



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 19, 2016

Rupiani
% Edward A. Kroll
President
Spectre Solutions, Inc.
5905 Fawn Lane
Cleveland, Ohio 44141

Re: K152827
Trade/Device Name: Weely Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: January 13, 2016
Received: January 19, 2016

Dear Edward A. Kroll:

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 and Part 809); 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 and Part 809), 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 yours,

Michael J. Hoffmann -A

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)
K152827

Device Name
Weely Manual Wheelchair

Indications for Use (Describe)

The indications for use for the Weely Manual Wheelchair is 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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Rupiani
Weely Manual Wheelchair
510(k) Summary
(Modified February 12, 2016)

I. SUBMITTER

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II. DEVICE

Name of Device: Weely 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

PDG Product Design Group Fuze T50 Manual Wheelchair (K063736)

IV. DEVICE DESCRIPTION

Device Description:

The Rupiani Weely Manual Wheelchair (Weely) is a manually operated, user propelled, manual, mechanical wheelchair. It's intended function and use is to provide mobility to persons limited to a sitting position. It may also be used in as an attendant propelled transport device in a health care environment such as a hospital, nursing home or extended care facility.

The Weely consists primarily of an upper and lower frame assembly, upholstery for seating, large wheels for propelling the chair and front and rear swivel type pivoting casters for turning. The wheels and casters are mounted to the lower frame assembly. The wheelchair seat and back mount to the upper frame assembly. Both frame assemblies are constructed from aluminum tubing. The rear casters act as "anti-tippers and provide added stability

The lower frame is of rigid (non-folding) design. The back rest can be folded to allow for storage and transport of the chair when it is not in use. The Weely is equipped with a Varilite rigid backrest and a Varilite EVOLUTION cushion covered by SooFleece III mesh fabric



provided by Ventex. The upholstery materials meet the requirements of ISO 8191-1 Part 1: Ignition Source: Smoldering Cigarette and - ISO 8191-2 Part 2: Ignition Source: Flame Match-Flame Equivalent Standard for Resistance to Ignition of Upholstered Parts.

The Weely includes a tilt mechanism which allows the seat and back of the wheelchair to be tilted. This feature is used to provide comfort to those users who may be confined to the wheelchair for extended periods of time. The tilt mechanism can also serve as an attendant aid in those situations where a patient needs to be tilted for attendant access.

Device Function

Device function is dependent solely upon the wheelchair user or caregiver. It does not function on its' own in any manner. The wheelchair user or caregiver 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 Weely manual wheelchair. It is a simple, basic, manually operated mobility device.

Significant Physical and Performance Characteristics:

Design:

The Weely manual wheelchair consists primarily of an upper and lower frame assembly, upholstery for seating, large wheels for propelling the chair and front and rear swivel type pivoting casters for turning. The rear casters also serve as an "anti-tipper" system which minimizes the potential for the chair to tip over backwards. The wheels and casters are mounted to the lower frame assembly. The wheelchair seat and back mount to the upper frame assembly. Both frame assemblies are constructed from aluminum tubing.

The Weely features a tilt mechanism which allows the seat and back of the wheelchair to be tilted. This feature is used to provide comfort to those users who may be confined to the wheelchair for extended periods of time. The tilt mechanism can also serve as an attendant aid in those situations where a patient needs to be tilted for attendant access.

Materials:

Materials used are:

- Aluminum frame, support members, wheels and components
- Steel fasteners and components
- Rubber and Polyurethane tires
- Fabric covered foam upholstery

Physical Properties:

The Weely manual wheelchair consists primarily of an aluminum frame assembly, a back rest frame, seat and back rest upholstery, large rear wheels with hand rims for self-propelling the chairs and front and rear swivel pivoting casters for turning.

V. INDICATIONS FOR USE

The indications for Use for the Weely Manual Wheelchair are to provide mobility to persons limited to a sitting position. This identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technology and principle of operation for the Weely and the Fuze T50 are identical. They both consist of aluminum frames with a seat and large 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 or the caregiver. They do not function on their own in any manner. The wheelchair user or caregiver controls motion, speed and direction by propelling the wheelchair.

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.

The tilt feature is manually operated and is activated by two release levers located at the rear of the wheelchair. It utilizes standard gas springs for maintaining the static position of the chair. The tilt angle is adjusted by squeezing the levers inward simultaneously until the desired tilt angle has been reached. Once any of the two levers are released, the chair will remain at the angle chosen.

Discussion of Similarities and Differences:

The Weely manual wheelchair is substantially equivalent to the predicate PDG Fuze T50 wheelchair (K063736) in technology, function, performance and materials. It has 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 differs slightly as the maximum patient weight for the Weely is 280 lbs. where the predicate is 250 lbs. This difference has no effect on safety or effectiveness and both devices are clearly labeled with maximum patient weight capacity.



With regard to accessories and add-ons, both devices offer the same types of armrests, backrests, hangers and footplates. These accessories are made of the exact same materials for both devices and thus do not raise any questions for the safety and effectiveness of the Weely wheelchairs.

VII. PERFORMANCE DATA

The Weely 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 7176-13:1989 Determination of Coefficients of Friction of Test Surfaces
- ISO 7176-15 Requirements for Information Disclosure, Documentation and Labeling
- ISO 8191-1: 1987 Furniture – Assessment of the Ignitability of Upholstered Furniture (Part 1: Ignition Source: Smoldering Cigarette)
- ISO 8191-2: 1989 Furniture – Assessment of the Ignitability of Upholstered Furniture (Part 2: Ignition Source: Flame Match-Flame Equivalent)

The performance data published by PDG Product Design Group states that PDG Wheelchairs are tested to ISO Standards. Test reports are published on the PDG web site but cannot be reproduced without permission.

The Fuze T50 510(k) Summary states that the Fuze T50 has been tested to and meets the requirements of ISO 7176 Determination of Static Stability. 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 Fuze T50 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 Weely to its' predicate.

VIII. CONCLUSIONS:

Based on the above discussion, Rupiani believes that the Weely wheelchair is substantially equivalent to the PDG Fuze T50 (K063736). While there are some differences between the Weely 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.

Performance testing and compliance with FDA guidance for manual wheelchairs supports the safety of the Weely manual wheelchairs. Since the predicate device was cleared based in part on



these data, conformance with the same requirements demonstrate that the Weely will perform as intended in the specified use conditions.

Further, technology, principle of operation and indications for use between Weely and the Fuze T50. This demonstrates that they perform comparably to the predicate device that is currently marketed for the same intended use. Therefore, the Weely manual wheelchairs are substantially equivalent to the Fuze T50 device.

**Weely Manual Wheelchair
Technological Comparison to Predicate Device**

Feature/Specification	Fuze T50	Rupiani Weely	Discussion of Differences
510(k) Accession Number	K063736	TBD	NA
Clearance Date	January 17, 2007	TBD	NA
Intended Use	To provide mobility to persons limited to a seated position	Same	No difference
Seat to Floor Height	13"-20"	16.5" – 18.5"	No difference. The Weely is within the same range as the Fuze.
Seat Width	15" – 20"	15", 17" and 19"	No difference. The Weely is within the same range as the Fuze
Seat Depth	15"-20"	17" – 22"	The Weely is slightly wider due to its' higher weight limitation for which it is labeled. Chair width does not affect safety or effectiveness. It indicates that the Weely will accommodate slightly larger patients.
Overall Length	45" with footrest	46" with footrest	A one inch difference in overall length does not affect safety or effectiveness.
User Weight Limit	250 lbs.	280 lbs.	This has no effect on safety or effectiveness. Both products are labeled with their maximum weight limit.
Tilt Feature	Yes	Yes	No difference. Both have the tilt feature.
Tilt Range	Zero to 50 degrees.	Zero to 35 degrees	No difference. The Weely is within the same range as the Fuze
Frame Material	Aluminum	Same	No difference
Frame Type	Rigid lower frame with folding backrest	Same	No difference
Front Caster	5", 6" or 8"	6"	No difference. Both offer 6" diameter casters
Large Wheel	12", 16", 20", 22", or 24"	12", 22" or 24"	No difference. The Fuze offers more sizes however the Weely sizes are with the range of the Fuze.