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

July 20, 2016

Danyang Sunco Machinery Co., Ltd
Jen Ke-Min
Official Correspondent
Taojing Road, Optics Industrial Park, Situ Town
Danyang City, 212300 CN

Re: K153328
Trade/Device Name: SUNCO Mechanical Wheelchair, model SKW-9003
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: March 4, 2016
Received: July 11, 2016

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

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)*
K153328

Device Name
SUNCO Mechanical Wheelchair, model SKW-9003

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.

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.

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SECTION D

510(k) Summary of Safety and Effectiveness

(per 21 CFR 807.92)

Danyang Sunco Machinery Co., Ltd.

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I. SUBMITTER

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Phone: +86-511-86733686
Fax: +86-511-86733116
Contact Person: Jen, Ke-Min, ceirs.jen@msa.hinet.net
Date Prepared: July 20, 2016

II. DEVICE

Name of Device:	SUNCO Mechanical Wheelchair, model SKW-9003
Common or Usual Name:	Mechanical Wheelchair
Classification Name:	Wheelchair, Mechanical (21 CFR 890.3850)
Regulatory Class:	Class I
Product Code:	IOR

III. PREDICATE DEVICE

Valentine International Ltd.

Valentine Steel Wheelchair, model 1000,

K130017

IV. DEVICE DESCRIPTION

The SUNCO Mechanical Wheelchair, model SKW-9003 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 EN 1021-1:2006 Furniture --Assessment of ignitability of upholstered furniture – Part 1: Ignition source smouldering cigarette & EN 1021-2:2006 Furniture --Assessment of ignitability of upholstered furniture – Part 2: Ignition source match flame equivalent

The features of the subject device include

- The back upholstery material is resistance-ignitability fabric.
- The removable desk-length armrest and swing-away detachable footrest..

Due to the device design of the body structure the following surfaces are recommended NOT to operate on:

- Sand surface
- 1Wet 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”
- Ground clearance: 2.3”
- Curb climbing ability: 0.8”

V. INDICATIONS FOR USE

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

- **Comparison table**

ITEMS	Predicate device	Subject device
Manufacturer	Valentine International Ltd.	DANYANG SUNCO Machinery Co., Ltd.
Brand name	Valentine	SUNCO
Device name	Steel Wheelchair, model 1000	Mechanical Wheelchair, model SKW-9003
510(k) Number	K130017	K153328

Danyang Sunco Machinery Co., Ltd.

Taojing Road, Optics Industrial Park, Situ Town,
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Similarities		
Indications for use	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.	Same indications for use
Operating environments	For Indoor / Outdoor use	Same operating environments
Technological characteristics	Testing per ISO 7176-1/-3/-5/-7/-8/-11/-13/ -15/-16 series standards	Same technological standards
Overall dimensions **Length** **Width** **Height**	 42” 25.2” 36.2”	 42” 25.2” 36”
FRAME **Cross brace** **Backrest height** **Reclining backrest** **Seat sling** **Frame color**	 YES Fixed Fixed Padded Nylon Blue Powder Coating	 YES Fixed Fixed Padded Nylon Silver hammer tone
HANGERS **Swing-away** **Elevating leg rest** **Articulating leg rest** **Footplate style** **Heel loop** **Footrest angle**	 YES YES YES Padded No $10\sim15^0$	Same hangers
REAR AXLE **Offset axle** **Quick-release axle**	 YES YES	Same rear axle
REAR WHEEL **Size** **Tire type** **Handrim Diameter / material**	 24”*1” PU Solid Material 21” / Steel Composite	Same rear wheel
Wheel Lock	Pull-to-Lock	Same wheel lock
Ground Clearance	2.3”	Same ground clearance
Climbing Angle	10 degrees	Same climbing angel
Curb climbing ability	0.8”	Same curb climbing ability
Minimum turning diameter	31”	Same minimum turning radius

Curb Stepper	YES	YES
ARMREST		
Arm pad	Padded	Padded
Flip back	YES	YES
Height-adjustable	NO	NO
Optional accessory		
Anti-tipper	YES	YES
Seat belt	YES	YES
Differences		
Seat dimensions		
Depth	16”	16”
Height	20”	20”
Width	18”	20”
Casters		
Size	8”*1”	7.9”*1”
Tire type	PU solid material	PVC solid material
Weight of wheelchair	40 lb / 18.1 kg	38.6 lb / 17.5 kg
Weight Capacity	250 lb /113.4 kg	220 lb / 100 kg
Warranty	12 months for the main parts (footrest, wheel locks, armrest, cross braces, backrest canes, front fork, fork stem house) The chair side frames are guaranteed for 5 years from the date of purchase.	12 months for the main parts (chair side frames, footrest, wheel locks, armrest, cross braces, backrest canes/Push handle tube, front fork, fork stem house)

- **Discussion**

From the above comparison table, we knew that the indications for use of both devices are the same. Both mainframes of two devices are foldable. The castor tires are PU 8” solid tires for predicate device and PVC 7.9” solid tires for subject device. The PU tires can absorb more vibrational impact from the unsmooth ground than PVC tires. The difference is not much as to raise any safety and effectiveness concerns. The weights of wheelchairs (40 lb vs. 38.6 lb) differ not so much to raise any safety and effectiveness concerns. This difference means the user needs less power to move the wheelchair for the subject device. The front/rear tire sizes PVC solid 7.9”*1”/ PU solid 24”*1” and weight capacity (220 lbs.) are indicated on the product durable label and user manual for the

subject device. The users can be informed of those limitations. The chair side frames are guaranteed for 5 years for predicate device and 1 year for the subject device. The difference in the chair side frames warranty periods just involves the more cost paid by the users of the subject device, and it does not raise any safety and effectiveness concerns. Overall dimensions are the same, and seat width has the difference of 2". No safety and effectiveness concerns are raised about this. The other safety and effectiveness concerns of the subject device have been considered and mitigated by complying with the ISO 7176 series standards.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the SUNCO Mechanical Wheelchair SKW-9003 was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The testing included the following tests:

- Cytotoxicity: ISO 10993-5:2009
- Sensitization: ISO 10993-10: 2009
- Irritation.: ISO 10993-10:2009

Safety testing

To ensure the safety and effectiveness of the device, the following ISO 7176 series standards were complied with:

1) ISO 7176-1 Wheelchairs - Part 1: Determination of static stability, 2014. (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)

VIII. CONCLUSIONS

The conclusions drawn from the nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph III of this section. They are substantially equivalent.