DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 5, 2016

Motion Composites
Stephane Le Beau
Marketing and International sales coordinator
519 J. Oswald Forest, suite 101
Saint-Roch-de-l'Achigan, Quebec City, J0K 3H0
Canada

Re: K161425
Trade/Device Name: APEX Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: October 28, 2018
Received: November 7, 2016

Dear Stephane Le Beau:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161425

Device Name
APEX Manual Wheelchair

Indications for Use *(Describe)*
The indications for use of the APEX Manual Wheelchair are to provide mobility to persons limited 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.

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Motion Composites
APEX Manual Wheelchair
510(k) Summary

I. SUBMITTER

Motion Composites
519 J – Oswald Forest Suite 101
Saint-Roch-de-l'Achigan
Quebec, Canada
J0K 3H0
Phone: (450) 588-6555
Fax: (450) 588-0200
Email: info@motioncomposites.com
Web Site: www.motioncomposites.com

II. DEVICE

Name of Device: APEX Manual Wheelchair
Common or Usual Name: Manual Wheelchair
Classification Name: Wheelchair, Mechanical (21 CFR 890.3850)
Regulatory Class: I
Product Code: IOR

III. PREDICATE DEVICE

Sunrise Medical Quickie Q7 Manual Wheelchair K123975
Helio C2 Manual Wheelchair K120628

IV. DEVICE DESCRIPTION

The Motion Composites APEX Manual Wheelchair is manually operated, user propelled, manual, mechanical wheelchairs. Their intended function and use is to provide mobility to persons limited to a sitting position.

The Apex wheelchairs are traditional rigid wheelchairs. They are made of aluminum alloy or carbon fiber. The frame which utilizes a standard geometry that creates a cantilever like rigid assembly. Upon the outside of this framework, and to the rear, are assembled two aluminum axle plates. Wheels of varying size and type are connected to the carbon fiber camber tube via stainless steel axles.

On the front end of the frame are assembled two aluminum caster mount. Caster forks are mounted to these mounts via steel axles. A variety of caster wheels and tires are then connected to the fork based on user preference.

Device Function

Device function is dependent solely upon the wheelchair user. It does not function on its' own in any manner. The wheelchair user controls motion, speed and direction by propelling themselves using the hand rims located on the rear wheels.

Scientific Concepts

There are no complex scientific concepts related to the APEX manual wheelchair. It's a simple, basic, manually operated mobility device.

Significant Physical and Performance Characteristics:

Design:

- The APEX utilizes a 2 sided aluminum or carbon fiber frame tubes that are linked by rigid cross-members improving greatly rigidity over regular interconnected side frames.

- The 2 rigid links called «Rigidizers» by Motion Composites are set at the front and rear of the frame camber tube. The 3 components of the frame, the front rigidizer tube, rear rigidizer tube and the camber tube serves to increase the rigidity of the frame. The camber tube also serves to receive the rear wheel on each side.

- A set of adjustable axle plates are attached vertically to each side frame and provide the wheelchair with ability to move the rear wheel position forward and backward in order to give the user an adjustment as to the center of gravity of the wheelchair. The vertical position can be also adjusted to set the height of the user on the wheelchair. These rear axle plates are linked by the camber tube to limits torsion and flexion for improved propulsion.

Materials:

Materials used are:

- Aluminum or Carbon fiber frame, support members
- Aluminum or Carbon fiber Components
- Aluminum wheels
- Steel fasteners and components
- Polyurethane tires
- Fabric covered foam upholstery

Physical Properties:

The APEX consist primarily of an aluminum or carbon fiber frame assembly, a back rest frame, seat and back rest upholstery, large rear wheels with hand rims for self-propelling the chair and front swivel pivoting casters for turning.

V. INDICATIONS FOR USE

The indications for use of the APEX Manual Wheelchair are to provide mobility to persons limited to a sitting position. This is identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technology and principle of operation for the APEX, Helio C2 and the Quickie Q7 are identical. They all consist of an aluminum frame or carbon fiber frame with a seat and large rear wheels with hand rims for propelling the device. Smaller, pivoting type casters are mounted on the front of the chairs for steering and turning.

Device function is dependent solely upon the wheelchair user. They do not function on their own in any manner. The wheelchair user controls motion, speed and direction by propelling themselves using the hand rims located on the rear wheels.

If both rear wheels are propelled at the same time, the chair will move forward in a straight direction. If only the left rear wheel is propelled the chair will turn to the right. If only the right rear wheel is propelled the chair will turn to the left.

Discussion of Similarities and Differences:

The APEX wheelchairs are substantially equivalent to the predicate Quickie Q7 (K123975) or Helio C2 wheelchairs (K120628) in technology, function, performance and materials. They have the same indications for use which is to provide mobility for persons restricted in a sitting position.

The frame width, depth and the back cane heights vary slightly between the devices, but since these are only used to better fit the device to the user's needs, these slight differences do not cause any concerns for the safety and effectiveness of the device. The weight limit is similar within 15 pounds for all devices. The Quickie Q7 is at 265 lbs. and the Helio C2 and APEX is at 250 lbs. and is clearly stated in the proposed device labeling.

With regard to accessories and add-ons, all devices offer the same types of armrests, backrests, hangers and footplates. These accessories are made of the exact same materials for all devices and thus do not raise any questions for the safety and effectiveness of the APEX wheelchairs. The same can be said of back types and extension tubes.

Axle plates for all devices are made out of the same material; however, the actual mounting systems differ slightly. The Quickie Q7 and APEX axle plates are mounted vertically on a single tube on each side of the frame and the Helio C2 are mounted vertically on 2 tubes on each side of the frame.

The mechanical difference found on the Quickie Q7 and Apex permits a larger range of adjustment of the Center of Gravity for the user. It does not raise any concerns for the safety and effectiveness of the device and actually improves the precision of the adjustment.

The same can be said for the caster housing that holds the front wheel into place. While the caster housing of the predicate device and those of the APEX are made all made of aluminum, the mounting system of the APEX casters housing is patented and thus slightly different from the one found on the Quickie Q7 or Helio C2 wheelchairs.

This mounting system embeds the caster housing directly into the fork stem support, and allows adjusting the angle of the castes for an efficient and more comfortable position for the user. The caster housing also imbeds a level to make sure the fork and casters are perpendicular to the ground, thus providing a better overall experience to the wheelchair user when turning and moving straight forward.

This small difference as well does not raise any concerns as far as the safety of the overall product against the predicate device, since all casters offer the same effectiveness as per the APEX successfully obtaining its ISO certification.

The seat and back upholstery offering of the APEX is equivalent to the one found on the predicate devices. It is made of high-quality durable sailcloth, which consists of 1000 denier fill and 250 denier wrap.

The rear wheels and hand rims of the predicate device and the APEX wheelchairs are offered in a wide range of different options. They are made of the same materials and are widely used in the wheelchair industry. The specific type, material and size of the wheels are chosen depending on the user's needs. These differences do not raise any concerns for the safety and effectiveness of the APEX wheelchairs. We also note the wheel locks are the same on all devices. The predicated devices were tested under the older ISO 7176-8 (1st Edition, 1998-07-15) standard for parking brakes, it's uncertain that these brakes could meet the new ISO 7176-8 (2nd Edition 2014-12-15) standard. The APEX push-to-lock and Graid-Aid brakes pass the new standard but when testing the pull-to-lock parking brakes we found that they failed. For this reason, the APEX will not offer an option with the pull to lock parking brake. This does not influence the ability of the user to park the

wheelchair, it only limits the number of options of parking brakes available. For this reason, Motion Composites feel that the APEX is offering a safer parking brake option.

Based on the above discussion, Motion Composites believes that the APEX wheelchairs are substantially equivalent to the Quickie Q7 wheelchair (K123975) and the Helio C2 (K120628). While there are some differences between the APEX and its predicate, these differences are minor and do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness.

VII. PERFORMANCE DATA

The APEX Manual Wheelchairs have been tested to the following standards;

- ISO 7176-1:1999 Determination of Static Stability
- ISO 7176-3:2012 Determination of Effectiveness of Brakes
- ISO 7176-5:2008 Determination of Overall Dimensions, Mass and Maneuvering
- Space
- ISO 7176-7:1998 Determination of Seating and Wheel Dimensions
- ISO-7176-8:1998 Requirements and Test Method for Static Impact and Fatigue Strength
- ISO 7176-15 Requirements for Information Disclosure, Documentation and Labeling

The performance data for the Quickie Q7 is not published. However, on page 13 of the Quickie Q7 Owner's Manual, the following statement is made;

> This wheelchair has been dynamically tested in a forward-facing mode with the specified crash test dummy, restrained by both pelvic and upper-torso belts in accordance with ANSI/RESNA WC Vol 4 Section

This statement indicates that the Sunrise Quickie Q7 has been tested to at least some of the ANSI/RESNA standards. These standards are comparable to the ISO 7176 standards which were used to test the Motion Composites APEX wheelchairs. (Note that a copy of the Quickie Q7 and Helio C2 Owner's Manual are provided in Volume 10 of this submission).

Further, manual wheelchairs are subject to the 1995 FDA guidance document entitled: "Guidance Document for the Preparation of Premarket Notification [(510(k)] Applications Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles." This guidance includes various safety and performance requirements that the Quickie 7 would have to have met or addressed prior to being cleared by FDA. Meeting these requirements also serves as a basis for substantial equivalence of the APEX to its' predicate.

VIII. CONCLUSIONS:

Performance testing and compliance with FDA guidance for manual wheelchairs supports the safety of the APEX manual wheelchair. Since the predicate device was cleared based in part on these data, conformance with the same requirements demonstrates that the APEX will perform as intended in the specified use conditions.

Further, technology, principle of operation and indications for use between APEX, the Quickie Q7 and Helio C2 are identical. This demonstrates that they perform comparably to the predicate device that is currently marketed for the same intended use. Therefore, the APEX manual wheelchair is substantially equivalent to the Quickie Q7 and Helio C2 devices.

APEX Predicate Device Comparison

Feature/Specification	Sunrise Medical LLC Quickie Q7 (K123975)	Motion Composites Helio (K120628)	APEX
Intended Use	The Quickie Q7 Wheelchair is a manually operated device intended to be used as a means of mobility for persons restrict to a sitting position.	The Helio wheelchair is a manually operated device intended to be used as a means of mobility for persons restrict to a sitting position.	The APEX wheelchair is a manually operated device intended to be used as a means of mobility for persons restrict to a sitting position.
Primary Materials	Aluminum	Carbon Fiber	Carbon Fiber and Aluminum
Folding Method	Rigid wheelchair	Collapsible Cross-brace	Rigid wheelchair
Frame Width	12" to 20"	14" to 22"	12" to 20"
Overall width	19" to 27"	21 1/2" to 29 ½"	18 ½'' to 33 ¼"
Seat Depth	12" to 20"	15" to 21"	12" to 20"
Back Heights	8" to 20"	9" to 21"	9" to 21"
Weight Limit :	265 lbs.	250 lbs.	250 lbs.
Front Seat height :	16" to 21"	13½" to 21 ¼"	14" to 20"
Chair Weight Standard configuration	14. lbs. Without wheels	16.5 lbs. Without footrests and wheels	10.7 lbs. without wheels Aluminum model 9.2 lbs. without wheels carbon fiber model
Warranty	Lifetime on frame	Lifetime on frame	Lifetime on frame
Armrests	-Padded Swing Away -Single Post Height Adjustable -T-Shaped Armrests - Height adjustable Tubular Swing-away	-Flip back armrest, removable, height adjustable (by user, no tool required) -T-Shaped, Single Post removable, Height adjustable (by user, no tool required) -Tubular Swing-away	-T-Shaped armrest, removable, height adjustable (by user, no tool required) -Tubular Swing-away
Front end types	Welded to frame	Mounted to frame Swing-in Swing-out	Factory clamped to the frame
Back Type	-Folding Lock-Down Angle Adjustable -Non-Folding Angle-Adjustable -Depth Adjustable	-Straight -8 degree bend back -Adjustable angle- straight or 8 degree bend	-Folding Lock-Down Angle Adjustable straight with or with-out push handle - Ultralight Folding without push Handle
Footrest	Integrated to the frame	Flip in, flip out; 60°, 70° , 90°, elevating legrest	Integrated to the frame
Footplates	-Aluminum Tubular -Aluminum Tubular w/ Snap-on Cover -Angle Adjustable Flip Back -Platform -Ultra Lite Platform	-Standard non adjustable -Angle Adjustable Oversized	-Aluminum Tubular with or without platform -Platform angle adjustable - Flip-back platform
Back Upholstery	Standard, Tension Adjustable	Standard, Tension Adjustable	Standard, Tension Adjustable
Axle Plates	-Adjustable COG (1"-4") -Adjustable Extended COG (0"-3")	Standard adjustable Extended adjustable for Amputee	Standard post type Adjustable COG (0''-5'')
Wheel sizes	20,22,24, 25,26 "	20 ,22,24, 25, 26 "	20 ,22,24, 25, 26 "
Wheel types	-Spoke -Composite Mag -Spinergy -Mountain	-Spoke -Composite Mag -Spinergy	-Spoke -Composite Mag -Spinergy
Tire types	-Pneumatic regular and high pressure -Pneumatic w/ airless insert -Full and low profile polyurethane	-Pneumatic regular and high pressure -High and low profile polyurethane -Hard Urethane	-Pneumatic regular and high pressure -High and low profile polyurethane -Hard Urethane
Handrims	-Aluminum Anodized -Plastic Coated -Natural Fit -Spinergy Flex Rim	-Aluminum Anodized -Plastic Coated -Natural Fit -Spinergy Flex Rim -Surge Handrim	-Aluminum Anodized -Plastic Coated -Natural Fit -Spinergy Flex Rim -Surge Handrim
Caster Sizes	3", 4",5", 6"	3", 4",5", 6", 8"	3", 4",5", 6"

APEX Predicate Device Comparison

Feature/Specification	Sunrise Medical LLC Quickie Q7 (K123975)	Motion Composites Helio (K120628)	APEX Wheelchair
Caster types	Polyurethane, semi-pneumatic, Soft Roll, Pneumatic	Composites wheels, Pneumatic, Soft Roll	Composites wheels, Pneumatic, Soft Roll
Fork Sizes	3”,4”,5”,6”,7”	3”,4”,5”,7”	4 ¾ ‘’
Fork Stem Sizes	Std,+3/4”,+1 ½”	Std, +1 , +2	Std, +1 , +2
Caster Options	Multi-position fork caster, pin locks	Multi-position fork caster, pin locks	Multi-position fork caster
Wheel Locks	Push to lock, pull to lock, scissor lock	Push to lock, pull to lock, scissor lock	Push to lock, scissor lock
Anti-tip tubes	Yes	Yes	Yes
Target population	Restricted to a sitting position	Restricted to a sitting position	Restricted to a sitting position
Standards	Unknown	ISO 7176 – (1, 3, 5, 7, 8 & 15)	ISO 7176 – (1, 3, 5, 7, 8 & 15)