April 19, 2021

Karma Medical Products Co., Ltd.
% Ke-Min Jen
Contact Person
Chinese-European Industrial Research Society
No. 58, Fu-Chiun St
Hsin-Chu City, Taiwan 30067
China

Re: K202506
Trade/Device Name: Karma Powered Wheelchair, KP-10.3S
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: January 16, 2021
Received: January 22, 2021

Dear Ke-Min Jen:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202506

Device Name
KARMA POWERED WHEELCHAIR, KP-10.3S

Indications for Use *(Describe)*
The device is intended for medical purposes to provide mobility to persons 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.

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510(k) Summary (per 21 CFR 807.92)

510(k) number: K202506

Submitter's Name:	***Karma Medical Products Co., Ltd.*** No. 2363, Sec. 2, University Road, Min-Hsiung Shiang, Chia-Yi 62144, Taiwan
Date summary prepared:	March 30, 2021
Proprietary Name:	Karma Powered Wheelchair, KP-10.3S
Common or Usual Name:	Powered Wheelchair
Classification Name	Powered Wheelchair, Class II, 21 CFR 890.3860
Product Code:	ITI
Company contact person:	Dr. KE-MIN JEN (email: ceirs.jen@msa.hinet.net) TEL: 886-3-5208829
Predicate Device	Manufacturer - Comfort Orthopedic Co. Ltd., Device name - Comfort Powered Wheelchair, Traveler LY-EB103, 510(k) number - K030356.

- **Indications for Use**:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

- **Intended use:**

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

- **Intended Patient Population:**

Physically challenged persons

- **Device Description:**

KP-10.3S is meant to provide mobility to persons who are not able to walk, stand or use a manual wheelchair, but who are very well able to control and use the interface of an electrically powered wheelchair. This wheelchair is not suitable for persons who do not have the cognitive skills to drive an electrically powered wheelchair by themselves. Also, it is not suitable for visually impaired persons. This wheelchair is suitable for users up to 264 lbs. (120 kg) in weight.

KP-10.3S is classified as a class B mobility product for indoor and outdoor use. It also has an extremely durable steel frame with tough components and does not suffer in dramatic extremes of temperature (neither the operator nor the attendant need touch metal parts in normal use). The compact size of this wheelchair, the excellent speed range and battery capacity makes the wheelchair suitable for both indoor and outdoor use. The KP-10.3S can be disassembled into four parts easily and can also be quickly assembled, which is convenient for storage and transportation.

The powered wheelchair KP-10.3S is an affordable rear wheel drive power chair. It features the patented S-Ergo Seating System and promotes a comfortable seating and a good posture. The device is powered by two 12 volt / 22 Ah lead acid batteries with 8.75 miles travel range that can be recharged by an off-board battery charger that can be plugged into an AC outlet (100 -240 V, 50-60 Hz), when the device is not in use.

Compact design makes it ideal for confined spaces mobility and short distance journey. The 36 inches turning radius for easy entry and exit of small elevator, making indoor activity effortless. It is tool-free disassembly, and can be easily placed in a car trunk, making travel possible and simple.

There are flip-back and height adjustable armrest, swing-away detachable footrest for KP-10.3S, and tool-free inclination angle adjustable backrest (15^{o} – 27^{o}) for KP-10.3S. The optional quick release steering controller enables maneuvering switches from the user to the attendants in seconds. The user can activate the joystick to move in the direction of the joystick is actuated. When the user releases the joystick, the device slows to stop and the brakes are automatically re-engaged. The maximum weight capacity of KP-10.3S is 264 lbs and its maximum speed is 3.75 mph. The following surfaces are recommended **NOT** to operate on:

- Sand surface
- Wet or icy surface
- Road maintenance hole metal cover
- Avoid going up multiple steps.
- Avoid using escalators. Use the elevator.
- Too steep slope over **6** degrees.
- Obstacle climbing ability: **1.96” (50 mm)**

- **Components:**

The main parts of the **drive unit** are as follows:

- Rotating drive wheel consisting of a brush motor with tire and aluminum fork,
- Integrated Lead acid battery pack with battery management system,
- On/Off button, remaining battery capacity level and operating mode indicator
- Joystick controller,
- Charging socket for the integrated battery for connecting the battery charger,

The main parts of the **control unit** are as follows:

- On/Off button, and speed setting on the controller
- Integrated Lead acid battery cell including battery management system
- Charging socket for charging via drive unit or other external charger
- Display for operating status and remaining capacities of drive unit and control unit

To charge the battery of the drive unit a battery charger is available.

Main attributes:

- Battery charger 100-240 VAC, 50 Hz
- Automatic charging and switch-off mechanism
- Indicating status and mains

- **Non-clinical performance tests**

ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability, FDA recognition #: 16-158

ISO 7176-2:2001 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs, FDA recognition #: 16-159

ISO 7176-3:2013 Wheelchairs - Part 3: Determination of effectiveness of brakes, FDA recognition #: 16-192

ISO 7176-4:2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range, FDA recognition #: 16-162

ISO 7176-5:2008 Wheelchairs - Part 5: Determination of dimensions, mass and maneuvering space, FDA recognition #: 16-163

ISO 7176-6:2018 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs, FDA recognition #: 16-204

ISO 7176-7:1998 Wheelchairs - Part 7: Measurement of seating and wheel dimensions, FDA recognition #: 16-196

ISO 7176-8:2014 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strength, FDA recognition #: 16-197

ISO 7176-9:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs, FDA recognition #: 16-167

ISO 7176-10:2008 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs, FDA recognition #: 16-164

ISO 7176-11:2012 Wheelchairs — Part 11: Test dummies, FDA recognition #: 16-190

ISO 7176-13: 1989 Wheelchairs – Part 13: Determination of coefficient of friction of test surfaces, FDA recognition #: 16-25

ISO 7176-14:2008 Wheelchairs -- Part 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods, FDA recognition #: 16-165

ISO 7176-15:1996 Wheelchairs -- Part 15: Requirements for information disclosure, documentation and labeling, FDA recognition #: 16-27

ISO 7176-16:2012 Wheelchairs -- Part 16: Resistance to ignition of postural support devices, FDA recognition #: 16-191

ISO 7176-21:2009 Wheelchairs – Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, FDA recognition #: 16-166

ISO 7176-22:2014 Wheelchairs - Part 22: Set-up procedures, FDA recognition #: 16-198

ISO 7176-25:2013 Wheelchairs – Part 25: Batteries and chargers for powered wheelchairs, FDA recognition #: 16-194

RESNA WC-2:2009 Section 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods, FDA recognition #: 16-180

RESNA WC-2:2009 Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters, FDA recognition #: 16-185

- **Biocompatibility of patient-contacting parts**

Statement for Biocompatibility Certification

The [PU Foam / Fabric / Polyester / Rubber / Nylon] [Armrest / Backrest / Seat / Pelvic belt / Push handle / Footplates] of the KARMA Powered Wheelchair, model **KP-10.3S**, are identical to the [Armrest / Backrest/ Seat / Pelvic belt / Push handle / Footplates] of the KARMA Power Wheelchair, Model **KP-25**, KARMA Medical Products Co., Ltd., **K041678**, clearance date 07/23/2004, in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents).

The patient-contacting materials of KARMA Powered Wheelchair, KP-10.3S, have the same nature of tissue contact and contact duration (e.g., surface device category, intact skin contact, less than 24-hour duration) as the KARMA Power Wheelchair, Model KP-25.

The corresponding materials to the components between subject and reference devices are presented as below. Those materials of components have no any changes since the clearance date 07/23/2004 of the reference device. Those materials of patient-contacting components of subject device have been demonstrated to be biocompatible.

Structural part

Subject device KP-10.3S, K202506		Reference device KP-25, K041678		Biocompatibility testing needed?
Component	Material	Component	Material	
Armrest	PU Foam	Armrest	PU Foam	Same material used, Biocompatibility testing not needed
Backrest	Fabric	Backrest	Fabric	Same material used, Biocompatibility testing not needed
Seat	Fabric	Seat	Fabric	Same material used, Biocompatibility testing not needed
Pelvic belt	Polyester	Pelvic belt	Polyester	Same material used, Biocompatibility testing not needed
Push handle	Rubber	Push handle	Rubber	Same material used, Biocompatibility testing not needed
Footplates	Nylon	Footplates	Nylon	Same material used, Biocompatibility testing not needed

Controller part

Subject device KP-10.3S, K202506		Reference device KP-25, K041678		Biocompatibility testing needed?
Component	Material	Component	Material	
Horn button	Dow Corning RBB-6671-70 + RBB-6671-70 + XE20-523-5U + Colourant Techi Black 1801	Horn button	Dow Corning RBB-6671-70 + RBB-6671-70 + XE20-523-5U + Colourant Techi Black 1801	Same material used, Biocompatibility testing not needed
Speed dial	Makrolon 6557 (PC material)	Speed dial	Makrolon 6557 (PC material)	Same material used, Biocompatibility testing not needed
REM060/110 bottom case	Makroblend EL700 (PC+PET materials)	REM060/110 bottom case	Makroblend EL700 (PC+PET materials)	Same material used, Biocompatibility testing not needed
REM050/100 (Full joystick control module)	Makroblend EL 700 + Makrolon 6557	REM050/100 (Full joystick control module)	Makroblend EL 700 + Makrolon 6557	Same material used, Biocompatibility testing not needed

- **Comparison table**

Characteristic	**Subject Device(s)**	**Predicate Device(s)**	**Comparison Verdict**
Manufacturer	Karma Medical Products Co., Ltd.	Comfort Orthopedics Co., Ltd.	--
Model(s)	Karma Powered Wheelchair, KP-10.3S (Ergo Nimble)	Comfort Powered Wheelchair, Traveler LY-EB103	--
Indications for use (IFU)	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position	Same
Intended patient population	Physically challenged persons	Physically challenged persons	Same
Frame Material	Steel	Steel	Same
Frame Design / Style	Foldable / The device consists of a foldable and non-rigid type of power wheelchair base with rear drive and 2 casters in the front and two anti-tippers in the rear.	Foldable / The device consists of a foldable and non-rigid type of power wheelchair base with rear wheel drive and 2 casters in the front.	Similar
Folding Mechanism	A foldable seat frames (The backrest could be folded to seat)	A foldable chassis frames (A cross-brace design)	**Different**
Seating Design	The seating frame design is an S-curved ergonomic seating system	Foam cushion design	**Different**
Seating Attachment	No	No	**Same**
Overall Dimensions			
Length	40.1” (1020 mm)	40”(1016 mm)	Similar
Width	24.2” (615 mm)	27”(685 mm)	Similar
Height	37.0” (940 mm)	34.5”(876 mm)	Similar
Seat Dimensions			
Width	17.5” (445 mm)	18” (457 mm)	Similar
Depth	18.3” (465 mm)	17” (432 mm)	Similar
Height	20.1” (510 mm)	21” (533 mm)	Similar
Weight	25.5 lbs.(11.6 kg)	Not specified	Similar
Folded Dimensions (if applicable)			
Length	29.3” (745 mm)	32” (812.8 mm)	**Different**
Width	24.2” (615 mm)	29” (736.6 mm)	**Different**
Height	15.1” (385 mm)	31” (787.4 mm)	**Different**

Wheelchair Weight			
With batteries	112 lbs. (51 kg)	166 lbs. (74 kg)	**Different**
Without batteries	83.1 lbs. (37.7 kg)	96 lbs. (43 kg)	**Different**
Controller	VR2	VSI	**Different**
Drive Style (e.g., rear, mid, front)	Rear drive	Rear drive	Same
Motor Type			
Motor Output	DC 24 V, 200 W * 2 pcs	DC 24 V, 450 W * 2 pcs	**Different**
Batteries			
Quantity	2	2	Same
Type	DC 12V, 22 Ah	DC 12V, 36 Ah	**Different**
Chemistry	Lead acid	Lead acid	Same
Range per Charge	8.75 miles (14 km)	18.75 miles (30 km)	**Different**
Charger Type (On-board/Off-board/ Carry-on)	Off-board	Off-board	Same
Input/Output Power	AC 100-240 V / DC 24V, 5A	AC 100-240 V / DC 29.2V, 5A	Similar
Actuator	None	None	Same
Brake	Electromagnetic brake	Electromagnetic brake	Same
Minimum braking distance / time			
Forward	1000 mm /1.20 s	870 mm / 1.01 s	**Different**
Reverse	550 mm /1.10 s	420 mm / 0.73 s	**Different**
Wheel Lock (type)	Hand brake	Hand brake	Same
Max speed			
Forward	3.75 mph (6 km/h)	5.00 mph (8.0 km/h)	**Different**
Reverse	2.31 mph (3.7 km/h)	2.7 mph (4.32 km/h)	**Different**
Rear Wheels Size	12” *2” (304 mm * 50 mm)	12” * 2.25” (304 mm * 57 mm)	Similar
Quantity	2	2	Same
Tire Pressure (if pneumatic)	PU solid tire	Pneumatic Pressure: 4.10/3.50-5	**Different**
Castors Size	8” * 2” (200 mm * 50 mm)	8” * 2” (200 mm * 50 mm)	Same
Quantity	2	2	Same
Tire Pressure (if pneumatic)	PU solid tire	PU solid tire	Same
Anti-tip Wheels			
Removable (Yes/No)	Yes	None	**Different**
Style	Installed next to the rear wheel	None	**Different**

Suspension (if applicable)	None	None	Same
Maximum Occupant Mass	264 lbs. (120 kg)	264 lbs. (120 kg)	Same
Curb Climbing ability	1.96”(50 mm)	1.96”(50 mm)	Same
Ground clearance	4.5”(115 mm)	1.96”(50 mm)	**Different**
Minimum Turning Radius	36.0” (915 mm)	37” (939 mm)	Similar
Maximum Incline	6 degrees	12 degrees	**Different**
Footplates	Detachable, adjustable	Detachable, adjustable	Same
Back Upholstery	Fabric	Fabric	**Same**
Armrest Type	Flip-back	Flip-back	Same
Operating surface / environment	Indoor & outdoor	Indoor and outdoor	Same
Storage environment	-20 ~ 85 ^{o}C, 20 ~ 80% RH	-20 ~ 85 ^{o}C, 20 ~ 80% RH	Same
Additional Accessory	None	None	Same
Warranty	Electronic items: 1 year Frame: 5 years	Electronic items: 1 year Frame: 3 years	Similar

- **Substantial equivalence discussion**

  The same or similar items in the comparison table are not discussed.

  The **folding mechanism** of the subject device is foldable seat frame, i.e., the backrest can be folded to seat, and it is foldable chassis frame for the predicate device, i.e., a cross-brace design. The overall dimensions of the subject device are originally 40.1” (length) x 24.2” (width) x 37.0” (height) and can be folded to 29.3” x 24.2” x 15.1” ; the overall dimensions of predicate device are 40”(length) x 27”(width) x 34.5”(height) and can be folded to 32” x 29” x 31”. The magnificent change of the height of the subject device is from 37.0” to 15.1”, and it changes only from 34.5” to 31” for the predicate device. This larger change of height of wheelchair means the subject device acquires much smaller storage or transportation space, and this is safer and more convenient for the subject device’s users. The difference of the folding mechanism does not raise any new safety and effectiveness concerns for the subject device.

  The **seating design** of the subject device is an S-curved ergonomic seating system and the predicate device is a regular foam cushion design. This S-curved ergonomic seating system can have more space to transmit more heat produced from the

contacting human body to the outside environment. The difference of the seating design does not raise any new safety and effectiveness concerns for the subject device.

The **folding dimensions** are different. All the folded dimensions 29.3" x 24.2" x 15.1" (length x width x height) of the subject device are smaller than the folded dimensions 32" x 29" x 31" of the predicate device. The smaller folded dimensions mean acquiring less space and possessing more safety and convenience for storage or transportation purposes. The difference of the folding dimensions does not raise any new safety and effectiveness concerns for the subject device.

The **weight** of the predicate device without batteries is 96 pounds and it is 83.1 pounds for the subject device. The weight of the predicate device with batteries is 166 pounds and it is 112 pounds for subject device. The difference of wheelchair weights without batteries between predicate and subject devices is purely due to the different device design aspects. The difference of wheelchair weights with batteries between predicate and subject devices is due to the inclusion of different sizes of batteries used. The heavier wheelchair is expected to have longer travel range per full charge and more comfortable driving feeling, and all these differences are not related to the safety or effectiveness aspects. These differences do not raise any new safety and effectiveness concerns for the subject device.

The **controller** used by the predicate device is VSI controller and it is VR2 controller for the subject device. Since the controller system of subject device passed the essential requirements of ISO 7176-14 and RESNA WC-2:2008 section 14, its essential performances and safety are validated. The differences of the electronic controller will not raise any new safety and effectiveness concerns for the subject device.

The **motor type** used by the subject device is DC 24 V / 200 W and it is DC 24 V / 450 W for the predicate device. The different motor types used by both devices are due to the maximum speed designs, i.e., higher maximum speed 5 mph for the predicate device of weight 166 pounds. According to the definition of power, power = force x speed, the predicate device thus requires larger motor power to attain the specified performance. The difference is related to the higher maximum speed and

heavier weight of the predicate device. The difference of the motor types will not raise any new safety and effectiveness concerns for the subject device.

The **batteries types** used by predicate and subject devices are same Lead-acid, but different types. The predicate device used two DC 12 V / 36 Ah batteries and subject device used two DC 12 V / 22 Ah batteries. The larger electric energy capacity used by predicate device leads to supporting its heavier weight of wheelchair, higher motor power output and longer **range per full charge.** This difference is not related to safety or effectiveness aspects. Specifically, the batteries used by subject device have been validated by the testing of Special Provision 238 in International Maritime Dangerous Goods Code 2016 Edition.(Amdt 38-16) and battery's Material Safety Data Sheet. There are no any new safety and effectiveness concerns raised due to this difference of batteries used by the subject device.

Traveling range per full charge for the predicate device is 18.75 miles (30 km) and it is 8.75 miles (14 km) for the subject device. The difference of traveling range is due to the use of larger batteries' capacities 36Ah used by predicate device and larger motor power output 450 W than those of the subject device. The traveling range per full charge is also related to the frequency of charging battery. The larger range leads to lower frequency of charging. So, the subject device needs higher frequency of charging than the predicate device does. This leads to a shorter lifetime of batteries of the subject device than the predicate device, because a battery normally can stand about 600 cycles of charging and discharging. Higher frequency of charging means shorter lifetime of batteries. So, we provide the instructions for use for batteries in Chapter 6 of user manual to remind the users of how to operate and maintain the batteries. Also, the batteries used by the subject device have been validated by the testing of Special Provision 238 in International Maritime Dangerous Goods Code 2016 Edition .(Amdt 38-16) and battery's Material Safety Data Sheet. There are no any new safety and effectiveness concerns raised due to this difference of traveling range per full charge for the subject device.

The **Minimum braking distance / time** for both devices are slightly different. Because the real braking distance & time during daily driving are related to that how fast the user reacts to the outside environment's action, these minimum values are just for user's reference. The differences are not related to the safety or effectiveness aspects. There are no any new safety and effectiveness concerns raised due to this difference of minimum braking distance / time for the subject device.

The **maximum forward speed** is 5 mph (8 km/h) for the predicate device and is 3.75 mph (6 km/h) for the subject device, due to the different motor power outputs for both devices. Since the maximum speed of the subject devices is lower than the predicate device, its speedy risk for the subject device is lower. Also, 3.75 mph is lower than the regulatory maximum speed of 6 mph (9.6 km/h). So, the difference of maximum speed will not raise any new safety and effectiveness concerns for the subject device.

The **tire types of the rear wheels** for both devices are different, and it is pneumatic tire for predicate device, and it is PU solid tire for subject device. The PU solid tire can feel more hard vibration reaction from the ground than the pneumatic tire. It is not necessary to inflate the PU solid tire, so the subject device does not have a flat tire situation. With respect to the flat tire situation, the PU solid tire is safer for the subject device. during driving. There are no any new safety and effectiveness concerns raised due to this difference of rear wheel tire types for the subject device.

The subject device is installed two **anti-tip wheels**, but the predicate device has no anti-tip wheels. Anti-tip wheels are installed on the subject device to prevent the wheelchair from tipping over easily. The subject device is safer than the predicate device with respect to the existence of the anti-tip wheels. There are no any new safety and effectiveness concerns raised due to this difference of anti-tip wheels for the subject device.

The **ground clearance** is 4.5” for the subject device and its 1.96” for the predicate device. The subject device can cross the clearance up to 4.5”, the predicate device can only cross the clearance up to 1.96”. The subject device can cross higher ground clearance than the predicate device, which means it is safer and more convenient for the subject device. There are no any new safety and effectiveness concerns raised due to this difference of ground clearance for the subject device.

Maximum incline is 6 degrees for subject device and 12 degrees for predicate device. The subject device passed the static and dynamic stabilities testing per ISO 7176-1/-2 and this information has been provided in the user manual, and the users are instructed to observe the relevant information when they operate the subject device. So, the difference of maximum incline does not raise any new safety and effectiveness concerns for the subject device.

- Conclusions

  The subject device, KP-10.3S, is as safe and effective as, and function in a manner equivalent to the predicate device, Comfort Powered Wheelchair, Traveler LY-EB103, K030356. The data generated from each test in the ISO 7176 series test reports of the subject device support a finding of substantial equivalence by comparison to the predicate device. The conclusions drawn from the non-clinical tests demonstrate that the device performs as well as the legally marketed device identified in the submission. Thus, the subject device is substantially equivalent to the predicate device.