DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 25, 2015

Ningbo Lecount Medical Technology Co., Ltd.
c/o Charles Shen
Manton Business and Technology Services
37 Winding Road
Oakland, NJ 07436

Re: K151797
Trade/Device Name: Nuocande Plastic Manual Wheelchair Model NKD L07
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: June 17, 2015
Received: July 2, 2015

Dear Mr. Shen:

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" (21CFR 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 -S

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)*
K151797

Device Name
Nuocande Plastic Manual Wheelchair Model NKD L07

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 5 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.

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 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Ningbo Lecount Medical Technology Co., Ltd**.**
57 Longfei Road, Yunlong Industry Zone, Yingzhou District,
Ningbo**,** Zhejiang, 315135 China
Submitter's FDA Registration Number：N/A

US Agent and Contact Person

Charles Shen
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37 Winding Ridge
Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: June 01, 2015

Device Name:	
Proprietary Name:	"Nuocande Plastic Manual Wheelchair Model NKD L07"
Common Name:	Mechanical Wheelchair
Classification Name:	Wheelchair, Mechanical
Device Classification:	1
Regulation Number:	21 CFR 890.3850
Panel: General	Physical Medicine
Product Code:	IOR

Predicate Device Information:

(1) K132257, "Manual Wheelchair Model SY100-MA02A", manufactured by "Zhejiang Jiafeng Electrical & Mechanical Co., Ltd"

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.

"Nuocande Plastic Manual Wheelchair Model NKD L07" is user propelled, manually operated folding wheelchairs that are indicated 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. Each consists of four wheels, a mechanical frame and nylon upholstery that is ignition resistant.

"Nuocande Plastic Manual Wheelchair Model NKD L07" has a physical dimension of a physical dimension of 1090 (depth) x 730 (width) x 850 (height) mm, with the seat itself has a dimension of 411 (depth) x 447 (width) x 365 (height) mm. The device has a weight capacity of 100 kilograms, and weighs about 19 kilograms. The color is dark yellow.

Intended 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 **5** degrees.

Comparison to Predicate Devices
"Nuocande Plastic Manual Wheelchair Model NKD L07" manufactured by *"Ningbo Lecount Medical Technology Co., Ltd.***"** is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K132257, "Manual Wheelchair Model SY100-MA02A", manufactured by "Zhejiang Jiafeng Electrical & Mechanical Co., Ltd"

The following table shows similarities and differences of use, design, and material between our devices and the predicate device.

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Subject Devices	Predicate Device (K132257), Model SY 100-MA02A
Indication 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 **5** degrees.	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 **8** degrees.
Basic Design	Four wheels, a plastic frame and a textilene upholstery that is flame resistant.	Four wheels, a metal frame and a nylon upholstery that is flame resistant.
Materials	Steel (wheel rim and caster rim), hard plastics (Frame), and flame resistant fabrics (seat)	Steel (frame) and flame resistant fabrics (seat)
Powder	Mechanical	Same
Dimension	1090 x 730 x 850 (depth x width x height)	1025 x 661 x 920 mm (depth x width x height)
Armrest	Non Flip Back/Non Height Adjustable	Non Flip Back/Height Adjustable
Rear Axle	Offset Axle, Quick Release Axle	Same
Back Wheel	58.5 cm (=23 inch)	61 cm (=24 inch)
Casters	8 inch	8 inch
Wheel Lock	Pull to Lock	Same
Weight Capacity	100 Kg	130 Kg
Weight	19 Kg	16.5 Kg
Color	Yellow	Dark Green

Our devices and the predicate device are almost identical in terms of all areas described in the above table (*Table 5.1*). There are some minor differences with the predicate device don't affect the safety or effectiveness of the subject device.

The following table shows similarities and differences of the performance between our devices and the predicate device. Tests were conducted following the recommended

procedures outlined in the respective consensus standards, and results for "Nuocande Plastic Manual Wheelchair Model NKD L07" met all relevant requirements in the test standards, our internal specifications, and are comparable to the predicate device.

Table 5.2: Comparison of Performance Testing

Description	Subject Device	Predicate Device (K132257)
Static Stability	Meets ISO 7176-1:1999	Meets ISO 7176-1:1999
Effectiveness of Brakes	Meets ISO 7176-3: 2003	Meets ISO 7176-3: 2003
Static Strength	Meets ISO 7176-8: 1998	Meets ISO 7176-8: 1998
Impact Strength	Meets ISO 7176-8: 1998	Meets ISO 7176-8: 1998
Fatigue Strength	Meets ISO 7176-8:1998	Meets ISO 7176-8:1998
Resistance to Ignition	Meets ISO 7176-16:1997	Meets ISO 7176-16:1997

The tests were performed following the general requirements outlined in ISO 7176-11: 2012, 7176-13: 1989. The product labeling conforms to requirements of 7176-15: 1996.

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

"Nuocande Plastic Manual Wheelchair Model NKD L07" meets performance requirements per ISO 7176-1:1999, ISO 7176-3: 2003, ISO 7176-8: 1998, ISO 7176-11: 2012, 7176-13: 1989, 7176-15: 1996 and ISO 7176-16:1997. They are safe and effective, and their performances meet the requirements of their pre-defined acceptance criteria and intended uses.

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.

Substantial Equivalent Conclusions

Based on the comparison of intended use, design, materials, and performance, our "Nuocande Plastic Manual Wheelchair Model NKD L07" is substantial equivalent to their predicate devices.