DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 31, 2016

Proactive Comfort, LLC
% EJ Smith
President
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

Re: K152021
Trade/Device Name: Pure Tilt
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: February 29, 2016
Received: March 1, 2016

Dear Mr. Smith:

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

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)*
K152021

Device Name
Pure Tilt™ wheelchair

Indications for Use *(Describe)*
The Pure Tilt™ 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:

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*"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."*

# Section 5: 510(k) Summary

# 510(k) Summary

## SPONSOR


Company Name: Proactive Comfort, LLC
Company Address: 3901 Centerview Drive, Suite L
Chantilly, VA 20151
USA
Telephone: 703-995-7104
Fax: 703-834-0039
Contact Person: Tracy Augustine


Summary Preparation Date: February 23, 2016

## DEVICE NAME

Trade Name: Pure Tilt™
Common/Usual Name: Mechanical Wheelchair
Classification Name: Physical Medicine
Regulation Number**:** 890.3850
Product Code: IOR
Device Class: Class I

## PREDICATE DEVICE

Legally Marketed Equivalent Device

| ***Company*** | ***Product*** | ***510(k) #*** |
|---|---|---|
| BRODA | 587 Manual Wheelchair | K032133 |

## DEVICE DESCRIPTION

The Proactive Comfort Pure Tilt™ wheelchair is an indoor / outdoor manual wheelchair composed of two (2) main components (assemblies): a lower frame assembly and a tilting seat assembly. The lower frame contains two rear wheels, two front casters, two anti-tippers, one pair of brakes and two armrest assemblies. The Seat assembly contains four sub-assemblies; a tilting seat, a leg rest, a backrest and a headrest. The Proactive Comfort Pure Tilt™ possesses the following features:

- A tilting seat with adjusting capability up to 45°;
- User-operated seat tilt adjusting mechanism, which is assisted by a mechanical spring piston;
- Hinged, non-detachable armrests that swing upward and toward the back to facilitate transfer of a subject into or out of the wheelchair;
- Built-in housing for compatible transfer board;
- Mechanical armrest locks that secure the armrests to be used safely as handles for lifting the wheelchair with the user in it;
- Two 21” diameter rear wheels with aluminum hand-rims for self-propelling;
- Two 6” diameter front casters that swivel for easy maneuvering;
- Adjustable seat-to-floor height (2 Settings: 19” and 17”);
- Angle-adjustable leg-rest assembly with the following features:
- Foot platform that swings upward to facilitate stowage
- Telescoping adjustable height

- User-operated mechanism to adjust leg-position angle, which is assisted by mechanical spring piston;
- Backrest that has adjustable vertical position and that folds 90° forward to facilitate storage and transport; and
- Headrest with adjustable vertical position.

## DEVICE INDICATIONS FOR USE

The Pure Tilt™ wheelchair is intended for medical purposes to provide mobility to persons restricted to a sitting position.

## COMPARISON OF TECHNICAL CHARACTERISTICS

| ITEMS | PROACTIVE WHEELCHAIR | PREDICATE DEVICE |
|---|---|---|
| **BRAND NAME** | Pure Tilt™ | Valentine |
| **K number** | | K130017 |
| **Product Code** | IOR | IOR |
| **MANUFACTURER** | Proactive Comfort, LLC<br>129 N. West Street,<br>Easton, MD 21601 | Valentine International Ltd |
| **MODEL** | Proactive – Pure Tilt™ | Steel Wheelchair model 1000 |
| **510K NO.** | | K130017 |
| **Indications for Use** | The device is intended to provide mobility to persons that are unable to ambulate safely or are restricted to a sitting position. | The device is intended for medical purposes to provide mobility to persons restricted to a sitting position. |
| **OPERATING** | To be used on a level surface Indoor or Outdoor | Indoor/Outdoor Wheelchair |
| **TECHNOLOGICAL CHARACTERISTICS** | According to ANSI/RESNA series standards (Sections 1, 3, 5, 7, 8 and 15) | According to ISO 7176-1/-3/-5/-7/-8/-l 1/-13/ - 15/-16 series standards |
| **FRAME** | | |
| Primary Material | Tubular Aluminum | |
| Overall Height | 35" (889mm) | |
| Overall Width | 30" (762mm) | |
| Seat Width | 16.9" (430mm) | 18" |
| Seat Depth | 17.4" (442mm) | |
| Seat Height | Max: 19" (482mm) Min: 17" (431mm) | 20" |
| Seat Angle | Up to 45° | |
| Cross Brace | Built-in | Yes |
| Backrest Height | 17.6" (447mm) | Un-adjustable / Fixed |
| Backrest Width | 15.4" (391mm) | |

| | | |
|---|---|---|
| Reclining Backrest | 13.2° - 52.7° | Fixed |
| Seat Sling | Padded cushion system | Padded nylon |
| Frame Colors | Black | Blue |
| **ARMREST** | | |
| Arm Pad | Padded | Padded |
| Flip Back | Yes, detachable padding | Yes, detachable |
| Height Adjustable | No | No |
| **HANGERS** | | |
| Swing-Away | Yes | Yes |
| Elevating Leg Rest | Yes | Yes |
| Articulating Leg Rest | Yes | Yes |
| Footplate Style | Flat, Non-Padded | Padded |
| Heel Loop | No | No |
| Footrest Angle | 18.9° - 90° | 10~15° |
| **REAR AXLE** | | |
| Offset Axle | Yes | Yes |
| Quick Release Axle | No | Yes |
| Whorl | No | |
| **REAR WHEEL** | | |
| Size | 21" (533mm) x 1” (25.4mm) | 24" |
| Tire Type | PU Solid Material | PU Solid Material |
| Handrim Material | Aluminum | Steel Composite |
| **CASTERS** | | |
| Size | 6” (152mm) | 8" |
| Tire Type | Non-Marking Rubber Tires | PU Solid Material |
| **WHEEL LOCK** | Push-to-Lock / Manual | Pull-to-Lock / Manual |
| **UPHOLSTERY MATERIAL** | Vinyl | |
| **WEIGHT CAPACITY** | 275 lbs / 125 kgs | 250 lbs / 113.5 kgs |
| **WEIGHT OF CHAIR** | 59.8 lbs (31.7 kgs) w/o cushions 69.8 lbs (31.7 kgs) including all cushions | 40 lbs / 18.2 kgs |
| **WARRANTY** | 12 Months from date of shipment | 12 Months for Main Parts (The chair side frames are guaranteed for 5 years from the date of purchase) |
| **ACCESSORIES** | | |
| Anti-tipper | Yes | No |
| Rear Stepper | No | Yes |
| Fold Down Push Handle | No | Yes |
| Safety Belt | No | Optional |

## NONCLINICAL PERFORMANCE DATA

| Standard | Test Description | Results |
|---|---|---|
| ISO 8191-1:1987<br><br>Attachment 18.1 | Assessment of Ignitability of Upholstered Furniture – Smoldering Cigarette | Passed |
| ISO 8191-2: 1988<br><br>Attachment 18.2 | Assessment of Ignitability of Upholstered Furniture – Match-Flame Equivalent | Passed |
| Resna standards: 2009 Version<br><br>Attachment 18.3 | • Section 1: Determination of Static Stability<br>• Section 3: Determination of Effectiveness of Brakes<br>• Section 5: Determination of Dimensions, Mass, and Maneuvering Space | Passed |

| | | |
|---|---|---|
| | • Section 7: Method of Measurement of Seating and Wheel Dimensions<br>• Section 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths<br>• Section 15: Requirements for Information Disclosure, Documentation and Labeling | |

## CONCLUSION

The data submitted in this 5 10(K) Premarket Notification supports the finding that this device (Proactive - Pure Tilt™) is substantially equivalent with respect to the intended use, technology, functionality, and safety features to the legally marketed Predicate Device (BRODA – 587 Manual Wheelchair). Therefore, we believe that this device meets the requirement for a "Substantial Equivalence" decision in accordance with the 510(K) guidelines.