G. HIRSCH
AND COMPANY INC.

HEALTH CARE PRODUCTS

AUG 31 1998

K982607

510(k) SUMMARY

(a) This is an Initial 510(k) Summary in accordance with 21 CFR 807.92.

(1) Submitted by: G. Hirsch and Company, Inc.
1815 Rollins Road
Burlingame, CA 94010-2204
Phone (650) 692-8770
Contact: Gary Hirsch
Prepared 07/24/98

(2) Proprietary Name: Manual Wheelchair
Common Name: Manual Wheelchair
Classification Name: Wheelchair, Mechanical

(3) Examples of four legally marketed devices of substantial equivalence, together with their 510(k) numbers are as follows:

Mechanical Wheelchair 980.3850, K945175
Tracer Series Manual Wheelchairs, K35398
Bantex Brand Wheelchairs, K915262
Universal Wheelchair, K930411

(4) The device consists of a folding chromed steel frame with cross braces, slung fabric seat and back, fixed or removable armrests, fixed or removable foot/legrests, front caster wheels for steering, rear push handles for attendant-assisted propulsion, rear drive wheels with handrims for self-propulsion, and lever-style wheel locks.

(5) The wheelchair is to be used for transportation of disabled persons.

(6) The wheelchair exhibits no material differences from the predicate devices listed in number (3) above. Please see the enclosed catalog pages of Invacare Tracer Series wheelchairs (510(k) #K935398) for a comparison of design features, which we believe to be equivalent to our submitted wheelchair. Some items for comparison are listed below.

	Our submitted wheelchair	Invacare Tracer Wheelchair (510(k)#K935398
1. Seat Ht.	20"	20"
2. Widths	14" – 22"	14" – 20"
3. Rear Wheels	24"	24"
4. Front Casters	8"	8"
3. Product Wt.	42 lbs.	44 lbs.
4. Weight Limit:	250 lbs.	250 lbs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 1998

Mr. Gary Hirsch
President
G. Hirsch and Company, Inc.
1815 Rollins Road
Burlingame, California 94010

Re: K982607
Trade Name: Manual Wheelchair
Regulatory Class: I
Product Code: IOR
Dated: July 24, 1998
Received: July 27, 1998

Dear Mr. Hirsch:

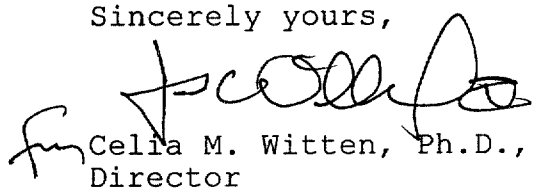
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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):_____

Device Name: MANUAL WHEELCHAIR

Indications For Use:

For transportation of disabled persons.

(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 K982607

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)