May 21, 2026

Guangdong Dayang Medical Technology Co., Ltd.
% Andrew Wang
Regulatory Affair Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Rm. 1401, Dongfang Bldg., 1500# Century Ave.
Shanghai, 200122
China

Re: K254141
Trade/Device Name: Manual Wheelchair (DY01903(2))
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: December 22, 2025
Received: December 22, 2025

Dear Andrew Wang:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254141

Please provide the device trade name(s).

Manual Wheelchair (DY01903(2))

Please provide your Indications for Use below.

The DY01903(2)) Manual Wheelchair is to provide mobility to persons limited to a sitting position.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #:

510(k) Summary

Prepared on: 2026-02-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Guangdong Dayang Medical Technology Co., LTD
Applicant Address	Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District Foshan 528234 China
Applicant Contact Telephone	+86 13432677580
Applicant Contact	Ms. Xueqiong Zhang
Applicant Contact Email	1816775882@qq.com
Correspondent Name	Shanghai SUNGO Management Consulting Co., Ltd.
Correspondent Address	Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China Shanghai China
Correspondent Contact Telephone	+86 17521605316
Correspondent Contact	Mr. Andrew Wang
Correspondent Contact Email	yuanju.wang@sungoglobal.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Manual Wheelchair (DY01903(2))
Common Name	Mechanical wheelchair
Classification Name	Wheelchair, Mechanical
Regulation Number	890.3850
Product Code(s)	IOR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K242560	Manual Wheelchair (SYIV100-CA9221)	IOR

Device Description Summary

21 CFR 807.92(a)(4)

The DY01903(2) Manual Wheelchair is a mechanical wheelchair which is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. It can be folded for transport by bring the two sides together.

The manual wheelchair incorporates a main frame, a seat, two footrests and four wheels. The larger rear wheels have push-rims of slightly smaller diameter projecting just beyond the tyre. These allows the user to manoeuvre the chair by pushing them on without requiring them to grasp the tyres. The manual wheelchairs have brakes that bear on the tyres of the rear wheels and two push handles at the upper rear of the frame to allow for manual propulsion by a second person.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The DY01903(2)) Manual Wheelchair is to provide mobility to persons limited to a sitting position.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The proposed device has same indications for use to the predicate device. Minor difference on dimension and specifications do not affect the safety and effectiveness of the proposed device.

Technological Comparison 21 CFR 807.92(a)(6)

The proposed device and predicate device are complying to the same ISO standards, ISO 7176-1, ISO 7176-3,ISO 7176-5, ISO 7176-7, ISO 7176-8, ISO 7176-11, ISO 7176-13, ISO 7176-15, ISO 7176-16(ISO 16840-10) , ISO 7176-22, and FDA guidance Submission for mechanical wheelchair. The proposed device and predicate device are also complies with ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-23.

The proposed device has similar design and technological characteristics to the predicate device, there are minor differences between the devices including overall dimensions, seat dimensions, tires size, total weight as well as foot rest function of the device. The subject manual wheelchair has already been tested for performance and biocompatibility according to above-mentioned standards, and complies with the standards. Therefore, the subject manual wheelchair is as safe, effective and performs as well as the legally marketed predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

N/A