April 28, 2026

Foshan Nanhai Hongchen Medical Equipment Co., Ltd.
Jinghan Tang
General Manager
Factory F, # 2, Nansha Rd., Nansha Community
Danzao Town, Nanhai District, Foshan City
Foshan, Guangdong 528000
China

Re: K260121
Trade/Device Name: Manual Wheelchair (7101L, 7102LHD)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: March 30, 2026
Received: March 30, 2026

Dear Jinghan Tang:

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 (the 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 available 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.
Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and Physical Medicine Devices
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K260121

Device Name

Manual Wheelchair (7101L, 7102LHD)

Indications for Use *(Describe)*

The manual wheelchair is a manually operated wheelchair intended to be used as a means of mobility for individuals 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.

510(k) Summary - K260121

1. Submission sponsor

Name:Foshan Nanhai Hongchen Medical Equipment Co., Ltd.

Address:Factory F, No. 2, Nansha Road, Nansha Community, Danzao Town, Nanhai District, Foshan City, Guangdong Province,P.R.China

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2. Submission correspondent

Contact person:Jinghan Tang

Title:General Manager

Tel: +8613537831351

Email: Jinghan_tang@126.com

3. Device

Name of Device: Manual Wheelchair

Model(s): 7101L, 7102LHD

Classification Name: Wheelchair, Mechanical

Regulatory Class: I

Product Code: IOR

Regulation Number: 21 CFR 890.3850

4. Predicate device(s)

Manufacturer	Predicate Device	510(k) Number
Bowhead Design Corp.	Bowhead ERA Wheelchairs	K243111

5. Device description

The Manual Wheelchairs are composite based mechanical, manually operated, wheelchairs intended to be used as a means of mobility for adults restricted to a sitting position.

The Manual Wheelchairs include 2 mechanical wheelchair models with each model containing slightly different design features. This product consists of a frame, armrest, push handle, foot bracket, foot pedal, brake, front and rear wheels, seat upholstery, back upholstery, and Anti-tippers.

6. Indications for Use

The manual wheelchair is a manually operated wheelchair intended to be used as a means of mobility for individuals restricted to a sitting position.

7. Comparison of Technological Characteristics with the Predicate Device(s)

The Manual Wheelchair has the same intended use, mode of action and operational characteristics as the predicate devices. Any minor differences between the subject device and the listed predicate devices do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device for its intended use.

Therefore, The Manual Wheelchair may be found substantially equivalent to its predicate devices.

The Manual Wheelchair is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance:

K243111 (Predicate Device), " Bowhead ERA Wheelchairs ", manufactured by " Bowhead Design Corp."

Comparison Elements	Subject Device	Predicate Device (K243111)	Remark
Device name	Manual Wheelchair	Bowhead ERA Wheelchairs	--
Indications for use	The manual wheelchair is a manually operated wheelchair intended to be used as a means of mobility for individuals restricted to a sitting position.	The Bowhead ERA wheelchairs are manually operated wheelchairs intended to be used as a means of mobility for individuals restricted to a sitting	SE

Comparison Elements	Subject Device	Predicate Device (K243111)	Remark
		position.	
Intended User	Adults	Adults	SE
Rx/OTC	OTC	OTC	SE
Operation Environment	indoor and outdoor use	indoor and outdoor use	SE
Control Mode	Self/user propelled, manual mechanical wheelchair	Self/user propelled, manual mechanical wheelchair	SE
Folding Method	Rigid	Rigid	SE
Weight of Devices	7101L:11.2kg with wheels 7102LHD:12.3kg with wheels	2.5-6 kg w/out wheels & dependent on configuration with or without removeable seat.	SE Note 1
Weight Capacity	7101L:250lbs/113.4 kg 7102LHD: 350 lbs/158.8 kg	110 kg (~242.5 lbs)	SE Note 2
Seat Width	7101L:43cm 7102LHD: 54cm	Adjustable: Small: 12” – 15” Medium: 14.5” – 17” Large: 17’’ – 19.5’’	SE Note 3
Seat Height	7101L:45cm 7102LHD: 45cm	Adjustable: 16’’ – 21’	SE Note 3
Seat Depth	7101L:45cm 7102LHD: 56cm	14” 16” 18’’	SE Note 3
Back Height	7101L:42cm 7102LHD: 42cm	8-25in (dependent backrest selected)	SE Note 3
Push Handle	Yes, optional	Yes, optional	SE
Safety feature (manual wheel lock)	Yes, push to lock style.	Yes, push to lock style.	SE

Comparison Elements	Subject Device	Predicate Device (K243111)	Remark
Brakes	One hand operation	One hand operation	SE
Anti-Tip	Yes - optional	Yes - optional	SE

Comparison in Detail(s):

Note 1: Weight of Devices

Minor difference on Weight of Devices will not cause new safety and effectiveness concerns raised as the subject device has been evaluated according to standard ISO 7176 series.

The Weight of Devices differences between the subject and predicate devices does not raise new concerns of safety and effectiveness for the clinical use.

Note 2: Weight Capacity

The Weight Capacity of the subject device is a little higher than that of predicate device as the subject device has been evaluated according to standard ISO 7176 series.

The Weight Capacity differences between the subject and predicate devices does not raise new concerns of safety and effectiveness for the clinical use.

Note 3: Seat Width,Seat Height,Seat Depth,Back Height

The Seat Width,Seat Height,Seat Depth,Back Height of the subject device is similar with that of the predicate device.

The Seat Width,Seat Height,Seat Depth,Back Height differences between the subject and predicate devices does not raise new concerns of safety and effectiveness for the clinical use.

8. Test Summary of Non-clinical Testing

The Manual Wheelchair has been evaluated the safety and performance by lab bench testing according to the following standards.

1) Performance test

The test results meet the specification of the product and the relevant standards are listed below.

- ISO 7176-1: 2014 Wheelchairs - Part 1: Determination of static stability
- ISO 7176-3: 2012 Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-7: 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 coefficient of friction of test surfaces
- ISO 7176-15:1996 Wheelchairs - Part15: Requirements for information disclosure,documentation and labeling
- ISO 7176-22: 2014 Wheelchairs - Part 22: Set-up procedures

9. Summary of Clinical Test

No animal study and clinical studies are available for our device. Clinical testing was not required to demonstrate the substantial equivalence of the Manual Wheelchair to its predicate device.

10. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the Manual Wheelchair is to be concluded substantial equivalent to its predicate devices.