

JAN 28 1999

A/RT - ActivX Wheelchair  
510(K) Premarket Notification

K984367

**VI. 510(K) SUMMARY**

**Submitter:** Adorno/Rogers Technology, Inc.  
PO Box 160337  
Austin, TX 78716  
512-474-7267  
Fax: 512-476-6460

**Contact Person:** Paul Gibb

**Date of Preparation:** December 3, 1998

**Common Name:** Mechanical Folding Wheelchair (per 21 CFR section 890.3850)

**Proprietary Name:** ActivX

**Predicate Device:** Quickie2 (K890050)

**Intended Use:** Wheelchair mobility, either self-propelled or propelled by an attendant, for the physically impaired.

**Device Description:** The wheelchair is a standard lightweight manual folding chair that provides mobility based on an individual user's needs and capabilities. Since it has the same intended use as typical wheelchairs, its features are also comparable. A sling seat and backrest are affixed to a sturdy frame that is supported by two large rear wheels and two forward swivel caster wheels. The two side frames are connected by a horizontal cross brace, rather than a vertical cross brace, that can assume a folded configuration. The wheelchair accommodates removable armrests, detachable footrests, rear anti-tippers, push handles, and wheel locks.

**Comparison With Predicate Device:** The ActivX wheelchair and the predicate device have an identical intended use and are identical with respect to the way the user propels and maneuvers the chair. The dimensions, construction materials, and standard features/options of the two chairs are substantially equivalent. The only difference between the A/RT chair and the predicate device is in the way the chairs are opened and folded. The A/RT chair has a horizontal cross brace, rather than the typical vertical cross brace of most folding wheelchairs. This new feature has been tested for Design Validation/Verification and has performed acceptably. The results of the ANSI/RESNA two-drum test and subject evaluations support a determination of "substantially equivalent" for the ActivX wheelchair.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 28 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Paul Gibb  
Vice President and Chief Operating Officer  
Adorno/Rogers Technology, Inc.  
P.O. Box 160337  
Austin, Texas 78716

Re: K984367  
Trade Name: ActivX  
Regulatory Class: I  
Product Code: IOR  
Dated: December 3, 1998  
Received: December 7, 1998

Dear Mr. Gibb:

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.

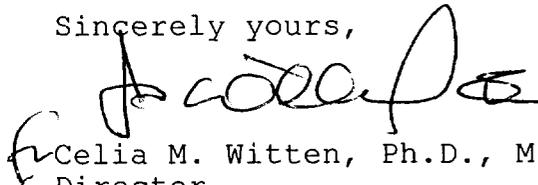
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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,



Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K984367

DEVICE NAME: Mechanical Folding Wheelchair - ActivX

INDICATIONS FOR USE:

Intended Use:

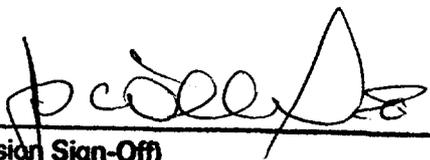
Wheelchair mobility, either self-propelled or propelled by an attendant, for the physically impaired.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

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

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K984367