510(K) SUMMARY

510(k) #: K111636

APR - 3 2012

Submitter: Gunnell, Inc.
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Contact Person: Chris Chen, Ph.D.

DEVICE IDENTIFICATION

Proprietary names: Collectively referred to as the Gunnell Rehab Series Wheelchairs (GRSW)

- Rehab Tough and Tilt (TNT)
- Rehab Recline and Mobility (RAM)
- Rehab Multi-Adjustable Chair (MAC)
- Rehab Kidster (Kidster).
- Bariatric Rehab Tough and Tilt (BTNT)
- Bariatric Rehab Recline and Mobility (BRAM)

Generic name: Manual Wheelchair

Classification Name: Wheelchair, Mechanical

Regulatory Class: Class I

Product Code: IOR

Identification of Predicate Devices:

PDG Eclipse 400	(#K971389)	5/9/1997
PDG Stellar	(#K990557)	3/22/1999
PDG Eclipse 600	(#K961743)	5/29/1996
Freedom CGX	(#K080270)	4/16/2008
PDG Fuze T50 Jr.	(#K063736)	1/17/2007

INTENDED USE

The purpose of The Gunnell Rehab Series Wheelchairs is to provide mobility to individuals limited to a seating position. They may also be used as attendant propelled transport devices in a health care environment such as a hospital, nursing home or

extended care facility. The Kidster is the only device in the GRSW that is solely intended for pediatric users.

DEVICE DESCRIPTION

The Gunnell Rehab Series of Wheelchairs (GRSW) are manually operated, mechanical wheelchairs. The GRSW are fabricated from materials common to many other wheelchairs in the industry. In addition, the GRSW offer the same options and exhibit the same features as many other mechanical wheelchairs in the market. The entire GRSW feature a recline function. The TNT, MAC, and Kidster include a tilt in space feature, which allows the upper frame of the wheelchair to be tilted. This feature is used to provide pressure relief as well as comfort to those users who may be confined to the wheelchair for extended periods of time. The tilt feature can also serve as an attendant aid in those situations where a patient needs to be tilted for attendant access. The TNT, RAM, and Kidster also have an optional lateral tilt feature allowing for 20° lateral tilt to the right and left. The lateral tilt feature is helpful in positioning individuals with a number of different conditions. For example, this feature allows for the seat to be on a lateral angle in response to the angle or degree of scoliosis exhibited by the user thereby providing better positioning for long term usage. The TNT and the RAM are available in bariatric sizes, featuring the same options and construction as that of their respective standard models.

SAFETY AND EFFECTIVENESS

The Gunnell Rehab Series of Wheelchairs have been developed based on extensive knowledge and experience gained by providing mobility for individuals requiring assistive technology since the introduction of Gunnell Inc. in the late 1950's. This knowledge and experience has provided many satisfied individuals with durable and safe wheelchairs through the years. The GRSW are fabricated from the same materials as many wheelchairs in the industry, and offer many of the same features and options. Additionally, the GRSW successfully tested in accordance with the applicable parts of ISO 7176 (1, 3, 5, 7, 8, and 15) which includes testing for static, impact and fatigue strengths.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Gunnell Incorporated
% Chris Chen, Ph.D.
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P.O. Box 308
Millington, Michigan 48746

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Re: K111636
Trade Name: Rehab Tough and Tilt (TNT)
Bariatric Rehab Tough and Tilt (BTNT)
Rehab Recline and Mobility (RAM)
Bariatric Rehab Recline and Mobility (BRAM)
Rehab Multi-Adjustable Chair (MAC)
Rehab Kidster (Kidster)
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: March 23, 2012
Received: March 27, 2012

Dear Dr. Chen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K111636**

Device Name: **Rehab Tough and Tilt (TNT)**
Bariatric Rehab Tough and Tilt (BTNT)
Rehab Recline and Mobility (RAM)
Baritric Rehab Recline and Mobility (BRAM)
Rehab Multi-Adjustable Chair (MAC)
Rehab Kidster (Kidster).
***All of the above, collectively referred to as the Gunnell Rehab Series Wheelchairs* (GRSW).**

Indications For Use: **The intended use of all of the GRSW's is to provide mobility to individuals restricted to a sitting position.**

Prescription Use _____ OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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