September 5, 2023

Ki Mobility LLC
Mark Murphy
VP Operations
5201 Woodward Drive
Stevens Point, Wisconsin 54481

Re: K200583
Trade/Device Name: Ki Mobility Focus CR, Ki Mobility Focus CRe, Ki Mobility Focus CR TTL
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I, reserved
Product Code: IOR
Dated: August 21, 2023
Received: August 22, 2023

Dear Mark Murphy:

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,

Tushar Bansal -S

for 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)*
K200583

Device Name
Ki Mobility Focus CR, Ki Mobility Focus CRe, Ki Mobility Focus CR TTL

Indications for Use *(Describe)*
The Ki Mobility Focus CR manual wheelchair is a manually operated device with wheels that is intended to provide mobility to adults 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
K200583

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

Submitter Information

Company:	Ki Mobility LLC 5201 Woodward Drive Stevens Point, WI 54481 United States Telephone: 715-254-0992 Fax: 715-254-0996
Contact:	Mark Murphy VP Operations Ki Mobility LLC 5201 Woodward Drive Stevens Point, WI 54481 United States Telephone: 715-254-0992 Fax: 715-254-0996 mmurphy@kimobility.com
Date Summary Prepared:	August 25, 2023

Name of the Device

Trade Name:	Ki Mobility Focus CR, Ki Mobility Focus CRe, Ki Mobility Focus CR TTL
Common Name:	Wheelchair, Mechanical
Classification Name:	Physical Medicine Devices, 21 CFR 890.3850 Mechanical Wheelchair
Review Panel:	Physical Medicine (PM)
Regulation:	890.3850
Class:	Class I
Product Code:	IOR

Equivalence Claimed to Predicate Device

The Ki Mobility Focus CR is equivalent to the Invacare (K181090), manufactured by Invacare Corporation. The reference device for this submission is Quickie IRIS (K123975).

Focus 510(k) Summary

I. Predicate Devices

Invacare Solara 3G manual wheelchair, K181090 and Sunrise Medical, Quickie IRIS wheelchair, K123975.

II. Device Description

The Ki Mobility Focus CR manual wheelchair is intended to provide mobility to adults limited to a sitting position. The primary use is by adult users in need of manual wheeled mobility offering an operator adjustable body support system. The Focus CR offers both seat tilt and an optional reclining backrest, with both adjustable by the attendant.

The Focus CR manual wheelchair can be propelled by the occupant with access to hand-rims on the rear wheels or moved by an attendant with access to push handles. The push handles are used by the attendant to control the seat tilt function and recline of the backrest. Hand control levers on the push handles or a foot-operated pedal on the frame are used to release a slide-locking mechanism for changing the seat tilt angle. The backrest recline is controlled through hand control levers on the push handles which release sliding mechanical wrapped spring rod locks to change the backrest angle.

The Focus CR wheelbase is of a welded high-strength aluminum frame, upon which an inner high-strength forged aluminum frame can rotate on four rollers (two on each side) fixed to the base frame. The use of two control paths rolling on the fixed rollers is designed to create a complex rotation (CR) with a neutral resting angle of 20° tilt and minimizes the translation of the user-loaded system weight for safely controlling the change in seat tilt angle. The high-strength tubular aluminum seat frame assembles to the inner rotating frame and can be adjusted for seat depth and to adjust the user loaded center of gravity (CG) relative to the frame. Seat adjustment is optimal when the user-loaded and unlocked seating system will rest without force applied at 20°. CG adjustment is made with two easily accessed bolts are align to a series of holes through the seat frame and connected to the inner rotating frame.

The Focus CR manual wheelchair has a folding backrest frame for ease of storage for transport. A non-folding backrest and a reclining backrest are options. The adjustable tubular aluminum seat and backrest frame assembly is made to adapt to planar seating systems which have hardware adapted to mount to tubes. A solid mounted and depth adjustable aluminum seat pan is available for use with wheelchair seat cushions and the backrest frame accepts contoured wheelchair backrests. The seating system is a separate medical device adapted for use to the Focus CR and is the primary contact surface to the occupant. Focus CR components such as armrests and footrests will also have contact to the occupant.

The Focus CR wheelchair is custom configured to the user requirements by order form selection of components and accessories. The standard weight capacity for all models is 300 pounds, with an option for configuration as a heavy-duty weight capacity of 400 lbs. The seat tilt range is -5° to 50° with an accessory tilt stop available to limit the range. The backrest recline option range is available from 0 to 65°, 10° to 75° or 20° to 85°. The Focus CR, CRe & TTL are the same product with order form variations to meet different market configuration requirements only for pricing.

III. Intended Use

The Ki Mobility Focus CR manual wheelchair is intended to provide mobility to persons limited to a sitting position.

IV. Indications for Use

The Ki Mobility Focus CR manual wheelchair is a manually operated device with wheels that is intended to provide mobility to adults restricted to a sitting position.

V. Comparison of Technological Characteristics with Predicate Devices

A tabulated device design comparison to the predicate devices is shown in:

- Table 1 – Ki Mobility Focus CR to Invacare Solara 3G
- Table 2 – Ki Mobility Focus CR to Sunrise Medical Quickie IRIS

The Ki Mobility Focus CR manual wheelchair in comparison to predicate devices share intended use, similarity of configuration of components, wheels and accessories. The seat tilt function shares similar operation, employing a rotational tilting frame mounted to a solid base frame supported by rear wheels and front caster wheels. The Focus CR is substantially equivalent to the predicate devices in intended use, design, materials and operating principals with no new issues of safety or effectiveness.
The Focus CR components and accessories do not pose new risks, being as safe and effective as the predicate devices, with exception of an electrically powered seat tilt accessory for which a separate 510(k) as a Class II device is to be submitted.

TABLE 1 - Focus CR Design Comparison to Invacare Solara 3G

DEVICE	**Ki Mobility Focus CR manual wheelchair**	**Invacare Solara 3G manual wheelchair**
510(k) Number	K200583	K181090
Intended Use	The Ki Mobility Focus CR manual wheelchair is intended to provide mobility to persons limited to a sitting position.	The Invacare Solara 3G Manual Wheelchair is intended to provide mobility to persons limited to a sitting position.
Indications for Use	The Ki Mobility Focus CR manual wheelchair is a manually operated device with wheels that is intended to provide mobility to adults restricted to a sitting position.	The Invacare Solara 3G Manual Wheelchair is intended to provide mobility to adults limited to a sitting position.
DESIGN	**Ki Mobility Focus CR manual wheelchair**	**Invacare Solara 3G manual wheelchair**

Weight Limit	300 Pounds - Standard 400 Pounds - Heavy Duty	300 Pounds - Standard 400 Pounds - Heavy Duty
Frame	Aluminum	Steel
Seat Width	14' - 22"	12" - 24"
Seat Depth	14' - 22"	12" - 22"
Seat Height	13.5" - 20.5"	12.5" - 19"
Back Height	18" - 25" or 20"- 27" Adjustable 20" or 24" Fixed	17" - 20" Adjustable 20" or 24" Fixed
Back Angle Range	5° closed angle to 25° open angle	0° to 30° open angle
Back Style	Standard Back Cane Adjustable Height Reclining Back Seating Dynamics Rocker Back	Standard Back Cane - Folding & Non-fold Low Sheer Recline (N/A @400 lbs) Degage Dynamic Rocker Back
Push Handles	Push Handles on Backcanes Stroller Handles Angle Adjustable Stroller Handles	Push Handles on Backcanes Stroller Handles Angle Adjustable Stroller Handles
Seating	Width/Depth Adjustable Seat Pan	Seat Pan option - Flush & Drop Mount Planar Mounted Seating Low Shear Reclining Back with/omit upholstery

Armrests	Height Adjustable T-Arm Height Adjustable T-Arm Low Height Adjustable Dual Post Flip Back Angle Adj. Locking Extendable Flip Up Desk & Full Length Armpad	Two Point-Adjustable Height Two Point Fixed Height Two Point Flip Back Adjustable Height T-Armrest Non-locking Cantilever Armrest Desk & Full Length Armpad
Anti-tips	Rear Anti-tipper	Rear Anti-tipper
Wheel Locks	Push to Lock Pull to Lock Attendant Foot Lock Drum Brake Dual Drum Brake with Push or Pull to Lock Combination Attendant Foot Lock	Push-to-Lock Pull-to-lock Footlock Hub-Lock -Foot Operated, Cane & Seat Rail Mount
Rear Wheels - Tire	12" - Pneumatic, Airless Insert, Urethane 16" Pneumatic, Airless insert, Urethane 20, 22, 24" Pneumatic, Airless Insert, Urethane	12" Pneumatic, Airless Insert, Urethane 16,18" Pneumatic, Airless insert, Urethane 20, 22, 24" Pneumatic, Airless Insert, Urethane
Handrims	Aluminum or Plastic Coated Projection - Vertical	Aluminum, Plastic Coated Chrome Plated Projection - Oblique & Vertical
Caster Wheels	5/6/7/8 X 1" Poly 5 X 1" Poly Aluminum 6/8 X 1" Pneumatic 5/6/7/8 X 1.5" Poly 5/6 X 1.5" Soft Roll Aluminum 6 X 2" Poly 8 x 2" Pnuematic with Foam Insert	4/5/6/8 X 1" Urethane 4/5/6/8 X 1.4", 8 X 1.5" SoftRoll Urethane 6 X 2" Semi-Pneumatic

Caster Forks	Aluminum Fork	Aluminum Fork Frog Legs Suspension Fork
Turning Radius	30”	25"
Footrests	Swing-Away Footrest Front Mount Swing- Away Footrest Pro Elevating Leg Rest Contracture Footrest	Swing-Away Footrest Articulating Swing-Away Footrest Elevating Swing-Away Footrest Lift-Off Footrest Contracture Footrest
Footplates	Composite Composite Angle Adjustable Aluminum Angle Adjustable Aluminum Locking Multi-Angle Adjustable One Piece Flip Up Angle Adjustable	Flip-up Composite Aluminum Adjustable Angle Flip-up
Tilt Range	-5° to 50°	-5° to 50°
Manual Tilt Actuation	Single Hand Tilt Left or Right Dual Hand Tilt Foot Tilt Left or Right	Dual Cable Trigger Foot Pedal
Transit	Transport Brackets (Optional)	Transport Brackets (Optional)
Product Weight	33 lbs without accessories	34.5 lbs without accessories
ACCESSORIES	**Ki Mobility Focus CR manual wheelchair**	**Invacare Solara 3G manual wheelchair**
Ventilator/Battery Tray	Vent Tray Battery Box Holder	Ventilator Tray Ventilator Battery Box Laptop Vent Tray

Powered Tilt Option	Power Tilt Toggle Switch Left, Right Pendant Switch Control or Adaptive Switching Interface	No
Residual Limb Support	Residual Limb Support	No
One Arm Drive	One Arm Drive	No
Side Guard	Composite Side Guards	No
Positioning Belt	Seat, Pelvic Stabilizer	Seat, Chest, Calf & Ankle Straps
Oxygen Holder	Yes	Yes
IV Pole	Yes	Yes
Tilt Stop	Tilt Lever Lockout	Tilt Lock Stop & Tilt Lever Lock Out
Canopy	Yes	No
Spoke Guard	Yes	No
Impact Guards	Yes	Neoprene Frame Protectors
Backpack/Pouch	Yes	Yes

5.2: TABLE 2 - Focus CR Design Comparison to Sunrise Medical Quickie IRIS		
DEVICE	**Ki Mobility Focus CR manual wheelchair**	**Quickie Iris manual wheelchair**

510(k) Number	K200583	K123975
Intended Use	The Ki Mobility Focus CR manual wheelchair is intended to provide mobility to persons limited to a sitting position.	The Sunrise Medical Quickie Series Wheelchairs are intended to provide mobility to persons limited to a sitting position.
Indications for Use	The Ki Mobility Focus CR manual wheelchair is a manually operated device with wheels that is intended to provide mobility to adults restricted to a sitting position.	The Sunrise Medical Quickie Series Wheelchairs are intended to provide mobility to persons limited to a sitting position.
DESIGN	**Ki Mobility Focus CR manual wheelchair**	**Quickie Iris manual wheelchair**
Weight Limit	300 Pounds - Standard 400 Pounds - Heavy Duty	250 Pounds - Standard 350 Pounds - Heavy Duty
Frame	Aluminum	Aluminum
Seat Width	14' - 22"	14' - 22"
Seat Depth	14' - 22"	14' - 22"
Seat Height	13.5" - 20.5"	12.5"- 19.5"
Back Height	18" - 25" or 20"- 27" Adjustable 20" or 24" Fixed	15" - 21" or 18" - 24" Adjustable 18", 21" or 24" Fixed
Back Angle Range	5° closed angle to 25° open angle	5° closed angle to 30° open angle
Back Style	Standard Back Cane Adjustable Height Reclining Back Seating Dynamics Rocker Back	Standard Back Cane Adjustable Height Reclining Back Mono Back Seating Dynamics Rocker Back

Push Handles	Push Handles on Backcanes Stroller Handles Angle Adjustable Stroller Handles	Push Handles on Backcanes Long Push Handles on Backcanes Stroller Handles Angle Adjustable Stroller Handles
Seating	Width/Depth Ajdustable Seat Pan	Seat Pan option - Flush & Drop Mount
Armrests	Height Adjustable T-Arm Height Adjustable T-Arm Low Height Adjustable Dual Post Flip Back Angle Adj. Locking Extendable Flip Up Desk & Full Length Armpads	Height Adjustable T-Arm Height Adjustable T-Arm Low Dual Post Dual Post Flip Back Height Adjustable Dual Post Height Adjustable Dual Post Flip Back Adjustable Locking Flip Up Length Adjustable Locking Flip Up Height Adjustable Cantilever Armrest Desk & Full Length Armpads
Anti-tips	Rear Anti-tipper	Rear Anti-tipper
Wheel Locks	Push to Lock Pull to Lock Attendant Foot Lock Drum Brake Dual Drum Brake with Push or Pull to Lock Combination Attendant Foot Lock	Push to Lock Attendant Foot Lock Hub Lock
Rear Wheels - Tire	12" - Pneumatic, Airless Insert, Urethane 16" Pneumatic, Airless insert, Urethane 20,22,24"- Pneumatic, Airless Insert, Urethane	12" - Pneumatic, Airless Insert, Urethane 16" Pneumatic, Airless insert, Urethane 20,22,24"- Pneumatic, Airless Insert, Urethane
Handrims	Aluminum or Plastic Coated Projection - Vertical	Aluminum or Plastic Coated Projection - Oblique
Caster Wheels	5/6/7/8 X 1" Poly 5 X 1" Poly Aluminum 6/8 X 1" Pneumatic 5/6/7/8 X 1.5" Poly 5/6 X 1.5" Soft Roll Aluminum 6 X 2" Poly 8 x 2" Pnuematic with Foam Insert	4 X 1.25" Semi Pnuematic 5/6/8 X 1.5 Semi Pneumatic 5/6/8 X 1" Poly 8 X 2" Pneumatic 8 X 2" Pneumatic with Insert

Caster Forks	Aluminum Fork	Aluminum Fork
Turning Radius	30”	NA
Footrests	Swing-Away Footrest Front Mount Swing- Away Hanger Pro Elevating Leg Rest Contracture Footrest	Swing-Away Footrest Front Mount Swing- Away Hanger Pro Elevating Leg Rest Contracture Footrest
Footplates	Composite Composite Angle Adjustable Aluminum Angle Adjustable Aluminum Locking Multi-Angle Adjustable One Piece Flip Up Angle Adjustable	Composite Composite Angle Adjustable Aluminum Aluminum Angle Adjustable One Piece Flip Up Angle Adjustable
Tilt Range	-5° to 50°	-5 - 55°
Manual Tilt Actuation	Single Hand Tilt Left or Right Dual Hand Tilt Foot Tilt Left or Right	Dual Cable Trigger Foot Pedal
Transit	Transport Brackets (Optional)	Transport Brackets (Optional)
Product Weight	33 lbs without accessories	39 lbs without accessories
ACCESSORIES	**Ki Mobility Focus CR manual wheelchair**	**Quickie Iris manual wheelchair**
Ventilator/Battery Tray	Vent Tray Battery Box Holder	Vent Tray
Powered Tilt Option	Power Tilt Toggle Switch Left, Right Pendant Switch Control or Adaptive Switching Interface	No

Residual Limb Support	Residual Limb Support	Lower Extremity Support
One Arm Drive	One Arm Drive	One Arm Drive
Side Guard	Composite Side Guards	Composite Side Guards
Positioning Belt	Seat, Pelvic Stabilizer	Seat, Pelvic Stabilizer, Thoracic
Oxygen Holder	Yes	Yes
IV Pole	Yes	Yes
Tilt Stop	Tilt Lever Lockout	Tilt Lever Lockout
Canopy	Yes	Yes
Spoke Guard	Yes	Yes
Impact Guards	Yes	Yes
Backpack/Pouch	Yes	Yes

VI. Performance Data

Non-Clinical Testing

The Focus CR has been tested to meet recognized standards for manual wheelchairs including ANSI/RESNA WC-1:2009 Requirements and Test Methods for Wheelchairs, ANSI/RESNA WC-4:2012 Wheelchairs and Transportation, and the ISO 7176 series. Note that Focus CR does not include upholstery and seating is not an integral part of the wheelchair frame Flammability testing was not required for the wheelchair, but resistance to ignition test data for the seating system mounted to the seat and back frame is provided for reference.

Third party lab testing performed per ANSI/RESNA includes:

WC-1:2009 Section 1: Determination of static stability

WC-1:2009 Section 5: Determination of dimensions, mass and maneuvering space

WC-1:2009 Section 8: Requirements and test methods for static, impact and fatigue strengths WC-1:2009 Section 11: Test Dummies

WC-4:2012 Section 19: Wheelchairs used as seats in motor vehicles

Third party lab testing performed per ISO 7176 includes:

ISO-7176-1:2014 Determination of static stability

ISO-7176-3:2012 Determination of effectiveness of brakes

ISO 7176-5:2008 Determination of dimensions, mass and maneuvering space

ISO 7176-7:1998 Measurement of seating and wheel dimensions

ISO 7176-8:2014 Requirements and test methods for static, impact and fatigue strengths

ISO 7176-11:2012 Test Dummies

ISO 7176-13:1989 Determination of Coefficient of Friction of Test Surfaces

ISO 7176-15:1996 Requirements for Information Disclosure, Documentation and Labelling

ISO 7176-22:2008 Set-up Procedures

ISO 7176-30:2018 Wheelchairs for changing occupant posture – Test methods and requirements

Performance testing of the Focus CR met or passed the recognized test standard requirements for a manual wheelchair, which provides data for comparison to predicate devices.

ISO 7176 Sections 1, 3, 5, 7, & 8 and ANSI-RESNA WC-1 Sections 1,3,5,7 & 8 as well as WC-4 Section 19 provide test data from consensus test standards of long-standing providing performance qualification (pass/fail) and comparison data (informative). Recent adoption of the ISO 7176-30 standard provides data that may not be available from predicate device test.

<u>Static Stability per ISO 7176-1 (WC-1, Section 1)</u>

The angle at which a wheelchair is no longer stable is measured in the anterior, posterior, and lateral position on an adjustable slope. The information is available for both the standard 300 pound and “heavy duty” 400 pound weight limits, which compare well to the predicate devices.

The test data is available in the least stable and most stable configuration of the test chair set-up to ISO 7176-22 (or WC-1: Section 22) requirements. The data recorded is informative and can be used for comparison of performance on a slope. There is not a limit defined for pass/fail.

<u>Effectiveness of Parking Brakes per ISO 7176-3 (WC-1, Section 3)</u>

Manual wheelchair “wheel locks” are adjusted and applied within the force limits allowed for engagement and the angle at which the wheelchair tips or slips on an adjustable slope in the up-slope & down-slope position is recorded. The configuration of the test chair is set-up to ISO 7176-22 (or WC-1: Section 22) requirements. The data recorded is informative and can be used for comparison of parking brake performance, but there are no limits defined for pass/fail.

<u>Determination of Dimensions, Mass, and Maneuvering Space per ISO 7176-5 (WC-1, Section 5)</u>

A method of measures of wheelchair size, mass and maneuvering space relevant to use in daily life provides a record for comparison of configurations set-up to ISO 7176-22. The measured values are informative with no limits defined for pass/fail.

Measurement of Seating and Wheel Dimensions per ISO 7178-7 (WC-1, Section 7)

A series of measurements of seating and wheel dimensions, intended to create a standard measure of the flexible elements of the wheelchair. The Focus CR is quite rigid with seating systems adapted that are not as flexible as sling style upholstery. The standard applies to chairs with a user weight limit of 120 kg (265 pounds) but has been applied for reference to the Focus CR. The wheelchair configuration for measurement has been based on ISO 7176-22 set-up, to provide consistency.

Comparison to predicate will need to take into account the wheelchair configuration cited as the standard allow the commissioner of the test to define the set-up for measurement.

Static, Impact, and Fatigue Strength Testing per ISO 7176-8 (WC-1,Section 8)

A series of test methods for wheelchairs and their integral components. The test set-up cites use of ISO 7176-22 and the Focus has test configurations for both standard 300 pound and heavy-duty 400 pound weight limits. The standard defines the test parameters with a limit defined for pass/fail, which allows for direct review of the wheelchair for meeting the requirements for strength at the defined weight limits and allows for comparison to the predicate wheelchairs.

Wheelchairs for Changing Occupant Posture – Testing per ISO 7176-30

A series of tests for wheelchairs with OABSS (operator adjustable body support systems) where different conditions for wheelchair set-up are defined for testing. The SRC (seated reference configuration) is defined by the ISO 7176-22 set-up requirements with the MAC (maximum adjustable configuration) and MDC (maximum drivable configuration) which are coincident for the Focus CR, defined by the fully tilted seat frame position.

Testing in the MAC/MDC is conducted for informational record per ISO 7176-1 and ISO 7176-5. The results from this testing can be used for comparison to data from predicate testing if available, with the MAC/MDC most equivalent to ISO 7176-1 testing to the “least stable” test condition.

Testing in the MAC/MDC is conducted for strength performance with pass/fail limits per modified multi-drum fatigue testing per ISO 7176-8 , The pass/fail of test can be compared to prior ISO 7176-8 test results.

ISO 7176-30 introduces additional strength tests with pass/fail limits such as the seat impact test (with 5°+/-2° seat angle which can coincide with SRC per ISO 7176-22 of 4°+/-1°), back support strength per ISO 16840-3 in SRC (1000 cycles), back support tipping fatigue (20,000 cycles) and ISO 7176-3 operation of levers force test applied to all levers or controls of OABSS. The pass/fail record of test for the FocusCR may not find comparable data in predicate testing due to the recent introduction of ISO 7176-30 as a consensus standard, but it does have relevance in exhibiting further proof of effective performance with Focus CR having passed these tests.

Wheelchairs Used a Seats in Motor Vehicles, WC-4, Section 19

Transit testing using defined tie-downs with design requirements and performance limits for pass/fail criteria related to wheelchair set-up, body excursion in test and wheelchair performance in a 20G/30mph impact test, using a prescribed ATD (anthropomorphic test device) for the maximum weight limit to be used if occupied in a motor vehicle. The Focus CR has a 400 pound weight limit for use as a seat in a motor vehicle, with a PASS rating in test. This can be compared to predicate device tests.

The following summary table provides a list of tests for the Focus CR that contain data for comparison to predicate devices.

TEST	DESCRIPTION	ACCEPTANCE CRITERIA	RESULTS	PREDICATE TEST
ISO 7176-1	Static Stability	Informative	Comparison Data	Yes
ISO 7176-3	Effectiveness of Brakes	Informative	Comparison Data	Yes
ISO 7176-5	Dimensions, Mass, Space	Informative	Comparison Data	Yes
ISO 7176-7	Measurements	Informative	Comparison Data	Yes
ISO 7176-8	Static, Impact, Fatigue Strength	Pass/Fail Limits	PASS	Yes
ISO 7176-30	OABSS – Tilt Wheelchair Testing	Informative & Pass/Fail Limits	Comparison Data PASS	Unknown
WC-4: 19	Transit test	Pass/Fail Limits	PASS	Yes

Additional Bench Testing

In-house performance testing run for verification test and not to consensus standards is included to establish record of test for durability of the wheel-locks (TR-0003.1), powder coat finish (TR-0003-2), and tilt mechanism (TR-0098). The testing is provided for information supporting product performance but the data is not a point of comparison to predicate devices.

Biocompatibility Testing

The Focus manual wheelchair has limited exposure for biocompatibility issues and no hazards were identified. The wheelchair does not include upholstery and seating products used with the wheelchair are separate medical devices with their own evaluation for issues related to body contact.

Risk Management

The Focus CR has been evaluated per ISO 14971:2012 Application of Risk Management to Medical Devices, using a 5 X 5 semi-qualitative risk matrix for assessing initial and residual risks. A Design Failure Modes and Effect Analysis (DFMEA) was conducted using a risk priority number scale of 0 to 1000, with reduction of RPN to less than 200.

Risk reduction actions and controls were applied to mitigate identified hazards and identify needed instructions for use and warnings in labeling for safe and effective use of the Focus CR.

Clinical Study

No clinical studies were applied or required for this submission.

VII. Conclusions

The Focus CR manual wheelchair has the same intended use and similar technological characteristics as the predicate devices. The non-clinical testing to recognized standards exhibits that the device will perform as intended and risk analysis has documented risk reduction and identified requirements for labeling for safe and effective use of the device. The Focus CR is substantially equivalent to the predicate devices as shown in the product design comparison.

The conclusion from testing and comparison to predicate devices demonstrates that the Focus CR is as safe, as effective, and performs as well than the legally marketed devices identified as predicate.