

JAN 6 2006

K052548

510(k) SUMMARY

**AMG Medical Inc.'s
URok Rocking Wheelchair**

Submitter's Name, address, Telephone Number, Contact Person and Date Prepared

AMG Medical Inc.

8505 Dalton

Montreal, Canada

H4T 1V5

Phone: 514-737-5251

Fax: 514-737-6572

Contact Person: Kenneth Levesque
Director, RA/QA

Date Prepared: September 07, 2005

Name of Device and Name/Address of Sponsor

URok Rocking Wheelchair

AMG Medical Inc.

8505 Dalton

Montreal, Canada

H4T 1V5

Phone: 514-737-5251

Fax: 514-737-6572

Common or Usual Name: Manual Wheelchair

Classification Name: Wheelchair, Mechanical 89IOR

Predicate Devices:

The URok Rocking Wheelchair is substantially equivalent to the RxRocker (K902438) wheelchair for the rocking feature.

The URok Rocking Wheelchair is substantially equivalent to the Invacare Solara wheelchair for the pressure redistribution feature.

Background

In 2001 AMG Medical Inc. purchased all rights to the RxRocker Corp. with the exception of the following: AMG granted RxRocker Corp. the right to continue to sell the RxRocker only to the US Government (including the Veteran's Administration and US military hospitals under the patents and existing technology and know how found the RxRocker wheelchair.

5-1

In consideration of the above sales agreement and continuing sales of the original 510k device, AMG is not submitting this 510k for a change to an existing device but rather submitting for a new 510k premarket approval referencing the RxRocker as a predicate device.

Intended Use:

The URok Rocking Wheelchair is intended to provide mobility to persons limited to a sitting position while the rocking mechanism is locked in an upright position.

The wheelchair is intended to redistribute pressures exerted on the buttocks and lower back when rocking or tilted at an angle.

The wheelchair is intended to provide comfort adjustment while rocking or tilted at an angle.

Technological Characteristics

The AMG Medical Inc. URok Rocking Wheelchair is a manually operated, attendant or user propelled, mechanical rocking wheelchair. The device is a lightweight wheelchair, suitable for both indoor and outdoor use.

The device consists of an aluminum frame, one size of rear wheel, and smaller front pivoting casters for steering and turning. The frame is constructed from aluminum tubing that is TIG-welded. This device is a rigid, non-folding type of wheelchair that incorporates a padded, sling style seat. The upholstery meets the requirements of ISO 7176-16, flammability standards.

The AMG URok Rocking Wheelchair includes a rocking feature which permits dynamic pressure management of the seating pressure upon the buttocks. The rocking feature is realized by the placement of two vertically positioned fiberglass leaf springs, which are connected to the seat and frame, under the seat's centre of gravity. The balance of the seat upon the springs is precise enough so that the rocking motion may be initiated by the user simply by gently moving the head backward and forward. Safety features such as anti tippers and rock arrestors limit the arc of the rocking motion. The rocking feature can be "locked out" by an attendant so that the device can be used as a wheelchair with no rocking motion.

The AMG URok wheelchair also has a "tilts in space" feature. The rocking mechanism can be locked in multiple positions to provide "tilt in space" that permits persons to be tilted backwards thereby allowing gravity to hold them in position. This is used to help in positioning, comfort, or head control. The tilt in space is initiated by the attendant pushing down on the push handles to tilt the seat and back and locking out the rocking action when the desired angle of tilt is reached.

The rocking feature is released or is locked out by two cable controlled pins that insert into holes within two vertically mounted metal plates located under the seat support tubes. The cables are controlled using bicycle brake type levers mounted on the rear push tube or handle.

Substantial equivalence:

The AMG URok Rocking Wheelchair is substantially equivalent to numerous manual, mechanical wheelchairs currently in the marketplace, for which FDA has granted marketing clearance through the 510(k) premarket notification process. More specifically the AMG rocking wheelchair is substantially equivalent to the RxRocker (K902438) wheelchair for its rocking feature and to the Invacare Solara wheelchair for its pressure redistribution feature.

Each of the products is manually operated, attendant or user propelled with the same intended functions and uses which are to provide mobility to persons that may be limited to a seated position and to provide pressure relief. Additionally, in one wheelchair pressure relief is achieved either by rocking or by "tilt in space" (URok Rocking Wheelchair) and in the other wheelchair pressure redistribution is achieved solely by "tilt in space" (Invacare Solara).

Performance data:

The AMG URok Rocking Wheelchair meets the performance requirements specified in the ANSI/RESNA WC series of wheelchair requirements.

Pressure redistribution obtained while rocking was observed and recorded using adult human volunteers seated on a pressure recording mat placed upon the seat cushion.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 2006

Mr. Kenneth Levesque
A.M.G. Medical, Inc.
8505 Dalton
Montreal, Quebec
H4T 1V5
CANADA

Re: K052548

Trade/Device Name: URok rocking wheelchair, Model 700-4xx
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: II
Product Code: IOR
Dated: December 21, 2005
Received: December 22, 2005

Dear Mr. Levesque:

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.

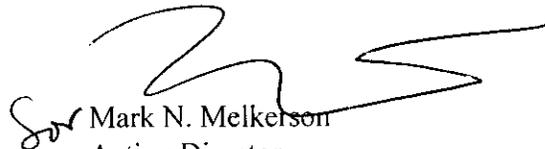
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: URok Rocking Wheelchair

Indications for Use:

The URok Rocking Wheelchair, by AMG Medical Inc., is intended to provide mobility to persons limited to a sitting position while the rocking mechanism is locked in an upright position.

The wheelchair is intended to redistribute pressures exerted on the buttocks and lower back when rocking or tilted at an angle.

The wheelchair is intended to provide comfort adjustment while rocking or tilted at an angle.

AMG Medical inc. recommends that an accredited rehabilitation or occupational therapist and supplier evaluate all customers of its products.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

Page 1 of 1

4 - 1

510(k) Number K052548