May 3, 2019

Jiangsu Jumao Medical Equipment Co., Ltd.
℅ Jinghua Zhou
Regulation Control Manager
Guangzhou Junyi Information Technology Co., Ltd.
Room 215, Huaming Building, Chebei Road
Guangzhou, Guangdong, 511660 CN

Re: K180309
Trade/Device Name: Manual Wheelchair W54
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: April 16, 2019
Received: April 16, 2019

Dear Jinghua Zhou:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Carlos Peña, PhD, MS
Director
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K180309

Device Name
Manual Wheelchair W54

Indications for Use *(Describe)*
The device is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is designed for use indoors and outdoors, over smooth surfaces (all standard indoor flooring surfaces, concrete, asphalt and pocked dirt) that are free of large obstacles and inclines greater than 6 degrees.

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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K180309 - 510(k) Summary

Revised Date of Summary: May 2, 2019
Date of Summary Preparation: August 1, 2018

1. Submitter's Identifications

Submitter's Name: Jiangsu Jumao Medical Equipment Co., Ltd.
Address: No.36 Danyan road, Danyang City, Jiangsu, China, 212300
Contact Person: Qian Gao
Contact Title: QA Manager
Contact E-mail Address: jsjmfda@126.com
Telephone: +86 (511) 86197066
Fax: +86 (511) 86197033

2. Correspondent's Identifications

Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.
Address: Room 215, Huaming Building, Chebei Road, Guangzhou, P.R. China
ZIP Code: 511660
Contact Person: Jinghua Zhou
Contact Title: Regulation Control Manager
Contact E-mail Address: admanzhou@126.com
Telephone: +86-20-82329549
Fax: +86-20-82329549

3. Name of the Device

Device Classification Name: Wheelchair, Mechanical
Product Name: Mechanical Wheelchair
Trade Name: Manual Wheelchair W54
Model: W54
Classification Panel: Physical Medicine
Product Code: IOR
Device Classification: Class I

4. The Predicate Devices

Primary Predicate: K170517 Merits Model R106/R136 Rehab Wheelchair
Secondary Predicate: K151797 Nuocande Plastic Manual Wheelchair Model NKD L07

5. Device Description

A mechanical wheelchair is a chair with wheels, designed to be a replacement for walking, where it is propelled by the seated occupant turning the rear wheels by hand. There are also handles behind the seat for someone else to do the pushing. Wheelchairs are used by people for whom

walking is difficult or impossible due to illness, injury, or disability.

Manual Wheelchair W54 is a mechanical wheelchair including four wheels, a steel frame and a textilene upholstery that is flame resistant. W54 has a physical dimension of 1160mm × 610mm × 890mm (depth × width × height) with the seat itself has a dimension of 470mm × 425mm × 488mm (depth × width × height). The device has a weight capacity of 136 kilograms, and weighs about 19.7 kilograms. The color is dark black.

The components include back upholstery, handgrip, back cane, arm pad, armrest, seat upholstery, seat extension, rear wheel, handrim, anti-tipper, wheel lock, crossbrace, frame, footrest, footplate, caster, caster housing, front fork.

Main materials: Steel (Frame, crossbrace, back cane, armrest, wheel lock, footrest, front fork), hard plastics (handgrip, rear wheel, handrim, castor, footplate, castor housing), flame resistant fabrics (seat and back upholstery) and flame retardant sponge (seat stuffing), armrest pad, tire of caster and rear wheel (PU), all kinds of pipe plugs and pipe shroud for the frame and steel parts (PP)

The specification table is as below:

SPECIFICATIONS

Type	W54
Occupant mass group	III
Control mode	Mechanical
Physical dimension	1160mm × 610mm × 890mm (depth × width × height)
Seat dimension	470mm × 425mm × 488mm (depth × width × height)
Stowage width	290mm
Handgrip height	870mm
Total mass	19.7kg
Weight capacity	300lb(136kg)
Required width of angled corridor	1000mm
Required doorway entry depth	1270mm
Required corridor width for side opening	1170mm
Armrest	Non flip back/Non height adjustable
Rear axle	Offset axle, Quick release axle
Real wheel	610mm(24inch)
Casters	190mm(8inch)
Wheel Lock	Pull to Lock
Color	Black

Note: Physical dimension is the dimension when the device is equipped with the ordinary hanging leg (without leg supports and/or foot supports), and the Overall length with legrest is 1270mm.

Information disclosure in manufacturer's specification sheets

Manufacturer: Jiangsu Jumao Medical Equipment Co., Ltd.

Address: No.36 Danyan road, Danyang City, Jiangsu, China, 212300

Model: W54

Maximum occupant mass: 300 lbs/136kg

Disclosure information (ISO)							
Standard reference		**Min.**	**Max.**	**Standard reference**		**Min.**	**Max.**
ISO 7176-5	Overall length with legrest	——	1270mm	ISO 7176-7 ISO7176-22	Seat plane angle	——	6.2°
ISO 7176-5	Overall width	——	610mm	ISO 7176-7 ISO7176-22	Effective seat depth	——	470mm
ISO 7176-5 ISO7176-7	Handgrip height	——	870mm	ISO 7176-7 ISO7176-22	Effective seat width	——	425mm
ISO 7176-5	Folded width	——	290mm	ISO 7176-7 ISO7176-22	Seat surface height at front edge	——	488mm
ISO 7176-5	Net weight	——	19.7kg	ISO 7176-7 ISO7176-22	Backrest angle	——	11.6°
ISO 7176-5	Maximum occupant mass	——	136kg (300 lbs)	ISO 7176-7 ISO7176-22	Backrest height	——	440mm
ISO 7176-5	Required width of angled corridor	——	1000mm	ISO 7176-7 ISO7176-22	Footrest to seat distance	430mm	550mm
ISO 7176-5	Required doorway entry depth	——	1270mm	ISO 7176-7 ISO7176-22	Leg to seat surface angle	——	107.2°
ISO 7176-5	Required corridor width for side opening	——	1170mm	ISO 7176-7 ISO7176-22	Armrest to seat distance	——	270mm
ISO 7176-3	Static stability downhill	——	14.6°	ISO 7176-7 ISO7176-22	Front location of armrest structure	——	270mm
ISO 7176-3	Static stability uphill	14.6°	16.5°	ISO 7176-7 ISO7176-22	Distance between armrest	——	430mm
ISO 7176-3	Static stability lateral orientation	11.6°	17.5°	ISO 7176-7 ISO7176-22	Footrest length	——	55mm
ISO 7176-1	Static stability forward	16.5°	16.8°	ISO 7176-7 ISO7176-22	Handrim diameter	——	530mm
ISO 7176-1	Static stability rearward	Over 25°	Over 25°	ISO 7176-7 ISO7176-22	Horizontal location of axle	——	20mm
ISO 7176-7 ISO7176-22	Front wheel diameter	——	190mm	ISO 7176-7 ISO7176-22	Rear wheel diameter	——	600mm

The wheelchair confirms to the following standards:

a) Requirements and test methods of static, impact and fatigue strengths (ISO 7176-8) Yes ☑

b) Requirements for resistance to ignition in accordance with ISO 7176-16 Yes ☑

Note:

About the dimensions: The wheelchair can be equipped with the hanging leg, including the ordinary hanging leg and the orthopaedic hanging leg (for wheelchairs with leg supports and/or foot supports). 1270mm length is the full overall length when being adjusted to the maximum length position which equipped with the orthopaedic hanging leg (overall length with legrest). 1160mm length is the full length of a regular leg-mounted wheelchair.

6. Indication for Use / Intended Use of Device

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is designed for use indoors and outdoors, over smooth surfaces (all standard indoor flooring surfaces, concrete, asphalt and pocked dirt) that are free of large obstacles and inclines greater than 6 degrees.

7. Summary of Substantial Equivalence

Table 1 Comparison to Predicate Device

	Proposed Device	Primary predicate device	Secondary predicate device	Comparison
510k Number	K180309	K170517	K151797	------
Product Code	IOR	IOR	IOR	Same
Proprietary Name	Manual Wheelchair W54	Merits Model R106/R136 Rehab Wheelchair	Nuocande Plastic Manual Wheelchair Model NKD L07	------
Model	W54	R106, R136	NKD L07	------
Manufacturer	Jiangsu Jumao Medical Equipment Co., Ltd.	Merits Healthcare Industries. (suzhou) Co., LTD.	Ningbo Lecount Medical Technology Co., Ltd.	------
Indications for Use	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is designed for use indoors and outdoors, over smooth surfaces (all standard indoor flooring surfaces, concrete, asphalt and pocked dirt) that are free of large obstacles and inclines greater than 6 degrees.	The Merits Model R106/R136 Rehab Wheelchair is to provide mobility to persons limited to a sitting position.	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is designed for use indoors and outdoors, over smooth surfaces (all standard indoor flooring surfaces, concrete, asphalt and pocked dirt) that are free of large obstacles and inclines greater than 5 degrees.	Similar The basic descriptions for intended use of the three devices are the same. The inclines of the proposed device is bigger than that of the predicate device K151797. The difference does not affect the effectiveness and safety.
Basic Design	W54 is a mechanical wheelchair including four	The Merits Model R106/R136 Rehab Wheelchair are manual	Four wheels, a plastic frame and a textilene upholstery that	Same

	wheels, a steel frame and a textilene upholstery that is flame resistant.	wheelchairs. They have adjustable headrest, adjustable armrests, cozy ergonomics seat and multiple axle position.	is flame resistant.	
Materials	Steel (Frame, crossbrace, back cane, armrest, wheel lock, footrest, front fork), hard plastics (handgrip, rear wheel, handrim, castor, footplate, castor housing), flame resistant fabrics (seat and back upholstery) and flame retardant sponge (seat stuffing), armrest pad, tire of caster and rear wheel (PU), all kinds of pipe plugs and pipe shroud for the frame and steel parts (PP)	Frame Material: Steel Seat/Backrest Pad: Cozy Ergonomics PU Foam	Steel (wheel rim and caster rim), hard plastics (Frame), PU (armrest) and flame resistant fabrics (seat)	Similar The frame material of the proposed device is same as that of the predicate device K170517. The seat and back upholstery material of the proposed device is same as that of the predicate device K151797. Other difference does not affect the effectiveness and safety.
Components	Back upholstery, handgrip, back cane, arm pad, armrest, seat upholstery, seat extension, rear wheel, handrim, anti-tipper, wheel lock, crossbrace, frame, footrest,	Back upholstery, handgrip, back cane, arm pad, armrest, seat upholstery, seat extension, rear wheel, handrim, anti-tipper, wheel lock, crossbrace, frame, footrest,	Back upholstery, handgrip, back cane, arm pad, armrest, seat upholstery, seat extension, rear wheel, handrim, anti-tipper, wheel lock, crossbrace, frame, footrest,	Same

	footplate, caster, caster housing, front fork.	footplate, caster, caster housing, front fork.	footplate, caster, caster housing, front fork.	
Occupant mass group	III	III	II	Same The occupant mass group of the proposed device is same as that of the predicate device K170517.
Control Mode	Mechanical	Mechanical	Mechanical	Same
Physical Dimension	1160mm × 610mm × 890mm (depth × width × height) Note: Physical dimension is the dimension when the device is equipped with the ordinary hanging leg (without leg supports and/or foot supports), and the Overall length with legrest is 1270mm.	Model R106: 47.5" (±1") × 28-32" (±1") × 42" (±1") i.e. 1026mm × 711mm ～ 813mm × 1067mm Model R136: 44.5" (±1") × 26-30" (±1") × 42" (±1") i.e. 1130mm × 660mm ～ 762mm × 1067mm	1090mm × 730mm × 850mm (depth × width × height)	Similar The three physical dimensions are different. The difference does not affect the effectiveness and safety.
Total Mass	19.7kg	Model R106: 89 lbs / 40.4kg Model R136: 62 lbs / 28.1kg	19kg	Similar The three total masses are different. The difference does not affect the effectiveness and safety.
Weight capacity	300lb (136kg)	300 lbs (136kg)	220 lbs (100kg)	Same The weight capacity of the

				proposed device is same as that of the predicate device K170517.
Seat dimension	470mm × 425mm × 488mm (depth × width × height)	Width:16-20”(406-508mm) Height: Model R106: 19-21”(483-533mm); Model R136: 21”(533mm) Depth: 18-20”(457-508mm)	411 (depth) x 447 (width) x 365 (height) mm	Similar The three seat dimensions are different. The difference does not affect the effectiveness and safety.
Armrest	Non flip back/Non height adjustable	Height Adjustable (8”~12”)	Non flip back/Non height adjustable	Similar The armrest stucture of the proposed device is same as that of the predicate device K151797, but differene form K170517. The difference does not affect the effectiveness and safety.
Rear Axle	Offset axle, Quick release axle	Model R106: Multiple Model R136: Fixed	Offset axle, Quick release axle	Same The rear axle stucture of the proposed device is same as that of the predicate device K151797 and Model R106 of K170517.
Real Wheel	610mm(24”)	Model R106: 610mm(24”) Model R136:	585mm (23”)	Same The real wheel diameter of the

		317.5mm(12-1/2”)		proposed device is same as that of the predicate device K170517.
Casters	190mm(8”)	177.8mm (7”)	190mm (8”)	Similar The casters diameter of the subject device is same as that of the predicate device K151797 and of larger than K170517. The difference does not affect the effectiveness and safety.
Headrest	None	Adjustable	/	Similar The difference does not affect the effectiveness and safety.
Back Recline	11.6°	9°~57°	/	Similar The difference does not affect the effectiveness and safety.
Seat Tilt	6.2°	4°~34°	/	Similar The difference does not affect the effectiveness and safety.
Elevating Legrest	Standard	Standard	Standard	Same
Turning Radius	Required width of angled corridor: 1000mm; Required doorway entry depth:	Model R106:30”~35.8”(76.5cm~91cm)	/	Similar The difference does not affect the effectiveness and safety.

	1270mm; Required corridor width for side opening: 1170mm	Model R136:32”~38.1”(81.5cm~96.8 cm)		
Shear Reduction	Aligned Backrest Recline & User Pivot Points	Aligned Backrest Recline & User Pivot Points	/	Same
Wheel Lock	Pull to Lock	Pull to Lock	Pull to Lock	Same
Frame Construction	Foldable Frame	Fixed Frame (Not foldable)	Foldable Frame	Same
Color	Black	/	Yellow	------
Standard	ISO7176-1 ISO7176-3 ISO7176-5 ISO7176-7 ISO7176-8 ISO7176-11 ISO7176-13 ISO7176-15 ISO7176-16 ISO7176-22 ISO10993-1 ISO10993-5 ISO10993-10	ISO7176-1 ISO7176-3 ISO7176-5 ISO7176-7 ISO7176-8 ISO7176-11 ISO7176-13 ISO7176-15 ISO7176-16 ISO7176-22 ISO10993-1 ISO10993-5 ISO10993-10	ISO7176-1 ISO7176-3 ISO7176-5 ISO7176-7 ISO7176-8 ISO7176-11 ISO7176-13 ISO7176-15 ISO7176-16 ISO7176-22	Same

Note: the purpose of the secondary predicate device for comparison is to be the same as the proposed device in terms of basic design, components, armrests, rear axles, casters, elevating legrest, wheel lock and frame structure, and to provide references in terms of substantial equivalence.

8. Substantial Equivalence discussion:

Our device and the predicate device are almost identical in terms of all areas described in the above table (*Table 1*). There are some minor differences with the predicate device don't affect the safety or effectiveness of the subject device.

The following table (*Table 2*) shows similarities and differences of the performance between our device and the predicate device. Tests were conducted following the recommended procedures outlined in the respective consensus standards, and results for "Mechanical Wheelchair W54" met all relevant requirements in the test standards, our internal specifications, and are comparable to the predicate device.

Table 2: Comparison of Performance Testing

Description	Proposed Device	Predicate device
Static stability	Meets ISO 7176-1:2014	Meets ISO 7176-1:2014
Effectiveness of brakes	Meets ISO 7176-3:2012	Meets ISO 7176-3:2012
Dimensions, mass and manoeuvring space	Meets ISO 7176-5:2008	Meets ISO 7176-5:2008
Seating and wheel dimensions	Meets ISO 7176-7:1998	Meets ISO 7176-7:1998
Static, impact, and fatigue strengths	Meets ISO 7176-8:2014	Meets ISO 7176-8:2014
Information disclosure, documentation and Labeling	Meets ISO 7176-15:1996	Meets ISO 7176-15:1996
Resistance to ignition	Meets ISO 7176-16:2012	Meets ISO 7176-16:2012

The tests were performed following the general requirements outlined in ISO 7176-11:2012, ISO 7176-13:1989, ISO 7176-22:2014.

A brief discussion of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Proposed Device is safe and effective, and whose performance meets the requirements of its user-defined acceptance criteria and intended uses:

"Mechanical Wheelchair W54" meets performance requirements per ISO 7176-1:2014, ISO 7176-3: 2012, ISO 7176-5:2008, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-11:2012, 7176-13: 1989, ISO 7176-15: 1996, ISO 7176-16:2012 and ISO 7176-22:2014. It is safe and effective, and its performances meet the requirements of the pre-defined acceptance criteria and intended use.
A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence.

Clinical data is not needed for manual wheelchair cleared by the 510(k) process.

According to the non-clinical test results, the proposed devices are as safe, as effective and perform as well as the predicate device. So the proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.

9. Non-Clinical Tests Performed:

The following testing was performed on the "Mechanical Wheelchair W54" in accordance with the requirements of the design control regulations and established quality assurance procedures.

Safety and performance:
ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability
ISO 7176-3:2012 Wheelchairs - Part 3: Determination of effectiveness of brakes
ISO 7176-5:2008 Wheelchairs - Part 5: Determination of dimensions, mass and manoeuvring space
ISO 7176-7:1998 Wheelchairs – Part 7: Measurement of seating and wheel dimensions
ISO 7176-8:2014 Wheelchairs – Part 8: Requirements and test methods for static, impact and fatigue strengths
ISO 7176-11:2012 Wheelchairs – Part 11: Test dummies
ISO 7176-13:1989 Wheelchairs – Part 13: Determination of friction of test surface
ISO 7176-15:1996 Wheelchairs – Part 15: Requirements for information disclosure, documentation and labeling
ISO 7176-16:2012 Wheelchairs – Part 16: Resistance to ignition of postural support devices
ISO 7176-22:2014 Wheelchairs – Part 22: Set-up procedures

Biocompatibility:
ISO 10993-1:2009/C1:2010 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity

10. Biocompatibility

Type of contact: Skin contact duration category A < 24 hours.
Patient contact: Contact of intact skin of hands, arms, back, neck and thigh with the following materials:
Handgrip: made up of PVC, contacts with intact skin of hands of user and/or caregiver.
Seat upholstery and back upholstery: made up of nylon, contact with intact skin of back, neck and thigh of user
Armrest pad: made up of PU, contacts with intact skin of hands and arms of user.
Handrim: made up of PP, contacts with intact skin of hands and arms of user.
Handgrip included PVC with additives, seat upholstery and back upholstery included nylon with additives, armrest included PU with additives, handrim included PP with additives were tested together respectively. The materials only contact with the user's intact skin within 24 hours, so according to ISO 10993-1:2009, the In Vitro Cytotoxicity Test, Skin Sensitization Test and Skin Irritation Test have been performed.
The Manual Wheelchair W54 uses the same contacting materials as the predicate device and does not raise any new biocompatibility issues.

11. Usability Study:
The 15 participants read the User Manual before initial use of the device. They can understand the questions and answer them. The 15 participants can operate the device referring to the User Manual.

Based on the verification & validation testing records provided, we concluded that the Manual Wheelchair, Model W54 is considered to meet the usability requirement as defined in the verification & validation test report.

These non-clinical tests demonstrate that the labeling for the Manual Wheelchair, Model W54, manufactured by Jiangsu Jumao Medical Equipment Co., Ltd. and also distributed by US-Distributors is comprehensive, was well understood by a variety of “patients”, and provided sufficient information for safe and proper use of the device.

12. Conclusion:

Based on the comparison of the proposed device of W54 is determined to be Substantially Equivalent (SE) to the predicate device of Merits Model R106/R136 Rehab Wheelchair and Nuocande Plastic Manual Wheelchair Model NKD L07, in respect of safety and effectiveness.

--- End of this section ---