Yes                                                          | Yes                                                    |
| <b><u>Tilt</u></b>               | 45°                                                          | 45°                                                    |
| <b><u>Chair Weight</u></b>       | 20, 22 24 lbs for the three models                           | 29 lbs w/o footrests                                   |

|                                                                     |                                                                                                               |                                                                                         |
|---------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| <b>Weight Capacity (w/o Seating)</b>                                | 185 lbs                                                                                                       | 165 lbs                                                                                 |
| <b>Overall Width</b>                                                | 18 to 28 inches                                                                                               | 18.25 to 24.25 inches                                                                   |
| <b>Tubing Diameter</b>                                              | 1 inch                                                                                                        | Frame 1 inch<br>Seat rail 1 inch                                                        |
| <b>Frame Seat Width</b>                                             | 10-20 inches                                                                                                  | 10 to 18 inches                                                                         |
| <b>Seat Depth</b>                                                   | 10-22 inches in one inch increments                                                                           | 13 to 20 inches                                                                         |
| <b>Seat to Back Angle Adjustment (recline)</b>                      | 90° to 115°                                                                                                   | 85° to 120°                                                                             |
| <b>Seat to Floor Height</b>                                         | 13 to 20 inches                                                                                               | 15.5 to 20 inches                                                                       |
| <b>Footrest / Frame Angle</b>                                       | 70°, 80°, 90° Swing Away                                                                                      | 60°, 70°, 80° Swing Away                                                                |
| <b>Back Type</b>                                                    | Fixed Height and Height Adjustable                                                                            | Fixed Height and Height Adjustable                                                      |
| <b>Back Cane (Handle) Height</b>                                    | Fixed Stroller Handles 21-25 inches, 23-27 inches, and 25-29 inches. Each is adjustable in 1 inch increments. | Fixed Stroller Handles 19, 22, 25 inches<br>Height Adjustable 16 to 22, 19 to 25 inches |
| <b>Center of Gravity Adjust (Varies depending on configuration)</b> | No                                                                                                            | No                                                                                      |
| <b>Rear Wheel Sizes (radius)</b>                                    | 12, 16, 18, 20, 22, 24 inches                                                                                 | 12, 16, 18, 20, 22, 24 inches                                                           |
| <b>Caster Sizes</b>                                                 | 3 to 8 inches                                                                                                 | 3 to 8 inches                                                                           |
| <b>Warranty</b>                                                     | Frame lifetime<br>Parts 1 year                                                                                | Frame lifetime<br>Parts 1 year                                                          |
| <b>Maximum Safe Slope</b>                                           | 5°                                                                                                            | 5°                                                                                      |

The Leggero *Element* has similar technological characteristics (design, materials) and indications for use as the predicate Sunrise Medical *Zippie*.

**G. Indications for Use [21 CFR 807.92(a)(5)]**

The Element pediatric wheelchair is intended for medical purposes to provide mobility to persons restricted to a sitting position.

**H. Performance Data [21 CFR 807.92(b)(2)]**

Specifically performance tests for the *Element* followed the standards:

ANSI/RESNA Section 1: Determination of static stability.

ANSI/RESNA Section 5: Determination of dimensions, mass, and maneuvering space

ANSI/RESNA Section 7: Method of measurement of seating and wheel dimensions.

ANSI/RESNA Section 8: Requirements and test methods for static, impact and fatigue strengths.

ANSI/RESNA Section 11: Test dummies.

ANSI/RESNA Section 13: Determination of coefficient of friction of test surfaces.

ANSI/RESNA Section 22: Set-up procedures.

ANSI/RESNA Section 26: Vocabulary

RESNA WC-2 Section 3: Determination of the effectiveness of brakes

RESNA WC-1 Section 15: Requirements for information disclosure, documentation and labeling

ISO 7176-19 Wheeled mobility devices for use as seats in motor vehicles.

ISO 7176-16 Resistance to ignition of postural support devices

ISO 10993-1 (4<sup>th</sup> Edition 2009) guided the biocompatibility assessments of the patient and operator contact surfaces.

Comparison of Functional Testing results for the *Element* compared to the predicate *Zippie*: Both Element and Zippie were tested to ANSI/RESNA and ISO standards.

| Test                                                       | <i>Element</i> |
|------------------------------------------------------------|----------------|
| Determination of static stability                          | PASS           |
| Static Impact and fatigue strength                         | PASS           |
| Determination of Dimensions, mass, turning space           | PASS           |
| Determination of safety when used as seat in motor vehicle | PASS           |
| Biocompatibility of contact surfaces                       | PASS           |

Both the *Element* and *Zippie* were tested to ISO 10993 for biocompatibility.

Nonclinical tests demonstrate that the *Element* is safe, effective and performs as well as the legally marketed device predicate.

**I. Conclusion** [21 CFR 807.92(b)(3)]

The Leggero *Element Pediatric Wheelchair* is substantially equivalent to the predicate devices, the *Sunrise Medical Zippie*; in terms of technology, function and indications for use. There are no new questions of safety or efficacy raised by the introduction of the Leggero *Element Pediatric Wheelchair*.