September 9, 2020

RGK Wheelchairs, Ltd.
Devin McElroy
Senior Director QA/RA at Sunrise Medical (US) LLC
Units 8 B/C Ring RD 2 Burntwood Business Park
Burntwood, Staffordshire, United Kingdom, WS7 3JQ

Re: K200135
Trade/Device Name: RGK Daily Range Wheelchairs
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: June 18, 2020
Received: June 19, 2020

Dear Devin McElroy:

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,

Heather Dean, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200135

Device Name
RGK Daily Range Wheelchairs

Indications for Use *(Describe)*
The RGK Daily Range Wheelchairs are mechanical wheelchairs with wheels that are turned manually and allows mobility to physically handicapped persons restricted to a sitting position and capable of manually causing the wheels to turn.

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) Summary

MANUFACTURER AND 510(k) OWNER

RGK Wheelchairs, Ltd.
Units 8 B/C Ring Rd 2, Burntwood Business Park, Burntwood,
Staffordshire, United Kingdom, WS7 3JQ Telephone:
+44-1543-670077

OFFICIAL CONTACT / U.S. AGENT

Devin I. McElroy, MBA/TM, Sr. Director QA/RA, North America
Sunrise Medical (US) LLC
5842 N Business Park Ave., Fresno, CA 93727
Telephone: +1 (559) 294-2374
Email: devin.mcelroy@sunmed.com
Website: www.sunmed.com

REPRESENTATIVE / CONSULTANT

Michelle Rubin-Onur, Ph.D.
Allison C. Komiyama, Ph.D., R.A.C.
AcKnowledge Regulatory Strategies, LLC
Telephone: +1 (619) 458-9547

Email: mrubin@acknowledge-rs.com, akomiyama@acknowledge-rs.com
Website: www.AcKnowledge-RS.com

DEVICE INFORMATION

Proprietary Name/Trade Name:	RGK Daily Range Wheelchairs
Common Name:	Mechanical wheelchair
Regulation Number:	21 CFR 890.3850
Class:	I
Product Code:	IOR
Premarket Review:	Physical Medicine
Review Panel:	Neurological and Physical Medicine Devices (OHT5) Neuromodulation and Physical Medicine Devices (DHT5B)

PREDICATE DEVICE IDENTIFICATION

The RGK Daily Range Wheelchairs are substantially equivalent to the following predicates:

510(k) Number	Predicate Device Name / Manufacturer	Primary Predicate
K021075	Mechanical Daily Use Wheelchair / First World Services, Inc.	✓
K123975	Quickie and Zippie Series / Sunrise Medical	

DEVICE DESCRIPTIVE INFORMATION

INTENDED USE

The RGK Daily Range Wheelchairs are intended to be manually propelled on level stable surfaces without loose materials such as gravel and stones. Typical urban road and pavement surfaces such as concrete,

asphalt, and tarmac are examples of outdoor intended use surfaces. The subject device can also be used on all traditional interior surfaces such as carpet, laminate and tile flooring. The RGK Daily Range Wheelchairs should not be used on unstable, inconsistent, or loose surfaces such as grass, loose stone, or cobblestone.

INDICATIONS FOR USE (FROM FORM FDA 3881)
The RGK Daily Range Wheelchairs are mechanical wheelchairs with wheels that are turned manually and allows mobility to physically handicapped persons restricted to a sitting position and capable of manually causing the wheels to turn.

DEVICE DESCRIPTION
The RGK Daily Range Wheelchairs are mechanical wheelchairs that include four wheels, an aluminum or titanium frame, and a black nylon upholstery that is flame resistant. Each wheelchair includes multiple components such as wheels, castors, sideguards, footplates and wheel locks.

The RGK Daily Range Wheelchairs include both aluminum and titanium frames. Aluminum frames are made from aluminum pipes provided by Thyssenkrugg Materials (UK) Ltd and inspected by Alumag Aluminum Corporation. The inspection reports from Alumag Aluminum Corporation, include chemical composition and tensile strength testing per:
1. EN573-3 Aluminum and Aluminum Alloys – Chemical Composition and Form of Wrought Products – Part 3: Chemical Composition and Form of Products
2. EN755-2 Aluminum and Aluminum Allows – Extruded Rod/Bar, Tube and Profiles – Part 2: Mechanical Properties
3. EN755-7 Aluminum and Aluminum Alloys – Extruded Rod/Bar, Tube, and Profiles. Seamless Tubes, Tolerances on Dimensions and Form
4. EN754-2 Aluminum and Aluminum Alloys- Cold Drawl Rod/Bar and Tube – Part 2: Mechanical Properties

Titanium frames are made from titanium pipes provided by Shenyang Dongli Titanium Company, Ltd. Dimensional measurements, chemical composition, and mechanical strength of each pipe are assessed to ensure compliance to EN 10204 Metallic Products: Types of Inspection Document.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS
RGK Wheelchairs, Ltd believes that the subject device is substantially equivalent to the predicate devices. There are no differences in: control mechanisms, operating principles, or energy types; sterilization, cleaning, or disinfection; intended use or effective lifetime; or dimensions, performance specifications, components, accessories, or patient/user interfaces between the RGK Daily Range Wheelchairs and the predicate devices. Design differences have no new considerations that impact safety, effectiveness, or indications for use.

The subject device has a similar design and dimensions and uses similar or identical materials as the device(s) cleared in K021075 (Primary Predicate) and K123975 (Secondary Predicate). The subject device has the same intended use and similar technological characteristics to the devices cleared in K021075 and K123975. The device has similar instrumentation to the device cleared in K021075 and K123975. The RGK Daily Range Wheelchairs have undergone testing to ensure that any differences in technological characteristics do not affect safety and effectiveness when compared to the predicate devices.

Table 5.1: Technological Comparison

Feature:	*Primary Predicate* *K021075* *RGK Titanium family chairs (Hi-Lite, Maxima, Ultima, and Style)*	*Secondary Predicate* *K123975* *Quickie Q7 Manual Wheelchair*	*Proposed:* *K200135* *RGK Aluminum family chairs (Tiga, Tiga Sub4, Tiga FX, Octane Sub4, Octane FX, and Hi-Lite)*	*Description of Similarities & Differences*
1. Intended Use:				
1.1 Intended Use:	The RGK Mechanical Daily Use wheelchair range features self-propelled rigid style wheelchairs that provide seating for patients who cannot stand on their own. These chairs are intended for patients with spinal cord injury, Paralysis, loss of extremity and other diseases and conditions which limit a patient's mobility.	The Sunrise Medical Quickie® Q7 manual wheelchair is a self-propelled rigid style wheelchair that provides seating for patients who cannot stand on their own. This chair is intended for patients with spinal cord injury, Paralysis, loss of extremity and other diseases and conditions which limit a patient's mobility.	The RGK Daily Range Wheelchairs features self-propelled rigid style wheelchairs that provide seating for patients who cannot stand on their own. These chairs are intended for patients with spinal cord injury, Paralysis, loss of extremity and other diseases and conditions which limit a patient's mobility.	Identical to Primary Predicate. No Impact on safety or effectiveness.
1.2 Indications for Use:	The device is a mechanical wheelchair with wheels that are turned manually and allows mobility to physically handicapped persons restricted to a sitting position and capable of manually causing the wheels to turn.	The Sunrise Medical Zippie and Quickie Series Wheelchairs' intended use is to provide mobility to persons limited to a sitting position.	The RGK Daily Range Wheelchairs are mechanical wheelchairs with wheels that are turned manually and allows mobility to physically handicapped persons restricted to a sitting position and capable of manually causing the wheels to turn.	Identical to Primary Predicate. No Impact on safety or effectiveness.
1.3 Target Population:	Patients with spinal cord injury, paralysis, loss of extremity and other diseases and conditions which limit a patient's mobility.	Patients with spinal cord injury, paralysis, loss of extremity and other diseases and conditions which limit a patient's mobility.	Patients with spinal cord injury, paralysis, loss of extremity and other diseases and conditions which limit a patient's mobility.	Identical to Primary Predicate. No Impact on safety or effectiveness.
1.4 Where Used:	Indoors and outdoors. Public, business and private residences.	Indoors and outdoors. Public, business and private residences.	Indoors and outdoors. Public, business and private residences.	Identical to Primary Predicate. No Impact on safety or effectiveness.

Feature:	Primary Predicate K021075 RGK Titanium family chairs (Hi-Lite, Maxima, Ultima, and Style)	Secondary Predicate K123975 Quickie Q7 Manual Wheelchair	Proposed: K200135 RGK Aluminum family chairs (Tiga, Tiga Sub4, Tiga FX, Octane Sub4, Octane FX, and Hi-Lite)	Description of Similarities & Differences
2. General:				
2.1 User Weight (Max):	125kg	120kg	125kg	Identical to Primary Predicate. No Impact on safety or effectiveness.
2.2 Structural Materials:	Titanium frame with standard foams and covers for the seat.	7000 grade aluminum frame with standard foams and covers for the seat.	7000 grade aluminium and titanium frames with standard foams and covers for the seat.	Identical to Primary and Secondary Predicates. No Impact on safety or effectiveness.
2.3 Biocompatibility:	Uses materials common to many wheelchairs.	Uses materials common to many wheelchairs.	Uses materials common to many wheelchairs.	Identical to Primary and Secondary Predicates. No Impact on safety or effectiveness.
2.4 Maximum Speed:	Manually propelled/ user controlled speed	Manually propelled/ user controlled speed	Manually propelled/ user controlled speed	Identical to Primary and Secondary Predicates. No Impact on safety or effectiveness.
3. Base:				
3.1 Overall dimensions (width by height)	Made to measure frame, typical Max 500mm x 700mm	500mm x 790mm	Made to measure frame, typical Max 500mm x 700mm	Identical to Primary Predicate. No Impact on safety or effectiveness.
3.2 Maximum total weight (without wheels)	9kg	9kg	9kg	Identical to Primary and Secondary Predicates (when using equivalent configurations). No Impact on safety or effectiveness.

Feature:	Primary Predicate K021075 RGK Titanium family chairs (Hi-Lite, Maxima, Ultima, and Style)	Secondary Predicate K123975 Quickie Q7 Manual Wheelchair	Proposed: K200135 RGK Aluminum family chairs (Tiga, Tiga Sub4, Tiga FX, Octane Sub4, Octane FX, and Hi-Lite)	Description of Similarities & Differences
3.3 Drive wheels	Fusion 16 spoke 24" Spinergy SPOX 25" Spinergy SPOX 26" Spinergy SPOX 24" Spinergy LX 25" Spinergy LX 26" Spinergy LX 24" Spinergy BLX 25" Spinergy BLX 26" Spinergy BLX 24" Spinergy CLX 25" Spinergy CLX 26" Spinergy CLX 24" Spinergy XLX 25" Spinergy XLX 26" Spinergy XLX	20" Mag Wheel 5-Spoke 22" Mag Wheel 5-Spoke 24" Mag Wheel 5-Spoke 20" Lite Spoke Wheel 22" Lite Spoke Wheel 24" Lite Spoke Wheel 25" Lite Spoke Wheel 26" Lite Spoke Wheel 22" Ultra Lightweight Spoke Wheel 24" Ultra Lightweight Spoke Wheel 25" Ultra Lightweight Spoke Wheel 22" Spinergy SPOX Black 24" Spinergy SPOX Black 25" Spinergy SPOX Black 26" Spinergy SPOX Black 22" Spinergy LX Black 24" Spinergy LX Black 25" Spinergy LX Black 26" Spinergy LX Black 24" Mountain	Fusion 16 spoke 24" Spinergy SPOX 25" Spinergy SPOX 26" Spinergy SPOX 24" Spinergy LX 25" Spinergy LX 26" Spinergy LX 24" Spinergy BLX 25" Spinergy BLX 26" Spinergy BLX 24" Spinergy CLX 25" Spinergy CLX 26" Spinergy CLX 24" Spinergy XLX 25" Spinergy XLX 26" Spinergy XLX	Identical to Primary Predicate. No Impact on safety or effectiveness.

Feature:	*Primary Predicate*	*Secondary Predicate*	*Proposed:*	*Description of Similarities & Differences*
	K021075	*K123975*	*K200135*	
	RGK Titanium family chairs (Hi-Lite, Maxima, Ultima, and Style)	*Quickie Q7 Manual Wheelchair*	*RGK Aluminum family chairs (Tiga, Tiga Sub4, Tiga FX, Octane Sub4, Octane FX, and Hi-Lite)*	
3.4 Castor Wheels	3" Froglegs Aluminium 4" Softroll 4" Froglegs Carbon Centre 4" Froglegs Aluminium Centre 5" Softroll 5" Pneumatic Aluminium Centre 5" Froglegs Aluminium Centre 6" Softroll	3" Micro 4" Low Profile Polyurethane 4" Micro Lighted 4" x 1" Aluminum Polyurethane 4" x 1.25" Semi Pneumatic 4" x 1.5" Aluminum Soft Roll 5" Low Profile Polyurethane 5" Micro lighted 5" x 1" Aluminum Polyurethane 5" x 1.5" Semi-Pneumatic 5" Soft Roll (Grey) 5" x 1.5" Aluminum Soft Roll 6" Polyurethane 6" Pneumatic 6" x 1.5" Semi Pneumatic 6" x 1.5" Aluminum Soft Roll	3" Froglegs Aluminium 4" Softroll 4" Froglegs Carbon Centre 4" Froglegs Aluminium Centre 5" Softroll 5" Pneumatic Aluminium Centre 5" Froglegs Aluminium Centre 6" Softroll 6" Froglegs Aluminium Centre	Identical to Predicate. No Impact on safety or effectiveness.
3.5 Handrim Options	Aluminium Hard Anodised Surge LT Tetra Grip Para Grip Titanium Stainless steel Ergo Grip	Aluminum Anodized Plastic Coated Natural Fit - Standard Grip Natural Fit - Super Grip Natural Fit - No Thumb Grip Natural Fit LT - Standard Grip Natural Fit LT - Super Grip Natural Fit LT - No Thumb Grip The Surge - Oval w/Griptionn Strip The Surge LT - Oval w/ Griptionn Strip Q-Grip Neoprene Coated Spinergy Flex Rim	Aluminium Hard Anodised Surge LT Tetra Grip Para Grip Titanium Stainless steel Ergo Grip	Identical to Primary Predicate. No Impact on safety or effectiveness.

Feature:	Primary Predicate K021075 RGK Titanium family chairs (Hi-Lite, Maxima, Ultima, and Style)	Secondary Predicate K123975 Quickie Q7 Manual Wheelchair	Proposed: K200135 RGK Aluminum family chairs (Tiga, Tiga Sub4, Tiga FX, Octane Sub4, Octane FX, and Hi-Lite)	Description of Similarities & Differences
3.6 Cosmetic	Product is made from a titanium frame with a selection of powder coated colour finished as well as a satin raw finish.	Product is made from an aluminum frame with a selection of powder coated color finishes as well as some anodized options.	Product is made from an aluminium frame or titanium frame with a selection of powder coated colour finishes as well as polished and brushed options.	Identical to Primary and Secondary Predicates. No impact on safety or effectiveness.
3.7 Picture				Substantially equivalent to Primary and Secondary Predicates. No impact on safety or effectiveness.
4. Seat:				
4.1 Seat Options	seatplate or seat sling with cushion	seatplate or seat sling with cushion	seatplate or seat sling with cushion	Identical to Primary and Secondary Predicates. No impact on safety or effectiveness.
4.2 Minimum Seat Height	360mm	330mm rear 400mm front	360mm	Identical to Primary Predicate. No impact on safety or effectiveness.
4.3 Camber angle	1° 2° 3°	0° 3° 6°	0° 1° 2° 3° 5°	Substantially equivalent to Primary and Secondary predicates. No impact on safety or effectiveness.

Feature:	Primary Predicate K021075 RGK Titanium family chairs (Hi-Lite, Maxima, Ultima, and Style)	Secondary Predicate K123975 Quickie Q7 Manual Wheelchair	Proposed: K200135 RGK Aluminum family chairs (Tiga, Tiga Sub4, Tiga FX, Octane Sub4, Octane FX, and Hi-Lite)	Description of Similarities & Differences
4.4 COG Adjustment	25-125mm	0-100mm	25-125mm	Identical to Primary Predicate. No impact on safety or effectiveness.
4.5 Seat Dimensions	Width 250-440mm	Width 300-500mm	Width 300-500mm	Identical to Secondary Predicate. No Impact on safety or effectiveness.
	Depth 250-440mm	Depth 300-500mm	Depth 300-500mm	
5. Accessories				
5.1 Brakes	Underseat Scissor Compact Scissor Out Front Compact Scissor Push to Lock Out Front Push to Lock Omit Wheel Locks	Direct Mount High Mount Push High Mount Pull Ergo Scissor Compact 6" Extension Handle Pair	Underseat Scissor Compact Scissor Out Front Compact Scissor Push to Lock Out Front Push to Lock Omit Wheel Locks	Identical to Primary Predicate. No Impact on safety or effectiveness.
5.2 Sideguards	Plastic Aluminium Aluminium Welded Aluminium Liftout Aluminium with Fender Carbon Fibre Carbon Fibre with Fender	Plastic - Standard Plastic - Low Aluminum Aluminum with Fender Carbon Fiber Carbon Fiber with Fender	Plastic Aluminium Aluminium Welded Aluminium Liftout Aluminium with Fender Carbon Fibre Carbon Fibre with Fender	Identical to Primary Predicate. No Impact on safety or effectiveness.
5.3 Backrest	Fixed Height Adjustable Height Folding Backrest Ergo Backrest	Non-Folding Folding Lock-Down Angle Adjustable Freestyle Backrest System Non-Folding Freestyle Backrest System Folding	Fixed Height Adjustable Height Folding Backrest Ergo Backrest	Identical to Primary Predicate. No Impact on safety or effectiveness.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for mechanical wheelchairs. Clinical testing is not applicable to mechanical wheelchairs; therefore, clinical testing was not performed.

The following tests were performed to demonstrate equivalence to the predicate devices:

- Determination of static stability (per ISO 7176-1)
- Effectiveness of Brakes (per ISO 7176-3)
- Dimension, Mass, and Maneuvering Space (per ISO 7176-5)
- Measurement of Seating and Wheel Measurements (per ISO 7176-7)
- Requirements and Test Methods for Static Impact and Fatigue Strength (per ISO 7176-8)
- Wheeled mobility devices for use as seats in motor vehicles (per ISO 7176-19) – Tiga model only
- Flammability (per EN 1021-1 and EN 1021-2)

CONCLUSION

Based on the information performed, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices.