May 21, 2021

Yamaha Motor CO., LTD.
Mikio Saitou
Official Correspondent
2500 Shingai
Iwata, Shizuoka 438-8501
Japan

Re: K203806
Trade/Device Name: JWX-1 Plus (Navigo 16"/Navigo 24")
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: March 1, 2021
Received: March 1, 2021

Dear Mikio Saitou:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 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,

Heather Dean, PhD
Assistant Director, Acute Injury Device 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203806

Device Name
JWX-1 PLUS(NAVIGO 16"/NAVIGO 24")

Indications for Use *(Describe)*
The device JWX-1 PLUS(NAVIGO 16"/NAVIGO 24") is a Powered Wheelchair Conversion Kit and suitable for a disabled person who can not walk or have restrictions on walking. It is intended for medical purposes to provide a means for a disabled person to take over the propulsion of the wheelchair and increase mobility and flexibility.

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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510(k) SUMMARY

1. Submitter information

Manufacture Name: YAMAHA MOTOR CO.,LTD.
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2. Date Prepared December 1, 2020

3.Device

Type in common name: Electric add-on drive for wheelchairs
Name: JWX-1 PLUS(NAVIGO 16″/NAVIGO 24″)
Classification Name: Wheelchair, Powered (21 CFR 890.3860), Class II
Product Code: ITI
Device Structure: Right Drive Unit
Left Drive Unit
Controller
Battery
Battery Charger

4. Predicate Device:

Alber GmbH e-fix E35/E36 (K161241)
YAMAHA MOTOR CO., LTD. JWX-2(K140204)

5. Device Description

The JWX-1 PLUS(NAVIGO 16″/NAVIGO 24″) is an add-on drive for wheelchairs. The JWX-1 PLUS turns a manually propelled wheelchair into a powered wheelchair. It is intended for medical purposes to provide a means for a disabled person to take over the propulsion of the wheelchair and increase mobility and flexibility.

The device consists of the left/ right drive units, controller, battery and the battery charger. The drive units replace the original wheels of the manual wheelchair.

Yamaha Ni-MH battery JWB2 and Yamaha Li-ion battery ESB1 can be used for the device. They are recharged with the charger ESC3. Both batteries can be charged in detached ‘desktop’ condition and the ESB1 can be charged also on the wheelchair condition. ESB1 does not supply the driving current during the charging to prevent the wheelchair to move.

6. Indications for use

The device JWX-1 PLUS(NAVIGO 16″/NAVIGO 24″) is a Powered Wheelchair Conversion Kit and suitable for a disabled person who can't walk or have restrictions on walking. It is intended for medical purposes to provide a means for a disabled person to take over the propulsion of the wheelchair and increase mobility and flexibility.

7. Comparison to Predicate Devices

The device has the similar technological characteristics as the predicate device. The microprocessors in both devices control the electrical current from the rechargeable batteries to the wheel-in motors in response to the user's joystick operations.
See COMPARISON TABLE below.

8. Non-Clinical Testing

The device JWX-1 PLUS(NAVIGO 16″/NAVIGO 24″) was tested with the following standards:

ISO 7176-1:1999,
Wheelchairs – Part 1: Determination of static stability

ISO 7176-2:2001
,Wheelchairs – Part 2:Determination of dynamic stability of electrically powered wheelchairs

ISO 7176-3 Third edition 2012-12-15,
Wheelchairs – Part 3: Determination of effectiveness of brakes

ISO 7176-4 Third edition 2008-10-01,
Wheelchairs – Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range

ISO 7176-6 Second edition 2001-10-01,
Wheelchairs – Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs

ISO 7176-8:1998,
Wheelchairs – Part 8: Requirements and test methods for static, impact and fatigue strengths

ISO 7176-9 Third edition 2009-11-15,
Wheelchairs – Part 9: Climatic tests for electric wheelchairs

ISO 7176-11 Second edition 2012-12-01,
Wheelchairs – Part 11: Test dummies

ISO 7176-14 Second edition 2008-02-15,
Wheelchairs – Part 14: Power and control systems for electrically powered wheelchairs and scooters – Requirements and test methods

ISO 7176-15 First edition 1996-11-15,
Wheelchairs – Part 15: Requirements for information disclosure, documentation and labeling

ISO 7176-21 Second edition 2009-04-01,
Wheelchairs – Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers

ISO 7176-22:2000,
Wheelchairs – Part 22: Set-up procedures

IEC 62304 edition 1.0 2015-06,
Medical device software – Software life cycle processes.

ISO 14971 Third Edtion 2019-12,
Medical devices – Application of risk management to medical devices

ISO 10993-1 Fifth edition 2018-10,
Biological evaluation of medical devices – Part 1:Evaluation and testing within a risk management process

ISO 10993-5 Third edition 2009-06-01,
Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.

ISO 10993-10 Third edition 2010-08-01,
Biological evaluation of medical devices -- Part 10: Tests for iriitation and skin sensitization

IEC 62133-1 Edition 1.0 2017-02,
Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 1: Nickel systems

IEC 62133-2 Edition 1.0: 2017-02,
Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

IEC 60601-1-2 Edition 4.0 2014-02,
medical electrical equipment - part 1-2: general requirements for safety - collateral standard: electromagnetic compatibility - requirements and tests (edition2:2001 with amendment 1:2004) (aami/ansi/iec 60601-1-2:2001 with amendment 1:2004 is the u.s..(General I (QS/RM))

IEC 60335-2-29 Ed. 5.0 :2016 (b) ,
Household and similar electrical appliances - Safety - Part 2-29:Particular requirements for battery chargers

9. Summary

The device JWX-1 PLUS(NAVIGO 16″/NAVIGO 24″) has the same intended use and similar technological characteristics as the predicate device. The device does not raise any new questions of safety or effectiveness.
The device is substantially equivalent to the predicate device.

Comparison table e-fix E35/E36 versus JWX-2 versus JWX-1 PLUS(NAVIGO 16″/NAVIGO 24″) (Same performance are indicated by boldface.)	**note:** **The primary predicate device is e-fix E35/E36(K161241).** **The reason why JWX-2(K140204) as complementary device is used in the Substantial Equivalence Discussion is that NI-MH, LI battery registered in the K140204 device will be used in the subject device. The NI-MH, LI battery are compatible to the subject devices.**

	primary predicate device		**complementary predicate device**	**JWX-1 PLUS (NAVIGO 16″/NAVIGO 24″)**	**Rationale**
	e-fix E35	**e-fix E36**	**JWX-2**		
510(k) Number	K161241		K140204	Subject Device	
Intended Use	The e-fix is an add-on drive for wheelchairs. The e-fix E35/E36 turns a manually propelled wheelchair into a powered wheelchair. It is intended for medical purposes to provide a means for a disabled person to take over the propulsion of the wheelchair and increase mobility and flexibility.		The device JWX-2 is a Power Assist Wheelchair Conversion Kit and suitable for the manual wheelchair users who are limited in their field of activities because of their physical conditions. The device can expand their field of activities by assisting their wheelchair operating force.	The device JWX-1 PLUS is a Powered Wheelchair Conversion Kit and suitable for a disabled person who can not walk or have restrictions on walking. It is intended for medical purposes to provide a means for a disabled person to take over the propulsion of the wheelchair and increase mobility and flexibility.	On safety and effectiveness view point, the subject device is as same as the predicate devices. Because it is equal to other ones at the concept of expanding driver's mobility by add-on device.
Total Weight	18.9kg(Li-ion)		17 kg (Ni-MH) 17.7kg (Li-ion)	20 kg (Ni-MH)/24″ , 18 kg (Ni-MH)/16″ 21kg (Li-ion)/24″ , 19kg (Li-ion)/16″	The Subject Device is similar weight. So it has no negative influence on the safety of the device.
Braking technologies	Manual parking brake Electromotive brake Electromechanical brake		Manual parking brake Electromotive brake	Manual parking brake Electromotive brake Electromechanical brake	The subject device has similar breaking means as e-fix E35/E36. So it has no negative influence on the safety of the device. Report Page: 18-38 to 18-47 10 Propulsion and braking system 17-75 8.12 Brakes Performance tests of parking brake, braking distance etc. passed. Test results conform to our intended use.

Speed, acceleration, deceleration	Preselected max-speed, microprocessor-controlled speed, acceleration and deceleration. The user controls these parameter with the joystick.	Microprocessor-controlled speed, acceleration and deceleration. The user controls these parameter with the hand-rim.	Preselected max-speed, microprocessor-controlled speed, acceleration and deceleration. The user controls these parameter with the joystick.	The subject device has similar speed control means as e-fix E35/E36. So it has no negative influence on the safety of the device. Report Page: 18-21 8.1.4 Maximum Downhill speed 18-26 8.1.8 Maximum speed 18-42 10.2.1(a) Requirement 17-72 5.3. Wheel Chair Performance tests of maximum forward/reverse/ downhill speed etc. passed. Test results conform to our intended use.
User interface	Joystick & push buttons	Hand-rim	Joystick & Toggle switch	On the subject device and e-fix E35/E36, joystick controls the direction and motor start/stop. Compare to e-fix E35/E36, the defferences between JWX-1 PLUS (See Owner's Manual 4.2 page 13-55 and 4.3 page 13-59) and E35/36 (User Manual page 13-139) are power on/off and speed setting means. JWX-1 PLUS uses toggle switch that can be operated even by people with weak hands. Toggle switch is easier to operate than push button or dial because it dosn't need complicated move or force. The toggle switch has no influence on the safety of the powered propulsion. Report Page: 17-64 TEST REPORT PPP31025:2011A 18-51 12 electrical system Performance tests of electrical safety passed. Test results conform to our intended use.
User interface 2 (For attendant / assistant)	Lever, Dial and Toggle switch	—	Dial and Push switch	User interface 2 is the input device for attendant. JWX-1 PLUS's power on/off switch (See Owner's Manual 6. page 13-65) is as same as the push button of E35/E36 (See User Manual Intuitive attendant control page 13-180) . Both E35/E36 and JWX-1 PLUS have a speed control dial. On JWX-1 PLUS, there are some distance from glip to dial, so there are less misoperation during operation. E35/E36 has a switch to toggle the direction forward and backward, and a lever to toggle motor start and stop. Whereas JWX-1 PLUS has a button to start or stop the motor for each forward and backward direction. Input means are slight different but functions are almost same. Motor on/off switches of JWX-1 PLUS are separated and different sizes in each direction so there are less confusion of the direction. So it has no negative influence on the safety of the device. Report Page: 17-64 TEST REPORT PPP31025:2011A 18-51 12 electrical system Performance tests of electrical safety passed. Test results conform to our intended use.

Max. User Weight	120kg	160kg	130kg	125kg/24″ , 100kg/16″ The subject device has a lower user weight capacity and has no negative influence on the safety of the device.	The subject device has a lower user weight capacity. So it has no negative influence on the safety of the device. Report Page: 17-72 5.2 Mass and configuration of test load 18-76, 18-80 TEST REPORT Performance tests of electrical safety, mechanical safety etc. passed. Test results conform to our intended use.
Speed Range with Power Assist	up to 6Km/h		up to 6Km/h	up to 6Km/h	Same Report Page: 18-21 8.1.4 Maximum Downhill speed 18-26 8.1.8 Maximum speed 18-42 10.2.1(a) Requirement 17-72 5.3. Wheel Chair Performance tests of electrical safety passed. Test results conform to our intended use.
Max Safe Slope	up to 20%	up to 15%	up to 6 degrees(up to 10%)	up to 6 degrees(up to 10%) The subject device has lower climbing capacity but it does not adversely affect safety or effectiveness of the subject device.	Compare to e-fix E35/E36, The Subject Device has less range. However, it has no negative influence on the safety of the device Report Page: 18-20 to 18-22 8.1.2 Ability to climb rated slope. Performance tests of Max Safe Slope passed. Test results conform to our intended use.
Max Range per Charge	up to 16km (up to 13miles with the optionally available high capacity battery pack)		40km & above (Li-ion) 20km & above (Ni-MH)	16km & above (Ni-MH)/24″ 30km & above (Li-ion)/24″ 15km & above (Ni-MH)/16″ 25km & above (Li-ion)/16″	Compare to e-fix E35/E36, the Subject Device has more range. However, it has no negative influence on the safety of the device. Report Page: 18-27 8.1.9 Distance range 18-61 13.2 q) Performance tests of Max Range per Charge passed. Test results conform to our intended use.
Type of Motor	**DC Brushless Motor**		**AC servomotor (DC Brushless Motor)**	**AC servomotor (DC Brushless Motor)**	**Same**
Rated Power of Motor	DC36V 110W×2	DC36V 150W×2	30mins rated DC24V 110W x 2	30mins rated DC24V 120W x 2	The differences in motor performance do not affect safety of the subject device.

Battery	Type: Li-ion Capacity: 36V 6.0Ah	Type: Ni-MH(Dry) Capacity: 24V 6.7Ah(Nom.) Type: Li-ion(Dry) Capacity: 25V11.8Ah(Nom.) *Selectable	Type: Ni-MH(Dry) Capacity: 24V 6.7Ah(Nom.) Type: Li-ion(Dry) Capacity: 25V11.8Ah(Nom.) *Selectable	The Subject Device's batteries are the same as JWX-2 ones that has already recognized at K140204. Report Page: 10-24 to 10-47 1. INTRODUCTION 17-84 to 17-186 TEST REPORT IEC62133-2 Performance tests of battery electrical safety passed. Test results conform to our intended use.
Battery Charger	Input : 100V-240V AC 50-60Hz 1.35A Output : 45V 1.5A DC	Ni-MH specific charger Input: 100-240V AC 50-60Hz 1.8A Output: 29V 2.6A DC (JWC-2) Li-ion specific charger Input: 100-240V AC 50-60Hz 2A Output: 29.2V 3A DC (ESC1)	Ni-MH & Li-ion common charger Input: 100-240V AC 50-60Hz 1.1A Output: 29V 2.6A DC (for Ni-MH) 29.2V 3A DC (for Li-ion) (ESC3)	JWC-2 is the charger for Ni-MH battery. ESC1 is the charger for Li-ion battery. Both chargers has discontinued so the new ESC3 charger is unified two chargers. (See EMC TEST REPORT Appendix 2 page 17-246) . ESC3 can charge both Ni-MH and Li-ion. Charging way of each battery is different. When charging Ni-MH battery, it is put on the receptacle on the body of the charger. When charging Li-ion battery, it is connected by charging cable from the charger. These manners are as same as each previous charger, therefore it is hard to misunderstand the usage of it. So it has no negative influence on the safety of the device. Report Page: 18-51 to 18-53 12.1 General requirement 17-189 EMC TEST REPORT 17-287 TEST RPORT IEC60335-2-29 Performance tests of battery charger for electrical safety, EMC passed. Test results conform to our intended use.
Battery Mount	Holder fixed to frame with Velcro strap.	Holder is in the bag, and the bag is fixed to frame with Velcro strap.	Holder is in the bag, and the bag is fixed to frame with Velcro strap.	Battery mount way is the same as JWX-2 one that has already recognized at K140204.

510(k) Number	K161241	K140204	Subject Device	

Wheel Size	24″/22″	24″/22″	24″/16″	16 inch model is for the user who needs the wheelchair with recline or tilt function (See Pre Sale Information Attachment-1 page 13-273) . 16 inch model has the same platform with 24 inch model, and it has the same safety function and reliability. Toruque, speed, and other parameters have been tuned for 16inch. 16 inch unit is proved to meet all regarding standards of EN12184:2014, such as max speed, stopping distance, static and dynamic stability, durability and so on. The wheel size has no influence on the safety of the powered propulsion. Report Page: 18-76 TEST REPORT NO.20-C061 18-80 TEST REPORT NO.20-C063 Performance tests of wheel chair mechanical safety with 24/16 inch wheel passed. Test results conform to our intended use.
Tire	**Puncture proof** / **Pneumatic**	**Pneumatic**	**Pneumatic**	**Same**
Quick Release Axle	**QR only**	**QR only**	**QR only**	**Same**
Left/Right wheel Synchronized Control	**Provided**	**Provided**	**Provided**	**Same**
Regenerative Brake	**Provided**	**Provided**	**Provided**	**Same** **Report Page:** **18-38 to 18-47 10 Propulsion and braking system** **17-75 8.12 Brakes** **Performance tests of braking system etc. passed.** **Test results conform to our intended use.**
Down Slope Speed Regulation	**Provided**	**Provided**	**Provided**	**Same** **Report Page:** **18-21 8.1.4 Maximum Downhill speed** **18-26 8.1.8 Maximum speed** **18-42 10.2.1(a) Requirement** **17-72 5.3. Wheel Chair** **Performance tests of downhill speed passed.** **Test results conform to our intended use.**
Certification	EN12184 (Electrically powered wheelchairs, scooters and their chargers – Requirements and test methods)	EN12184:2014 (Electrically powered wheelchairs, scooters and their chargers – Requirements and test methods)	EN12184:2014 (Electrically powered wheelchairs, scooters and their chargers – Requirements and test methods)	