AUG 12 1999

K 98 2724

A. 510(K) Summary

510(K) SUMMARY

SUBMITTER:	Theradyne Healthcare Products, a Division of Kurt Manufacturing Company.
CONTACT PERSON:	Phil Schlangen 1325 Quincy Street, Northeast Minneapolis, MN 55413
DATE PREPARED:	July 19, 1999
TRADE NAME:	Theradyne Rover Express™ Powered Wheelchair
CLASSIFICATION NAME AND NUMBER PRODUCT CODE:	Wheelchair, Powered Class II, 21 CFR 890.3860, Code: ITI
PREDICATE DEVICE(S):	The Theradyne Rover Express™ Powered Wheelchair is substantially equivalent to previously marketed powered wheelchairs, as demonstrated by its conformance to FDA recognized consensus standards and FDA's guidance documents.
DEVICE DESCRIPTION:	The Theradyne Rover Express™ Powered Wheelchair.
INTENDED USE:	The Theradyne Rover Express™ Powered Wheelchair is intended for medical purposes to provide mobility to persons restricted to a sitting position.
FUNCTIONAL & SAFETY TESTING:	The Theradyne Rover Express™ Powered Wheelchair was examined and tested as provided in FDA's Guidance Documents, except for any deviations noted in the Declaration of Conformity and Summary Report. The results of examination and testing were successful, and did not raise any issues of safety and effectiveness of the device.
CONCLUSION:	The Theradyne Rover Express™ Wheelchair is substantially equivalent to previously marketed powered wheelchairs as demonstrated by its conformance to FDA recognized consensus standards and FDA's Guidance Documents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1999

Mr. Phil Schlangen
Kurt Manufacturing Company
Theradyne Healthcare Products
1325 Quincy Street NE
Minneapolis, Minnesota 55413

Re: K982724
Trade Name: Theradyne Rover Express Powered Wheelchair
Regulatory Class: II
Product Code: ITI
Dated: July 20, 1999
Received: July 21, 1999

Dear Mr. Schlangen:

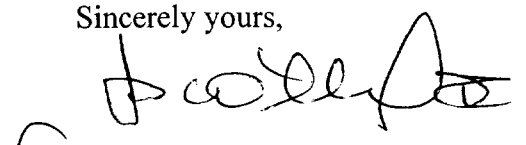
We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 control provisions of the Act. The general control 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.

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

Indications for Use Page

510(k) Number (if known): _____

Device Name: Theradyne Rover Express™ Powered Wheelchair

Indications for Use:

The Theradyne Rover Express™ Powered Wheelchair is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982724

Over-the-Counter Use X