

DEC 17 1999



Rehabilitation Technologies Division

Applied Resources Corp.

October 6, 1999

~~K993443~~

K993443

1052

RE: 510(k) Summary

Submitter's Name, Address, Phone number:

Rehabilitation Technologies Division
1275 Bloomfield Avenue
Fairfield, New Jersey 07004
973-575-0650, fax: 973-575-0704

Contact Person:

Richard M. Mahoney
Director of Business Development

Date Prepared:

October 6, 1999

Common Names:

Rehabilitation Robot
Wheelchair Robot
Assistive Robot
Telethesis
Robotic Aid
Powered Arm
Electric Reacher

Proprietary/Trade Name:

RTD Arm

Classification Name:

Prosthesis

K993443

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Predicate Devices:

<u>Device Name</u>	<u>Company</u>	<u>510(k)</u>
Helping Hand	Kinetic Rehabilitation Instruments	K954427
Prehensile Hand	Therapeutic Recreation Systems	K791931

Description:

The RTD Arm is a wheelchair-mountable powered electromechanical arm which permits persons with severe disabilities to manipulate objects in their personal environment. The RTD Arm is controlled through standard switch-based input devices and can be mounted on either side of most powered wheelchairs. At full reach (48 inches), the RTD Arm can lift four pounds and, as the arm is retracted, the lifting capacity becomes proportionally greater. The arm has 4 degrees of freedom to enable the arm to access an object, which is augmented by the two planar degrees of freedom of the wheelchair.

Using the RTD Arm input control device, the operator retrieves an object by guiding the arm one joint at a time until it is in the correct position. The operator then activates the gripper to grasp the object and directs the arm to the desired end point. The arm can be operated by the user's existing chair switch mechanism (e.g. joystick, head pad sensor, or sip and puff), with wiring modifications, or with the 8 Position Joystick or Keypad provided with the arm. The arm includes four 24V motors controlled by a solid state motor controller powered by the wheelchair battery. Wheelchair installation is performed using a mounting bracket, which secures the unit to the chair frame directly behind the front caster.

The RTD Arm includes the following primary safety features:

Gripper strength limit. limited to 5 pounds per square inch.

Slip clutches. All joints include an in-line, maintenance-free slip clutch at each motor which begin to slip when 5 pounds per square inch is exerted by the arm.

Low center of gravity. The center of gravity of the arm is kept very low on the wheelchair by mounting it under the seat behind the front wheels. In most cases, the center of gravity of the overall chair and arm is lower than without the arm.

Intended Uses:

The RTD Arm is designed to be mounted on a powered wheelchair, and used to carry out simple manipulation tasks.



DEC 17 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Richard M. Mahoney
Director of Business Development
Rehabilitation Technologies Division
1275 Bloomfield Avenue
Fairfield, New Jersey 07004

Re: K993443
Trade Name: RTD Arm Assistive Robotic Device
Regulatory Class: II
Product Code: ITI
Dated: October 7, 1999
Received: October 12, 1999

Dear Mr. Mahoney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

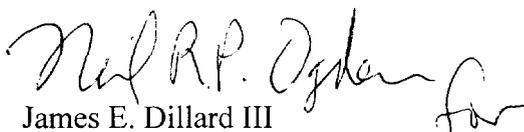
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Richard M. Mahoney

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III". The signature is written in a cursive style and is positioned above the typed name.

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER (IF KNOWN): K993443

DEVICE NAME: RTD ARM ASSISTIVE ROBOTIC DEVICE

INDICATIONS FOR USE:

The RTD Arm permits persons with severe disabilities to manipulate objects in their personal environment and thus to establish a greater measure of functional independence. The client population for this device includes individuals with

- very limited or complete absence of bilateral upper extremity function,
- lower extremity impairment requiring the use of a power wheelchair, and
- intact cognitive and visual perceptual ability.

The medical diagnoses of the target user populations include high-level quadriplegia, neuromuscular disabilities, cerebral palsy, and other congenital disabilities such as spina bifida, or arthrogyposis.

In addition, individuals with other types of disabilities resulting in permanent or temporary impairment to upper extremity function may also benefit from use of the RTD Arm as an aid in performing manipulation of objects. These disabilities include paraplegia, stroke, severe head injury, multiple broken bones, and severe rheumatoid arthritis, among others.

The RTD Arm may be purchased as an over-the-counter device.

(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 **General Restorative Devices**

510(k) Number _____

NRO for

K993443

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)