



Food and Drug Administration
10903 New Hampshire Avenue
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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

Indications for Use

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.

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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

<i>Company</i>	<i>Product</i>	<i>510(k) #</i>
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 129 N. West Street, 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/-11/-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 Attachment 18.1	Assessment of Ignitability of Upholstered Furniture – Smoldering Cigarette	Passed
ISO 8191-2: 1988 Attachment 18.2	Assessment of Ignitability of Upholstered Furniture – Match-Flame Equivalent	Passed
Resna standards: 2009 Version Attachment 18.3	<ul style="list-style-type: none">• Section 1: Determination of Static Stability• Section 3: Determination of Effectiveness of Brakes• Section 5: Determination of Dimensions, Mass, and Maneuvering Space	Passed

	<ul style="list-style-type: none"> • Section 7: Method of Measurement of Seating and Wheel Dimensions • Section 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths • Section 15: Requirements for Information Disclosure, Documentation and Labeling 	
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CONCLUSION

The data submitted in this 510(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.