



January 31, 2025

Suzhou Master Machinery Manufacturing Co., Ltd.  
% Boyle Wang  
Manager  
Shanghai Truthful Information Technology Co., Ltd.  
Room 1801, No. 161 East Lujiazui Rd., Pudong  
Shanghai, 200120  
China

Re: K242982

Trade/Device Name: Mobility Scooter (MS160A)  
Regulation Number: 21 CFR 890.3800  
Regulation Name: Motorized Three-Wheeled Vehicle  
Regulatory Class: Class II  
Product Code: INI  
Dated: January 3, 2025  
Received: January 3, 2025

Dear Boyle Wang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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](mailto: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

## Indications for Use

Submission Number (if known)

K242982

Device Name

Mobility Scooter (MS160A)

Indications for Use (Describe)

It is a motor driven, indoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited 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.**

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## **510(k) Summary**

### **K242982**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

#### **1.0 Submitter's information**

Name: Suzhou Master Machinery Manufacturing Co., Ltd.

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Contact: Siqi.Shangguan

Date of Preparation: Aug.09, 2024

#### **Designated Submission Correspondent**

Mr. Boyle Wang

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#### **2.0 Device information**

Trade name: Mobility Scooter

Common name: Scooter

Classification name: Motorized Three-Wheeled Vehicle

Model(s): MS160A

#### **3.0 Classification**

Production code: INI

Regulation number: 21 CFR 890.3800

Classification: Class II

Panel: Physical Medicine

#### **4.0 Predicate device information**

Manufacturer: Nanjing Jin Bai He Medical Apparatus Co., Ltd.

Trade/Device: Scooter (Model: FDB01)

510(k) number: K201196

## **5.0 Indication for Use Statement**

It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

## **6.0 Device description**

The subject device, Model MS160A scooter is mainly battery-powered and driven by a DC motor, with the speed adjusted by a user-controlled panel.

The motor is driven, and the speed is adjusted by a user-controlled panel and speed knob.

The scooter consists of two folding armrests, a backrest, a seat cushion, a folding frame, two front wheels, two rear drive wheels with a motor/electromagnetic brake assembly, a rechargeable lithium-ion battery, an off-board battery charger, a control panel, and a motor controller.

The MS160A scooter is designed to provide mobility for people limited to those who walk unchanged or for the elderly.

**Folding design:** Pull out the seat and backrest fixing pins, push the backrest forward, the seat and backrest fold into each other, release the handlebar locking knob, push the handlebar backward, the handlebar folds down, the whole scooter is folded.

**Control panel:** Includes speed knob, battery gauge, power key switch, horn button, throttle control lever, headlight switch, charger port, fuse.

**Wheel and frame connection method:** the motor is connected to the differential, the differential is connected to the frame, the wheels are mounted on both ends of the differential, the motor rotates with the differential, thus driving the scooter.

### **Frame design:**

- 1) The frame of MS160A is aluminum alloy.
- 2) The folding mechanism is operated in two ways:
  - a. In the non-riding state, pull out the seat fixing pin, push the backrest forward, the seat and backrest can be folded.
  - b. Loosen the handlebar locking knob, push the handlebar forward, the handlebar will fold down.

The front wheels of the scooter are 7 inches and the rear wheels are 10 inches.

The motor of the scooter is ST-62D24-120W; the lithium-ion battery is 25.55V 10.4AH; the charger is 24V/2A.

Max. loading cannot be over than 125kg.

The maximum distance travelled with a fully charged battery is 8.2km and the maximum forward speed is 1.8m/s.

Braking time is about 2 seconds, braking distance is  $\leq 1.5$  meters.

## **7.0 Summary of Non-Clinical Testing**

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability  
ISO 7176-2:2017 Wheelchairs - Part 2: Determination of dynamic stability of electrically powered wheelchairs  
ISO 7176-3:2012 Wheelchairs - Part 3: Determination of effectiveness of brakes  
ISO 7176-4:2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range  
ISO 7176-5:2008 Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space  
ISO 7176-6:2018 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs  
ISO 7176-7:1998 Wheelchairs - Part 7: Measurement of seating and wheel dimensions  
ISO 7176-8:2014 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths  
ISO 7176-9:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs  
ISO 7176-10:2008 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs  
ISO 7176-11: 2012 Wheelchairs - Part 11: Test dummies  
ISO 7176-13:1989 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces  
ISO 7176-14:2008 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods  
ISO 7176-15:1996 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling  
ISO 16840-10:2021 Wheelchair seating - Part 10: Resistance to ignition of postural support devices - Requirements and test method  
ISO 7176-22:2014 Wheelchairs - Part 22: Set-up procedures  
ISO 7176-25:2013 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs  
EN 12184 :2014 Electrically powered wheelchairs, scooters and their chargers- Requirements and test methods  
IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests  
IEC TR 60601-4-2 Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

### **Biocompatibility of patient-contacting parts**

Patient-contacting material are carried out biocompatibility assessment in accordance with ISO 10993-1: 2018, including:

Cytotoxicity per ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity

Skin Sensitization per ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests For Skin Sensitization.

Irritation per ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 23: Tests For Irritation.

## **8.0 Summary of Clinical Testing**

No clinical study implemented for the scooter.

## **9.0 Technological Characteristic Comparison Table**

**Table 1 - General Comparison**

| <b>Item</b>                     | <b>Subject device</b>                                                                                                                                                                                                | <b>Predicate device<br/>K201196</b>                                                                                                                                                                                                                      | <b>Remark</b> |
|---------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| Product Code                    | INI                                                                                                                                                                                                                  | INI                                                                                                                                                                                                                                                      | Same          |
| Regulation No.                  | 21 CFR 890.3800                                                                                                                                                                                                      | 21 CFR 890.3800                                                                                                                                                                                                                                          | Same          |
| Class                           | II                                                                                                                                                                                                                   | II                                                                                                                                                                                                                                                       | Same          |
| Product name                    | Scooter (Model: MS160A)                                                                                                                                                                                              | Scooter (Model: FDB01)                                                                                                                                                                                                                                   | -             |
| 510(k) No.                      | K242982                                                                                                                                                                                                              | K201196                                                                                                                                                                                                                                                  | -             |
| Intended Use/Indication for Use | It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.                                              | It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.                                                                                  | Same          |
| Use environment                 | Indoor and outdoor use                                                                                                                                                                                               | Indoor and outdoor use                                                                                                                                                                                                                                   | Same          |
| Patient Population              | This product is suitable for disabled people with mobility difficulties and elderly people.                                                                                                                          | This product is suitable for disabled people with mobility difficulties and elderly people.                                                                                                                                                              | Same          |
| Product structure               | It has a base with frame, two front wheels, two rear wheels, two anti-tip wheels, a seat, a tiller, a control panel, an electric motor, an electromagnetic brake, a rechargeable Lithium-Ion Battery with a charger. | It has a base with metal alloy frame, two front wheels, two rear wheels, two anti-tip wheels, a seat, an adjustable steering column, a tiller console, an electric motor, an electromagnetic brake, 2 rechargeable Lithium-Ion Battery with an off-board | Similar       |

|                     |                                                               |                                                                  |                                                                                                                  |
|---------------------|---------------------------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
|                     |                                                               | charger.                                                         |                                                                                                                  |
| Driving system      | Direct drive on the rear wheels                               | Direct drive on the rear wheels                                  | Same                                                                                                             |
| Number of wheels    | 4                                                             | 4                                                                | Same                                                                                                             |
| Main frame material | Aluminium alloy                                               | Aluminium alloy                                                  | Same                                                                                                             |
| Motor               | Brushless motor,<br>DC24V * 120W * 1 pcs                      | brush differential rear axle.<br>24V * 180W                      | Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence. |
| Battery             | DC 25.55V 10.4Ah Lithium-ion,<br>1 pc                         | 24V 6AH Lithium-ion,<br>2 pcs                                    |                                                                                                                  |
| Battery charger     | Off-board charger<br>Input: 100-240 VAC<br>Output: DC 24V, 2A | Off-board charger<br>Input: 100-240 VAC<br>Output: DC 24V, 6 Amp |                                                                                                                  |

**Table 2 - Performance Comparison**

| Item                   | Subject Device                                                                                                                                                                                                  | Predicate Device<br>K201196                                                                                                                                                                                     | Remark                                                                                                                  |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| Dimensions (mm)        | 1000 x 540 x 900                                                                                                                                                                                                | 1050 x 550 x 870                                                                                                                                                                                                | Minor differences in the dimensions will not impact the safety and effectiveness of the substantial equivalence.        |
| Folded dimensions (mm) | 1000 x 540 x 410                                                                                                                                                                                                | 480 x 550 x790                                                                                                                                                                                                  | Minor differences in the folded dimensions will not impact the safety and effectiveness of the substantial equivalence. |
| Weight, w/ Battery     | 48.5lbs. /22kg                                                                                                                                                                                                  | 63.1lbs. /29 kg                                                                                                                                                                                                 | The difference will not raise any new safety and effectiveness concerns.                                                |
| Frame design           | Foldable/<br>Electric scooter is driven by electricity scooter, is a transportation tool and auxiliary tools for the purpose of walking, without removing the battery can be folded, easy to carry and storage. | Foldable/<br>Electric scooter is driven by electricity scooter, is a transportation tool and auxiliary tools for the purpose of walking, without removing the battery can be folded, easy to carry and storage. | Same                                                                                                                    |
| Seating Design         | In non-riding state, pull out the seat fixing pin, push forward the backrest, the seat and backrest can be folded.                                                                                              | One-click folding intelligent electric scooter, with a sensitive remote control, gently press, the                                                                                                              | The difference will not raise any new safety and effectiveness concerns.                                                |

|                                                              |                                                                                                   |                                                                                                                                                                                                                                                                                          |                                                                                                                             |
|--------------------------------------------------------------|---------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
|                                                              | Loosen the handlebar locking knob, push forward the handlebar, the handlebar will be folded down. | car automatically completed folding contraction, folding volume small, electromagnetic automatic brake, the overall simple design, convenient and practical, Travel does not have to consume physical force to do folding, poor physical strength and the elderly the best walking tool. |                                                                                                                             |
| Seating Attachment - integrated, power base, specialty power | Without any seat accessories (integrated, power base, dedicated power supply)                     | Without any seat accessories (integrated, power base, dedicated power supply)                                                                                                                                                                                                            | Same                                                                                                                        |
| Folding mechanism                                            | A foldable seat frames (The backrest could be folded to seat)                                     | Seat can be folded; battery can be dismantled; The frame can be folded back and forth                                                                                                                                                                                                    | Same                                                                                                                        |
| Front wheel(inch)                                            | 7<br>(Solid tire)                                                                                 | 7<br>(Solid tire)                                                                                                                                                                                                                                                                        | Same                                                                                                                        |
| Rear tire (inch)                                             | 10<br>(Solid tire)                                                                                | 8<br>(Solid tire)                                                                                                                                                                                                                                                                        | Larger size of rear wheels bring steadier pivoting function than predicate device.                                          |
| Anti-tip Wheels (inch)                                       | 2.5                                                                                               | 2.5                                                                                                                                                                                                                                                                                      | Same                                                                                                                        |
| Cruising Range(km)                                           | 8.2                                                                                               | Not Publicly Available                                                                                                                                                                                                                                                                   | The difference will not raise any new safety and effectiveness concerns.                                                    |
| Obstacle climbing(mm)                                        | 15                                                                                                | 60                                                                                                                                                                                                                                                                                       | The smaller height in the obstacle climbing will not impact the safety and effectiveness of the subject device.             |
| Ground clearance                                             | 94mm                                                                                              | 50mm                                                                                                                                                                                                                                                                                     | The device has been tested according to ISO7176 series standards and the test records support its safety and effectiveness. |
| Static stability                                             | 40°                                                                                               | 30°                                                                                                                                                                                                                                                                                      | Both of the devices are                                                                                                     |

|                                  |                                                                                                                                                                              |                                                                                                                                                                               |                                                                                                                                                                                                                                                        |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| forward                          |                                                                                                                                                                              |                                                                                                                                                                               | evaluated according to standard ISO 7176-1:2014, so the different static stability will not impact the safety and effectiveness                                                                                                                        |
| Static stability rearward        | 14.5°                                                                                                                                                                        | 20.1°                                                                                                                                                                         |                                                                                                                                                                                                                                                        |
| Static stability sideways        | 18°                                                                                                                                                                          | 15.3°                                                                                                                                                                         |                                                                                                                                                                                                                                                        |
| Max. loading (kg)                | 275lbs(125kg)                                                                                                                                                                | 265lbs (120kg)                                                                                                                                                                | Similar<br>The difference will not raise any new safety and effectiveness concerns.                                                                                                                                                                    |
| Maximum safe operational incline | Maximum safe operational incline for posteriorly is >40°<br>Maximum safe operational incline for anteriorly is 14.5°<br>Maximum safe operational incline for sideways is 18° | Maximum safe operational incline for posteriorly is 20.1°<br>Maximum safe operational incline for anteriorly is 30°<br>Maximum safe operational incline for sideways is 15.3° | Larger safe operational incline of subject brings more convenient for the use environment                                                                                                                                                              |
| Min. Turning radius              | 1500mm                                                                                                                                                                       | 1200mm                                                                                                                                                                        | The little difference in the turning radius will bring more convenience when it turns. The difference will not raise any new safety and effectiveness concerns.                                                                                        |
| Minimum braking distance         | 1.2m for the speed of 6.4km/h<br>1s                                                                                                                                          | 1.1 m for the speed of 6km/h<br>1s                                                                                                                                            | Similar                                                                                                                                                                                                                                                |
| Max Speed Forwards               | 1.8 m/s (6.4 km/h)                                                                                                                                                           | 1.67m/s (6 km/h)                                                                                                                                                              | The devices are evaluated according to standard ISO 7176-6:2018, so the different will not impact the safety and effectiveness                                                                                                                         |
| Max. Speed Backward              | 0.7 m/s (2.5 km/h)                                                                                                                                                           | 0.83m/s (3 km/h)                                                                                                                                                              | The devices are evaluated according to standard ISO 7176-6:2018, so the different will not impact the safety and effectiveness                                                                                                                         |
| Controller                       | Yangzhou Jinnew Electronic Technology co., ltd.<br>FY05-7-F                                                                                                                  | British PG Controller<br>PG45A                                                                                                                                                | Although different controller is used, both the control system, including the electromagnetic brakes and the user interface are similar. Both devices have the same user interface, the patient uses the foldable tiller handle/handlebar for steering |

|                      |                       |                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------------|-----------------------|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                      |                       |                       | and a thumb operated potentiometer throttle control lever located at the top of the tiller to engage and disengage the scooter motion in both the forward and reverse directions. When the throttle control lever is released, the electromagnetic brake will be actuated and the scooter is slow to stop. The speed mode of the both devices was single mode and the speed control dial can control the maximum speed. Both of the control systems are evaluated according to standard ISO 7176-14:2008 and software validation requirement and there are no new safety and effectiveness concerns due to the difference. |
| Wheel Lock<br>(type) | Electromagnetic brake | Electromagnetic brake | Same                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

**Table 3 - Safety Comparison**

| Item                                          | Proposed Device                                                                                                                                                                                 | Predicate Device                                                                                                                                              | Remark                                                                                                                                     |
|-----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| Materials contacting user                     | Hand grips: PVC;<br>Backrest (Back support): PVC, sponge;<br>Armrest (Arm support): PVC, sponge;<br>Seat: PVC, sponge;<br>Foot support pad: PEVA;<br>Throttle controller lever: ABS.            | Armrest: PU Foamed;<br>Backrest/seat: Leather package<br>Footplates: ABS plastics                                                                             | Biocompatibility evaluation has been carried out per ISO 10993-1. There are no new safety and effectiveness concern due to the difference. |
| Biocompatibility of materials contacting user | Comply with ISO 10993-1, FDA Guidance, Tests included:<br>Cytotoxicity (ISO 10993-5:2009),<br>Skin Sensitization test (ISO 10993-10:2021)<br>Intracutaneous Reactivity Test (ISO 10993-23:2021) | Comply with ISO 10993-1, FDA Guidance, Tests included:<br>Cytotoxicity (ISO 10993-5:2009),<br>Sensitization and Intracutaneous Reactivity (ISO 10993-10:2010) | Same                                                                                                                                       |

**Summary of substantial equivalence discussion:**

Despite of the above differences, the two devices all completed the performance tests in accordance with ISO 7176 series standards. There are no safety and effectiveness aspects concerned. In conclusion, the technological characteristics, features, specifications, materials, mode of operation, and intended use of the device substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

**10.0 Conclusion**

The conclusions drawn from the comparison and analysis above demonstrate that the subject device K242982 is as safe, as effective, and performs as well as the legally marketed predicated device in K201196 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.