January 21, 2022

PowerBaseTec GmbH
% Juliane Dinter, PhD
Consultant (Lead Project Manager)
QiP GmbH
Struveweg 40
Ludwigsfelde, 14974
Germany

Re: K203761
Trade/Device Name: ParaMotion
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup Wheelchair
Regulatory Class: Class II
Product Code: IPL
Dated: November 25, 2021
Received: December 3, 2021

Dear Dr. Juliane Dinter:

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)*
K203761

Device Name
ParaMotion

Indications for Use *(Describe)*
• Any individual who needs a power wheelchair and can not stand up on their own such as people with paraplegia, spina bifida, cerebral paresis, multiple sclerosis, muscular dystrophy and polio
• any individual to take part in sports activities requiring an upright 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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This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807.92.

Contact Information

Date of preparation	January 2022
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Application Correspondent (Consultant)

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Alternate Contact	Dr. rer. medic. Juliane Dinter Lead Project Manager
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Phone	+49 3378 2055 180
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Subject Device

Trade Name	ParaMotion
Common Name	Standup Wheelchair
Classification Name	Wheelchair, Standup
Regulatory Number	21 CFR 890.3900
Product Code	IPL
Device Class	II

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info@powerbasetec.de

Review Panel	Physical Medicine

Predicate Device

Trade Name	ParaGolfer
Common Name	Standup Wheelchair
Classification Name	Wheelchair, Standup
Regulatory Number	890.3900
Product Code	IPL
Device Class	II
Review Panel	Physical Medicine
510(k) number	K060936
Clearance	August 07, 2006

Subject Device Description

The ParaMotion is an all-terrain electric wheelchair with an integrated standing function.
All functions are controlled via the joystick control panel. Strong electric motors on the front wheels with wide terrain tires ensure safe handling, and obstacles are overcome easily. The ParaMotion is steered by targeted control of the drive wheels with appropriate operation of the joystick. The dual rear wheel is freely mounted on a steering shaft and thus has a 360° turning radius. This ensures excellent manoeuvrability of the ParaMotion.
The joystick control panel also manages the standing function in addition to the driving functions. An electric motor ensures adjustment of the seat from the horizontal position to the upright position. At the same time, the angle of the backrest and the hinges of the leg support are adjusted so that the operator assumes an upright position in the end position. Thanks to the infinitely variable linear motor, any position between the seated position and the standing position can be assumed.
All control functions are carried out by means of an R-Net wheelchair control. Thanks to the easy programmability of the R-Net system, the driving functions can be adapted to suit the user's needs.

Indications for Use

- Any individual who needs a power wheelchair and can not stand up on their own such as people with paraplegia, spina bifida, cerebral paresis, multiple sclerosis, muscular dystrophy and polio
- any individual to take part in sports activities requiring an upright position

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Intended Use Statement

The sports wheelchair is designed solely for persons who are unable to walk or have a walking impediment for doing indoor or outdoor sports that require an upright body position. The ParaMotion was specially designed for users who are able to independently move in a sports wheelchair.

Comparison with Predicate Device

The ParaMotion is substantially equivalent to the ParaGolfer Otto Bock HealthCare, cleared on August 07, 2006 as K060936.
The ParaMotion is the follow-on device of the ParaGolfer and was designed on the technical basis by the company PowerBaseTec. The ParaMotion has the identically constructed drives, batteries and performance data and is based on the Design of the ParaGolfer. The control technology was replaced by an advanced control technology from Curtis Wright (R-NET). The stand-up unit (seat unit) was developed based on the stand-up unit of the ParaGolfer and optimized in order to improve he usability of the user (for instance an active seat shifting for Decubitus prevention was integrated) and to ensure more efficient repairs by trained technicians. The intended use and the intended users are identical for both devices (ParaGolfer and ParaMotion). Based on technical, clinical and biological characteristics the ParaMotion is substantially equivalent to the ParaGolfer and may be viewed as follow-up product.

The following table provides a comparison of technological characteristics with the predicate device and the reference device to demonstrate substantial equivalence.

Characteristic	**Subject Device**	**Predicate Device K060936**	**Justification for Substantial Equivalence**
Manufacturer	PowerBaseTec GmbH	Otto Bock	Not applicable
Model	ParaMotion	ParaGolfer	Not applicable
Device Classification	Class II		Identical
Classification Panel	890.3900, IPL		Identical

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Characteristic	Subject Device	Predicate Device K060936	Justification for Substantial Equivalence
Regulation Name	Physical Medicine Devices, Physical Medicine Prosthetic Devices Standup Wheelchair		Identical
Indications for Use	• Any individual who needs a power wheelchair and can not stand up on their own such as people with paraplegia, spina bifida, cerebral paresis, multiple sclerosis, muscular dystrophy and polio • any individual to take part in sports activities requiring an upright position	• Any individual who needs a power wheelchair and can not stand up on their own such as people with paraplegia, spina bifida, cerebral paresis, multiple sclerosis, muscular dystrophy and polio • any individual to take part in sports activities requiring an upright position	Identical
Intended Use Statement	The sports wheelchair is designed solely for persons who are unable to walk or have a walking impediment for doing indoor or outdoor sports that require an upright body position. The ParaMotion was specially designed for users who are able to independently move in a sports wheelchair.	The ParaGolfer Standup Wheelchair is a front wheel drive powered standup wheelchair with an air-filled rear wheel for active users. These wheelchairs provide mobility to physically challenged persons. The wheelchair can be moved by the user operating the Curtis Instruments MC-2 Control System that is connected to the Micro Motor. The wheelchair is steered by different rotation of the rear wheel. It features a servo-steering with release mechanism. The ParaGolfer has an integrated stand-up	The intended use of the subject and predicate device is similar.

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		function. When actuating the standup function via the control console, a motorized lifting device moves the seat of the ParaGolfer from a horizontal to vertical position. At the same time the angles on the backrest and footrest adapt in such a way that the user is brought to an upright posture.	
Characteristic	**Subject Device**	**Predicate Device K060936**	**Justification for Substantial Equivalence**
Patient Population	active handicapped users or disabled people unable to walk	Information not publicly available	Identical
Intended Users	active handicapped users or people unable to walk	Information not publicly available	Identical
Frame material	• Base frame- Steel powder Coated • Seat frame- Steel powder Coated and Aluminium Powder Coated • Covering- GRP laminate with gelcoat coating	Information not publicly available	Similar with differences; not clinical relevant due to ISO 10993-series compliance.
Frame Design/ Style	U frame	Information not publicly available	Identical
Folding mechanism	No, backrest and footrest for transport	Information not publicly available	Very similar in terms of folding of the backrest and the footrest only for the subject device. Not clinically relevant in terms of safety and performance.

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Seating design	mechanical seat construction with stand-up function	Information not publicly available	Identical
Seating attachment (integrated, power base, specialty power)	integrated	Information not publicly available	Identical
Overall Dimensions	-	-	-
Length (when driving forward): Total length (packing size)	When driving forward:1620mm Total length:1375mm	Information not publicly available	Different but no clinical relevant of critical differences for the user and therefore

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Characteristic	Subject Device	Predicate Device K060936	Justification for Substantial Equivalence
			no adverse impact on safety and effectiveness of the subject device.
Width	900 mm	Information not publicly available	Identical
Height	1010 mm (in sitting position – depending on the position of the backrest)	Information not publicly available	Different. The subject device has a longer total height than the predicate device. A different height is not clinically relevant or has critical differences for the user. The different has therefore no adverse impact on safety and effectiveness of the subject device.
Seat dimensions	-	-	-
Seat width	295 – 465 mm	Information not publicly available	Identical
Seat depth	340 – 520 mm	Information not publicly available	Identical with a different range.
Seat height	500 – 645 mm	Information not publicly available	The subject device has a smaller seat height than the predicate device.
Weight	40,2 kg	Information not available	No comparison possible. Due to similar wheelchair weight this information is not clinically relevant.
Wheelchair Weight	212,2 kg	Information not publicly available	Subject device is heavier than the predicate device. Not relevant in terms of intended purpose.
With batteries	80 kg	Information not publicly available	Identical
Without batteries	132,2 kg	Information not publicly available	Subject device is heavier than the predicate device. Not relevant in terms of intended purpose.

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Controller	120 Amps	Information not publicly available	The subject device has a smaller controller
Characteristic	**Subject Device**	**Predicate Device K060936**	**Justification for Substantial Equivalence**
			output than the predicate device.
Drive style (e.g. rear, mid, front)	front	Information not publicly available	Identical
Motor type	2 DC Motors pulse width modulation	Information not publicly available	Identical
Motor output	550 W (24V)	Information not publicly available	Identical
Batteries	-	-	-
Quantity	2	Information not publicly available	Identical
Type	2 x gel battery 12 V 93,5 Ah (C5)	Information not publicly available	Identical
Chemistry	Lead acid	Information not publicly available	Identical
Range per Charge (off-road, golf course*)**	approx. 24,9 miles (40 km)	Information not publicly available	Identical
Charger Type (On-board/Off-board/Carry-on)	Off- board Swede classic 10A IP 54	Information not publicly available	Different, but no negative effect in terms of safety or performance of the subject device.
Input/Output Power	AC 115 V 60 Hz (325W) DC 10A (24V)	Information not publicly available	Identical
Actuator	Linak LA 30 12/24V DC permanent magnet motor	Information not publicly available	Identical
Brake	electromagnetic spring brake	Information not publicly available	Identical
Minimum braking distance and time	-	-	-

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<table>
<tr><td>Forward</td><td>At speed of 10,0km/h[6.2 mph] 1710 mm (on the horizontal)
2800 mm (-17° slope)

At speed of 10,0km/h[6.2 mph] 1710 mm (on the horizontal)

Time:
1,7 m/s</td><td>Information not publicly available</td><td>Identical</td></tr>
<tr><td>Reverse</td><td><table><tr><td></td><td></td></tr><tr><td>v [km/h]</td><td>s [m]</td></tr><tr><td>4</td><td>0,6</td></tr><tr><td>5</td><td>0,8</td></tr><tr><td>6</td><td>1</td></tr><tr><td>7</td><td>1,2</td></tr><tr><td>8</td><td>1,5</td></tr><tr><td>9</td><td>1,8</td></tr><tr><td>10</td><td>2,1</td></tr><tr><td>11</td><td>2,5</td></tr><tr><td>12</td><td>2,9</td></tr><tr><td>13</td><td>3,4</td></tr><tr><td>14</td><td>3,9</td></tr><tr><td>15</td><td>4,5</td></tr></table></td><td>Information not publicly available</td><td></td></tr>
<tr><td>Wheel Lock (type)</td><td>Magnetic spring loaded brake</td><td>Information not publicly available</td><td>Identical</td></tr>
<tr><td>Max speed</td><td></td><td></td><td></td></tr>
<tr><td>Forward</td><td>6.2 mph [10.0 km/h]</td><td>Information not publicly available</td><td>Identical</td></tr>
<tr><td>Reverse</td><td>2,91 mph [4,68 km/h]</td><td>Information not publicly available</td><td>Cannot be evaluated.</td></tr>
<tr><td>Rear Wheels Size</td><td>10,82 Inch (11x6.00-5)</td><td>Information not publicly available</td><td>Identical</td></tr>
<tr><td>Quantity</td><td>2</td><td>Information not publicly available</td><td>Different, bot uncritical in terms of safety and performance between subject and predicate device.</td></tr>
<tr><td>Tire pressure (if pneumatic)</td><td>recommended: 21,5 PSI
minimal:14,5 PSI
maximum: 43,51 PSI</td><td>Information not publicly available</td><td>Identical</td></tr>
</table>

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Castors size	15,35 inch (16x7.50-8)	Information not publicly available	Almost identical; no influence on safety and performance of the devices.
Quantity	2	Information not publicly available	Identical
Tire Pressure (if pneumatic)	recommended: 21,5 PSI minimal:14,5 PSI maximum: 24,65 PSI	Information not publicly available	Almost identical; no influence on safety and performance of the devices.
Anti-tip Wheels	None	Information not publicly available	Identical
Removable (Yes/No)	None	Information not publicly available	Identical
Style	none	Information not publicly available	Identical
Suspension (if applicable)	Coil Spring	Information not publicly available	Different.
Maximum Occupant Mass	140 kg (308,6 LBS)	Information not publicly available	Identical
Curb Climbing ability	no	Information not publicly available	Identical
Ground clearance	3,94 inch (10cm)	Information not publicly available	Identical
Minimum Turning Radius	1900 mm	Information not publicly available	Identical
Maximum Incline	17,2 ° (31%)	Information not publicly available	Identical
Footplates	Foldable	Information not publicly available	Different, but no influence on safety and performance of the devices.
Back Upholstery	Material identical to seat cushion	Information not publicly available	Identical
Armrest Type	Material identical to seat cushion	Information not publicly available	Identical
Operating surface & environment	off-road, golf course	Information not publicly available	Identical
Additional Accessory	Golf Bag holder Knee pad Safety belt Special Paint Seat Cushion Stow Box Inside pads	Information not publicly available	Identical
Warranty	2 years (24 month) Except wearing parts	Information not publicly available	Identical
Additional characteristics			
Seat inclination	0°	Information not publicly available	Identical

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Armrest height	155 – 245 mm (steplessly adjustable)	Information not publicly available	Identical
Armrest length	280 mm	Information not publicly available	Identical
Lower leg length	430-530mm	Information not publicly available	The subject device has a smaller lower leg length than the predicate device.
Backrest height	340 – 445 mm (steplessly adjustable)	Information not publicly available	Different, but no critical difference which is not clinically relevant and has therefor no adverse impact on safety and effectiveness of the device.
Tire size	390 mm	Information not publicly available	Identical
Characteristic	**Subject Device**	**Predicate Device K060936**	**Justification for Substantial Equivalence**
Tire size (rear tire)	275 mm	Information not publicly available	Identical
Radius turning circle	1900 mm	Information not publicly available	Identical
Drive	Electrical	Information not publicly available	Identical
Batteries	Group 24	Information not publicly available	Identical
Engines	Kolektor	Information not publicly available	Identical
Tires	Knobby-3	Information not publicly available	Identical
Rollable	Yes	Information not publicly available	Identical
Type of drive	Front-wheel drive	Information not publicly available	Identical
Control system	R-Net /Curtis-Wright	Information not publicly available	The control system of the subject device is different than the control system of the predicate device.
stand-up function	Yes	Information not publicly available	Identical
Charger / Manufacturer	Swede Electonics	Information not publicly available	The manufacturer of the charger of the subject device is different than the charger of the predicate device.

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Nominal slope	Gradeability (in sitting position*): 17° (30%) Lateral tilt stability (in sitting position*): 17° (30%)	Information not publicly available	Identical
Max. User Weight	308 lbs (140 kg)	Information not publicly available	Identical
Material	• Base frame- Steel powder Coated • Seat frame- Steel powder Coated and Aluminium Powder Coated • Covering- GRP laminate with gelcoat coating • Cushions- Foam- Polyethylene / polypropylene foams RX46065 and Alveobloc NA AB 2600	Information not publicly available	The subject device is manufacturer from different material than the predicate device.
Compliance	ISO 71776 series EN 12184 DIN EN 61429	Information not publicly available	Identical
Characteristic	**Subject Device**	**Predicate Device K060936**	**Justification for Substantial Equivalence**
	DIN EN 60529 IEC 60335-2-29 EMC		

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Performance Data

The ParaMotion conforms with the following FDA-recognized standards:

- (Recognition number 5-40) EN ISO 14971:2012 - Medical devices - Application of risk management to medical devices (ISO 14971:2007, corrected version 2007-10-01).
- (Recognition number 16-195) ISO 7176-1:2014-10 - Wheelchairs - Part 1: Determination of static stability
- (Recognition number 16-202) ISO 7176-2:2017-10 Third edition 2017-10 Wheelchairs - Part 2:Determination of dynamic stability of electrically powered wheelchairs
- (Recognition number 16-192) ISO 7176-3:2012-12 - Wheelchairs - Part 3: Determination of effectiveness of brakes
- (Recognition number 16-162) ISO 7176-4:2008-10 - Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
- (Recognition number 16-163) ISO 7176-5:2008-06 - Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
- (Recognition number 16-204) ISO 7176-6:2018-06 - Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
- (Recognition number 16-196) ISO 7176-7:1998-05 - Wheelchairs - Part 7: Measurement of seating and wheel dimensions
- (Recognition number 16-197) ISO 7176-8:2014-12 - Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
- (Recognition number16-167) ISO 7176-9:2009-11 - Wheelchairs - Part 9: Climatic tests for electric wheelchairs
- (Recognition number 16-164) ISO 7176-10:2008-11 - Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
- (Recognition number 16-190) ISO 7176-11:2012-12 Second edition 2012-12-01 Wheelchairs - Part 11: Test dummies
- (Recognition number 16-25) ISO 7176-13: First edition 1989-08-01 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
- (Recognition number 16-165) ISO 7176-14:2008-02 - Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods

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- (Recognition number 16-27) ISO 7176-15:1996-11 - Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling)
- (Recognition number 16-191) ISO 7176-16 Second edition 2012-12-01 Wheelchairs - Part 16: Resistance to ignition of postural support devices
- (Recognition number 16-166) ISO 7176-21:2009-04 - Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- (Recognition number 16-198) ISO 7176-22:2014-09 Second edition 2014-09-01 Wheelchairs - Part 22: Set-up procedures
- (Recognition number 16-194) ISO 7176-25 First edition 2013-07-15 Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs
- (Recognition number 16-206) ISO 7176 - 30 First edition 2018-12 Wheelchairs --Part 30: Wheelchairs for changing occupant posture --Test methods and requirements

Additionally, the ParaMotion complies with the following non-FDA-recognized standards

- EN 12184:2014 - Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods
- DIN EN 61429/A11:2000-01 - Marking of secondary cells and batteries with the international recycling symbol ISO 7000-1135 and indications regarding directives 93/86/EEC and 91/157/EEC
- DIN EN 60529:2014-09 - Degrees of protection provided by enclosures (IP Code)

Clinical Studies

- Clinical testing was not required to demonstrate the safety and effectiveness of the subject device.

Conclusions

The conclusions drawn from the nonclinical and clinical tests demonstrated that the device is as safe, as effective, and performs as well as or better than the legally marketed device ParaGolfer (K060936). The Paramotion and Predicate device, Paragolfer are substantially equivalent.

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