September 3, 2020

21st Century Scientific, Inc.
RD Davidson
COO
4931 N Manufacturing Way
Coeur d'Alene, Idaho 83815

Re: K193599
Trade/Device Name: BOUNDER 300 Power Wheelchair, BOUNDER Plus 300 Power Wheelchair, BOUNDER 450 Power Wheelchair, BIG BOUNDER 600 Power Wheelchair, BIG BOUNDER 1000 Power Wheelchair
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 11, 2020
Received: August 12, 2020

Dear RD Davidson:

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, Ph.D.
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193599

Device Name
BOUNDER Series Power Wheelchair. Models: BOUNDER 300, BOUNDER Plus 300, BOUNDER 450, BIG BOUNDER 600, BIG BOUNDER 1000

Indications for Use *(Describe)*
The indication for use of the BOUNDER Power Wheelchair is to provide mobility to persons limited 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5

510(k) SUMMARY

BOUNDER Power Wheelchair

SUBMITTER per 21 CFR 807.92(a)(1):

21st Century Scientific, Inc.
4931 N Manufacturing Way
Coeur d'Alene, ID 83815
Phone: (208) 667-8800
Email: rdd@wheelchairs.com

Contact Person

RD Davidson, COO

Manufacturer

21st Century Scientific, Inc.
4931 N Manufacturing Way
Coeur d'Alene, ID 83815

FDA Registration number of Manufacturer

2027797

DATE PREPARED **per 21 CFR 807.92(a)(1):**

November 15, 2019

PRIOR SUBMISSIONS

The previous 510(k) for the BOUNDER series power wheelchair was K90210.

Section 5...: 510(k) Summary (continued)

DEVICE INFORMATION per 21 CFR 807.92 (a) (2)

Name of Device.....: BOUNDER Series Power Wheelchair. Models: BOUNDER 300, BOUNDER Plus 300, BOUNDER 450, BIG BOUNDER 600, BIG BOUNDER 1000

Common or Usual Name.....: Wheelchair, Powered

Classification Name.....: Powered Wheelchair 21 CFR § 890.3860

Product Code.....: ITI

Classification of New Device.....: Class II

Patient Population.....: Physically Challenged Persons

PREDICATE DEVICE per 21 CFR 807.92 (a) (3)

Name of Device.....: AMYPOWER ALLTRACK Series Power Wheelchair (K092225)

Common or Usual Name.....: Wheelchair, Powered

Classification Name.....: Powered Wheelchair 21 CFR § 890.3860

Product Code.....: ITI

Classifications of Predicate Device: Class II

Patient Population.....: Physically Challenged Persons

DEVICE DESCRIPTION per 21 CFR 808.92(a)(4)

The subject device is an update to the existing previously cleared BOUNDER Power Wheelchair (K901210). The BOUNDER utilizes components found on most power wheelchairs. These include a rigid or "non-folding", rear wheel drive power wheelchair base with two drive wheels in the rear with two anti-tip wheels mounted behind and two casters in the front. It has two motors and is powered by two 12V DC Batteries (connected in series), and electronic controller. It also includes a seat, footrests, arms, positioning strap and charger. The design offers a modular approach and can be configured in multiple versions to suit different user needs.

The new models will include: BOUNDER 300, BOUNDER Plus 300, BOUNDER 450, BIG BOUNDER 600 & BIG BOUNDER 1000.

The updated subject version of the BOUNDER Power Wheelchair has the following changes:

- Increase in the weight capacity of the previously cleared device from 500 lb to 1000 lb
- Add Power Tilt, Power Anterior Tilt, Power Recline and Power Seat Elevator options
- Addition of LiNX and R-net electronics
- Add Independent Drive Wheel Suspension
- Add an Off-Road tire option for BOUNDER 300, BOUNDER Plus 300 and BOUNDER 450
- Top speed: 8.5 mph

Section 5...: 510(k) Summary (continued)

INTENDED USE per 21 CFR 807.92(A)(5):

The intended use of the BOUNDER Power Wheelchair and the predicate device is to provide mobility to persons limited to a sitting position.

INDICATIONS FOR USE per FORM FDA 3881:

The indication for use of the BOUNDER Power Wheelchair is to provide mobility to persons limited to a sitting position.

COMPARISON OF DEVICE TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICE per CFR 807.92(A)(6):

The device comparison showed that the subject device is substantially equivalent in design, materials, and operational principles to the previously cleared predicate device in regard to providing mobility to persons limited to a sitting position. There is no difference in intended use and indications for use between the predicate device and the subject device.

This device has similar technological characteristics as the predicate device. Both devices utilize steel and aluminum in their frames and components, and standard foams and covers for seat cushions and backs. The user controls the chair by using a joystick or other equivalent command mode through a controller. It includes two motors and operates at 24 Volts using rechargeable batteries as a source of energy. The operating speeds, maneuverability, power modules, hand controls, seat types, and climbing ability are substantially equivalent. Both the BOUNDER Power Wheelchair and the predicate are recommended for indoor and outdoor use. The standard accessories and components are common to all power wheelchair devices.

BASIS OF SUBSTANTIAL EQUIVALENCE per 21 CFR 807.100(b)(2)(3):

The substantial equivalence of the subject device was determined as per the FDA guidance document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" and the technological characteristics which include materials, design, and other device related features, as defined in section 513(i)(1)(B) of the FD&C Act and 21 CFR 807.100(b)(2)(ii)(A). The subject device components are as safe and effective as the predicate device and do not raise different questions of safety and effectiveness. The design verification and validation testing, device comparison, and dimensional analysis demonstrates that the subject device components are substantially equivalent to the predicate device.

DESIGN VERIFICATION AND VALIDATION TESTING DATA

Design verification and validation testing was performed on the subject device and was found to meet performance requirements. Further, it is substantially equivalent to the predicate device identified throughout this submission and does not raise any new questions of safety and effectiveness. The acceptance criteria for the full verification of the design and acceptance criteria for each section of the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) testing standard have been met.

Non-Clinical Test per 21 CFR 807.92(b)(1) Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) testing was performed to demonstrate that the BOUNDER Power Wheelchair meets the performance requirements and is substantially equivalent to the predicate device identified throughout this submission and do not raise any new questions of safety and effectiveness.

The following testing was performed according to FDA recognized consensus standards:

- ANSI/RESNA WC-1:2009 Section 1: Determination of Static Stability
- ANSI/RESNA WC-2:2009 Section 2: Determination of Dynamic Stability of electrically Powered Wheelchairs
- ANSI/RESNA WC-2:2009 Section 3: Determination of Effectiveness of Brakes
- ANSI/RESNA WC-2:2009 Section 4: Energy Consumption of Electrically Powered Wheelchairs and Scooters for Determination of Theoretical Distance Range
- ANSI/RESNA WC-1:2009 Section 5: Determination of Dimensions, Mass and Maneuvering Space
- ANSI/RESNA WC-2:2009 Section 6: Determination of Maximum Speed, Acceleration and Deceleration of Electrically Powered Wheelchairs
- ANSI/RESNA WC-1:2009 Section 7: Method of Measurement of Seating and Wheel Dimensions
- ANSI/RESNA WC-1:2009 Section 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths
- ANSI/RESNA WC-2:2009 Section 9: Climatic Tests for Electrically Powered Wheelchairs
- ANSI/RESNA WC-2:2009 Section 10: Determination of Obstacle-Climbing Ability of Electrically Powered Wheelchairs
- ANSI/RESNA WC-1:2009 Section 11: Test Dummies
- ANSI/RESNA WC-1:2009 Section 13: Determination of Coefficient of Friction of Test Surfaces
- ANSI/RESNA WC-2:2009 Section 14: Power and Control Systems for Electrically Powered Wheelchairs
- ANSI/RESNA WC-1:2009 Section 15: Requirements for Information Disclosure, Documentation and Labeling
- ANSI/RESNA WC-1:2009 Section 16: Resistance to Ignition of Upholstered Parts
- ANSI/RESNA WC-2: 2009 Section 21: Requirements and Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Motorized Scooters
- ANSI/RESNA WC-1:2009 Section 22: Set-up Procedures
- ISO 7176-30:2018[E] Part 30: Wheelchairs for Changing Occupant Posture

Verification testing demonstrated that the BOUNDER Power Wheelchair is substantially equivalent to the marketed predicate device.

Animal Study

Animal testing was not required for this submission.

Clinical Testing

Clinical testing was not required for this submission.

CONCLUSIONS per 21 CFR 807.92(b)(3)

The subject device has the same intended use and technological characteristics as the predicate device. The design verification and validation data support the safety and performance of the subject device and demonstrate that the subject device will perform as intended in the specified use conditions. Therefore, the subject BOUNDER Power Wheelchair is comparable with the previously cleared AMYPOWER ALLTRACKS Series Power Wheelchair and demonstrates a basis of substantial equivalence.