July 24, 2026

Free Wheelchair Mission
Bonnie Gonzalez
Mechanical Engineer
15279 Alton Pkwy. Suite 300, Irvine
CA, 92618, USA

Re: K252370
Trade/Device Name: GEN 4 JOY Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: June 17, 2026
Received: June 18, 2026

Dear Bonnie Gonzalez:

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,

Digitally signed by
ZACHARY MCKINNEY -S
Date: 2026.07.24
08:35:59 -04'00'

for 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)*

K252370

Device Name

GEN 4 JOY Wheelchair

Indications for Use *(Describe)*

The GEN 4 JOY Wheelchair is intended to provide mobility to persons restricted to a seated 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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510(k) #: K252370

510(k) Summary

Prepared on: 2026-06-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Free Wheelchair Mission
Applicant Address	15279 Alton Parkway Suite 300 Irvine CA 92618 United States
Applicant Contact Telephone	949-273-8470
Applicant Contact	Mrs. Nuka Hart
Applicant Contact Email	nhart@freewheelchairmission.org
Correspondent Name	Free Wheelchair Mission
Correspondent Address	15279 Alton Parkway Suite 300 Irvine CA 92618 United States
Correspondent Contact Telephone	949-273-8470
Correspondent Contact	Ms. Bonnie Gonzalez
Correspondent Contact Email	bgonzalez@freewheelchairmission.org

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	GEN 4 JOY Wheelchair
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
K141691	GEN_3 Mechanical Wheelchair	IOR

Device Description Summary

21 CFR 807.92(a)(4)

The GEN 4 JOY Wheelchair (Project name: "Wheely") by Free Wheelchair Mission is a manual, four-wheeled wheelchair intended to provide mobility to persons restricted to a seated position. It supports both self-propulsion and attendant-assisted propulsion and is suitable for indoor and outdoor use, including rural environments. The wheelchair features an adjustable center of gravity, achieved by repositioning the rear wheels, to improve maneuverability. It includes a foldable frame for ease of transport and storage. Key components include two large rear wheels, two front casters, a padded seat and backrest, wheel locks, armrests, and adjustable leg rests.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The GEN 4 JOY Wheelchair is intended to provide mobility to persons restricted to a seated position.

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

The Indications for Use is identical to that of the primary predicate.

Technological Comparison 21 CFR 807.92(a)(6)

The GEN 4 JOY Wheelchair is substantially equivalent in design, materials, and intended use to GEN_3 Mechanical Wheelchair. The indications for use for the GEN 4 JOY and the GEN_3 mechanical wheelchairs are identical. The size ranges for the GEN 4 JOY in terms of frame width, seat depth, back depths, chair weight and weight limit overlap those of the GEN_3. The GEN 4 JOY is provided in 6 sizes compared to 4 sizes for the GEN_3. All other features are identical with the exception that the wheels for the GEN 4 JOY are quick-release. The materials used in the seat, backrest, fire retardant upholstery, and wheel locks are also identical between the GEN 4 JOY and the GEN_3. The fundamental technology used in the GEN 4 JOY chairs is identical to that of the GEN_3. The information provided supports a substantial equivalence decision based on the repeat non-clinical testing of the static, impact and fatigue strengths. Any differences in features to the predicate do not affect the performance of the device and do not raise new types of safety or effectiveness questions.

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

ISO Standard 7176 for Wheelchairs was used as the basis for performance testing of the GEN 4 JOY Mechanical Wheelchair. FDA recognizes the following applicable parts of ISO 7176 as consensus standards:
1) ISO 7176-1:1999 Determination of static stability
2)ISO 7176-3:2006 Determination of effectiveness of brakes
3) ISO 7176-5:2008 Determination of dimensions, mass and maneuvering space
4) ISO 7176-7:1998 Measurement of seating and wheel dimensions
5) ISO 7176-8:1998 Requirements and test methods for static, impact and fatigue
6) ISO 7176-15:1996 Requirements for information disclosure, documentation and labeling
7) ISO 16840-10:2021 Resistance to ignition of upholstered parts- Requirements and test methods
The ISO tests were conducted with methods that met the following standards:
1) ISO 7176-11:1992 Test dummies
2) ISO 7176-13: 1989 Determination of coefficient of friction of test surfaces

Biocompatibility
The biocompatibility of the subject device is based on the use of low-biocompatibility risk materials and supporting information in accordance with Attachment G of FDA's 2023 Biocompatibility Guidance, and cytotoxicity, sensitization, and irritation testing per ISO 10993-5:2009, ISO 10993-10:2021, and 10993-23:2021, respectively.

Clinical tests are Not Applicable.

The non-clinical test results demonstrate the GEN 4 JOY Wheelchair does not raise any different questions of safety and effectiveness. The GEN 4 JOY, like the predicate, meets the ISO Standard 7176 for wheelchairs. The testing supports a determination of substantial equivalence between the GEN 4 JOY Wheelchair and predicate device.