



Food and Drug Administration  
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February 3, 2016

Danyang Suntec Auto Parts Co., Ltd.  
Jen Ke-Min  
Official Correspondent  
Jiepai Industrial Zone, Jiepai, Danyang  
Zhenjiang, 212300  
CHINA

Re: K152878

Trade/Device Name: SUNTEC Mechanical Wheelchair, Model ST-WL-1000  
Regulation Number: 21 CFR 890.3850  
Regulation Name: Mechanical Wheelchair  
Regulatory Class: Class I  
Product Code: IOR  
Dated: December 8, 2015  
Received: December 16, 2015

Dear Jen Ke-Min:

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 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)

K152878

Device Name

SUNTEC Mechanical Wheelchair, model ST-WL-1000

Indications for Use (Describe)

The device 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.

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## **SECTION D**

### **510(k) Summary of Safety and Effectiveness**



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## **510(k) SUMMARY of Safety and Effectiveness**

Submitter's Name: **DANYANG SUNTEC AUTO PARTS CO., LTD.**

**Jiepai Industrial Zone, Jiepai, Danyang, Zhenjiang, Jiangsu  
Province, 212300 China**

Date Summary Prepared: January 24, 2016

Proprietary Name: SUNTEC Mechanical Wheelchair, model ST-WL-1000

Common or Usual Name: Mechanical Wheelchair

Classification Name: Mechanical Wheelchair, Class I, 21 CFR 890.3850

Product Code: IOR

Official Correspondent: Dr. Jen, Ke-Min

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**Predicate Device** Valentine International Ltd.

Valentine Steel Wheelchair, model 1000 (K130017)

**Indications For Use:** The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.



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**Description of the device:**

The SUNTEC Mechanical Wheelchair, model ST-WL-1000 is an indoor / outdoor wheelchair that has a base with four-wheeled with a seat. The device can be disassembled for transport and it is foldable easily. The device uses a standard sling type back and seat, and the upholstery fabric meets the Requirements of Section E, Part I for Upholstery Fabrics of California Technical Bulletin CAL 117: 2000 standard for flame retardance.

Following are features for the ST-WL-1000

- Foldable wheelchair frame, lift up backrest handles and strap into place.
- Handy pocket for transporting lightweight items.
- One button easy release wheels.

Due to the features of the body structure, the rear two wheels can always contact the surface, and the vehicle can be operated on the rough surface. But the following surfaces are recommended NOT to operate on:

- Sand surface
- Wet or icy surface
- Road maintenance hole metal cover
- Avoid going up multiple steps.
- Avoid using escalators. Use the elevator.
- Too steep incline over 10 degrees.
- Turning diameter: 31" / 785 mm
- Ground clearance: 2.3" / 58.4 mm
- Curb climbing ability: 0.8" / 20.3 mm



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**Performance Testing:**

- 1) ISO 7176-1 Wheelchairs - Part 1: Determination of static stability, 1999. (FDA Recognition Number: 16-158 )
- 2) ISO 7176-3 Wheelchairs - Part 3: Determination of effectiveness of brakes, 2012. (FDA Recognition Number: 16-192)
- 3) ISO 7176-5 Wheelchairs - Part 5: Determination of overall dimensions, mass and maneuvering space, 2008. (FDA Recognition Number: 16-163)
- 4) ISO 7176-7 Wheelchairs - Part 7: Determination of seating dimensions - Definitions and measuring method, 1998. (FDA Recognition Number: NA)
- 5) ISO 7176-8 Wheelchairs - Part 8: Static, impact and fatigue strength for manual wheelchairs, 2014. (FDA Recognition Number: NA)
- 6) ISO 7176-11 Wheelchairs - Wheelchairs - Part 11: Test dummies, 2012. (FDA Recognition Number: 16-190)
- 7) ISO 7176-13 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces, 1989. (FDA Recognition Number: 16-25)
- 8) ISO 7176-15 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labelling, 1996. (FDA Recognition Number: 16-27)
- 9) ISO 7176-16 Wheelchairs - Part 16 Requirements and test methods for resistance to ignition of upholstered parts, 2012. (FDA Recognition Number: 16-191)
- 10) ISO 7176-22 Wheelchairs - Part 22 Set-up procedures, 2014 (FDA Recognition Number: NA)



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**COMPARISON TABLE**

Comparison items	Predicate device (K130017)	Subject device (K152878)	Pose any change in safety or effectiveness, compared with the predicate device?
BRAND NAME	Valentine	SUNTEC	There is no change in safety or effectiveness.
MANUFACTURER	Valentine International Ltd.	DANYANG SUNTEC Auto Parts Co., Ltd.	There is no change in safety or effectiveness.
MODEL NO	Steel Wheelchair, model 1000	Mechanical Wheelchair, model ST-WL-1000	There is no change in safety or effectiveness.
510(k) No.	K130017	K152878	There is no change in safety or effectiveness.
<b>Similarities</b>			
INTENDED USE	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	Same intended use	There is no change in safety or effectiveness.
OPERATING ENVIRONMENTS	For Indoor / Outdoor use	Same operating environments	There is no change in safety or effectiveness.
TECHNOLOGICAL CHARACTERISTICS	According to ISO 7176-1/-3/-5/-7/-8/-11/-13/-15/-16 series standards	Same technological characteristics	There is no change in safety or effectiveness.
Overall dimensions Length Width Height	42" 25.2" 36.2"	Same overall dimensions	There is no change in safety or effectiveness.
Seat dimensions Length Height Width	18" 20" 18"	18" 20" 17.3" – 18.1"	There is no change in safety or effectiveness.
FRAME Cross brace Backrest height Reclining backrest Seat sling Frame color	YES Un-adjustable fixed Padded Nylon Blue Powder Coating	Same frame	There is no change in safety or effectiveness.



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ARMREST Arm pad Flip back Height-adjustable	Padded YES, detachable Pre-installed armrests	Same armrest	There is no change in safety or effectiveness.
HANGERS Swing-away Elevating leg rest Articulating leg rest Footplate style Heel loop Footrest angle	YES YES YES Padded No 10~15 <sup>0</sup>	Same hangers	There is no change in safety or effectiveness.
ACCESSORIES Anti-tipper Fold down push handle Seat belt	YES YES Optional	YES YES Optional	There is no change in safety or effectiveness.
REAR AXLE Offset axle Quick-release axle	YES YES	Same rear axle	There is no change in safety or effectiveness.
REAR WHEEL Size Tire type	24" * 1" PU Solid Material	Same size Same tire type	There is no change in safety or effectiveness.
Wheel Lock	Pull-to-Lock	Same wheel lock	There is no change in safety or effectiveness.
Ground Clearance	2.3" / 58.4 mm	Same ground clearance	There is no change in safety or effectiveness.
Climbing Angle	10 degrees	Same climbing angle	There is no change in safety or effectiveness.
Curb climbing ability	0.8" / 20 mm	Same curb climbing ability	There is no change in safety or effectiveness.
Minimum turning diameter	31" / 785 mm	Same turning diameter	There is no change in safety or effectiveness.
<b>Differences</b>			
Weight Capacity	250 lbs. /113.4 kg	220 lbs. / 100 kg	The users will maneuver the wheelchair more easily for a lighter wheelchair.
Casters Size Tire type	8"*1" PU solid material	Same size PVC solid material	PVC material will endure for a longer period than PU material. There is no change in safety or effectiveness.
Handrim Diameter /material	22" / Steel Composite	19.8" / Steel Composite	10% smaller in handrim diameter is not related for a change in safety or effectiveness.
Weight of Chair	39.6 lb / 18 kg	38.5 lb / 17.5 kg	2.7% lighter in total mass will make the user or attendant more easily maneuver the wheelchair.



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<b>Warranty</b>	12 months for the main parts (footrest, wheel lock, armrest, cross braces, backrest canes, front fork, fork stem house)  The chair side frames are guaranteed 5 years from the date of purchase.	12 months for the main part (footrest, wheel locks, armrest, cross braces, backrest canes, front fork, fork stem house).  The chair side frames are guaranteed 3 years from the date of purchase.	The 2 years less guarantee period for chair side frames will make the user pay more money and it is not to do with the change in safety or effectiveness.
<b>ISO 7176-5:2008</b>			
<b>Wheelchairs - Part 5: Determination of overall dimensions, mass and maneuvering space</b>			
Full overall length	41" / 1050 mm	Same overall length	There is no change in safety or effectiveness.
Overall width	25" / 640 mm	Same overall width	There is no change in safety or effectiveness.
Handgrip height	36" / 920 mm	29" / 740 mm	19.5% lower in handgrip height will cause some uncomfoting to a taller person and she/he may bow their waist to hold the wheelchair. As long as the attendant's height is not too large, a normal person will not feel uncomfortable (or to bow his/her waist) to hold the handgrip. There is no change in safety or effectiveness.
Stowage length Stowage width Stowage height	42" / 1066 mm 11.4" / 290 mm 36.2" / 915 mm	35.4" / 900 mm 14.5" / 370mm 36.2" / 915 mm	Shorter stowage length means the device can fit the limited width space of the more vehicles, leading to more convenience, and larger stowage width means you cannot stack more stuff on the wheelchair. There is nothing to do with the safety and effectiveness concerns.
Total mass	39.6 lb / 18 kg	38.5 lb / 17.5 kg	2.7% lighter in total mass will make the user or attendant more easily maneuver the wheelchair.
Mass of heaviest part	39.6 lb / 18 kg	25.5 lb / 11.7 kg	Lighter mass will make the user or attendant easier to maneuver the wheelchair.
Ground clearance	2.3" / 58.4 mm	Same ground clearance	There is no change in safety or effectiveness.
Required width of angled corridor	35.8" / 910 mm	34.4" / 875 mm	3.8% less in angled corridor width has nothing to do with safety or effectiveness.
Required doorway entry depth	52" / 1320 mm	59" / 1500 mm	13.6% larger in depth may bring some inconvenience, but we have recommended users to "ALWAYS ASK FOR HELP". There is no change in safety or effectiveness.



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Required corridor width for side opening	37.4" / 950 mm	28.5" / 725 mm	23.6% narrower in required corridor width will let the user move more easily in the narrower space.
<b>ISO 7176-7:1998</b>			
<b>Wheelchairs - Part 7: Determination of seating dimensions - Definitions and measuring method</b>			
Seat plane angle	3.8 <sup>0</sup>	4 <sup>0</sup>	5.3 % larger in seat plane angle cannot pose any change in safety or effectiveness.
Effective seat depth	20"/514 mm	16.9"/430 mm	16% less in effective seat depth may bring less free space for adjustment, but there is no change in safety or effectiveness.
Seat width	16.5"/420 mm	17.3" – 18.1" / 440-460 mm	Larger seat width lets users feel more comfortable. There is no change in safety or effectiveness.
Effective seat width	19.3" / 490 mm	17.3"- 17.5"/ 440 - 445 mm	Less effective seat width means not to pose a change in safety or effectiveness.
Seat surface height at front edge	19.2"/488 mm	18.9"/480 mm	1.6% lower in seat surface height has a negligible difference and will not pose a change in safety or effectiveness.
Backrest angle	8.4 <sup>0</sup>	10 <sup>0</sup>	19% larger in backrest angle can bring a more comfortable feeling to the user and there is no change in safety or effectiveness since it passes static and dynamic stabilities tests.
Backrest height	17.2"/439 mm	16.9"/430 mm	2% less in backrest height is negligible for posing a change of safety or effectiveness.
Backrest width	16.1"/410 mm	18.1"/460 mm	12% larger in backrest width will bring more space for user to load the body. There is no change in safety or effectiveness.
Footrest-to-seat	14.3"/365 mm	16.5"/420 mm	15% longer in footrest-to-seat will make the wheelchair easily load a taller person. There is no change in safety or effectiveness.
Footrest clearance	5.8"/148 mm	6.7"/170 mm	14.8% higher in footrest clearance will make the wheelchair more easily overcome an obstacle and there is no change in safety or effectiveness.
Footrest length	7.2"/184 mm	5.9"/150 mm	18.7% shorter in footrest length will not make a change in safety or effectiveness since 150 mm in footrest length can easily hold a foot of a normal person.
Footrest-to-leg angle	94.6 <sup>0</sup>	90 <sup>0</sup>	4.8% smaller in footrest-to-leg angle is negligible to pose a change in safety or



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			effectiveness.
Leg-to-seat-surface angle	91.6 <sup>0</sup>	97 <sup>0</sup>	5.8% larger in leg-to-seat-surface angle is negligible to pose a change in safety or effectiveness.
Armrest height	9.5"/242 mm	10.2"/260 mm	7.4% larger in armrest height will not pose a change in safety or effectiveness.
Front-of-armrest to backrest	14"/358 mm	11.4"/290 mm	18.9% less distance in Front-of-armrest to backrest will let the user feel limited in space but will not pose a change in safety or effectiveness.
Armrest length	10.2"/260 mm	Same length	There is no change in safety or effectiveness.
Armrest width	21.6"/550 mm	Same width	There is no change in safety or effectiveness.
Armrest angle	4.8 <sup>0</sup>	4 <sup>0</sup>	16.6% smaller in armrest angle is related to the arm feeling, not related to the safety or effectiveness.
Distance between armrests	18.2"/463 mm	18.1"/460 mm	0.64% shorter in distance between armrests does not pose a change in safety or effectiveness.
Front location of armrest structure	13.9"/355 mm	11"/280 mm	21% less in front location of armrest structure will not pose a change in safety or effectiveness since 280 mm can provide an enough holding space.
Handrim diameter	21.4"/546 mm	19.8"/505 mm	7.6% smaller in Handrim diameter is not related to a change in safety or effectiveness.
Propelling wheel diameter	24"/612 mm	23.6"/600 mm	1.9% smaller in propelling wheel diameter has nothing to do with a change in safety or effectiveness.
Horizontal location of axle	2"/53 mm	1.18"/ 30 mm	43.4% shorter in Horizontal location of axle has nothing to do with the safety or effectiveness.
Vertical location of axle	3.9"/101 mm	7"/180 mm	78% larger in Vertical displacement of wheel axle has nothing to do with the safety or effectiveness.
Castor wheel diameter	7.5"/191 mm	7.8"/200 mm	4.7% larger in castor wheel diameter can provide more capability to move on the road, but it is not to pose a change in safety or effectiveness.



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### **COMPARISON DISCUSSION**

From the above comparison table, we know that the intended uses of the subject device and the predicate device are the same. Mainframes of two devices are foldable. Removable desk-length armrest and the swing-away detachable elevating footrest are the same. Besides, back upholstery material is the same resistance-ignitability fabric and also meets the requirements for flame retardant. The minor differences in the castor tire type (PU vs. PVC) and the weight of chair (39.6 lb vs. 38.5 lb) do not raise any safety and effectiveness concerns or changes. The tire sizes are indicated on the product durable label. Thus the same safety level for the two devices is assured. At last, the chair side frames are guaranteed for 5 years from the date of purchase for predicate device and 3 years for the subject device. The difference is related with the more cost paid by the user for the chair side frames and does not raise any safety and effectiveness concerns.

Despite of the differences above and shown in the ISO 7176-5: 2008 and ISO 7176-7:1998 comparison table, the subject devices completed the performance tests in accordance with ISO 7176 series standards. They function safely and effectively. There are no safety or effectiveness concerns.

### **CONCLUSIONS**

From the comparison table, we know that the subject device is as safe and effective as, and functions in a manner equivalent to the predicate device. The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate device.