

JAN 13 2000

K99 3963

510(k) SUMMARY

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

(1) Submitted by: Sigma Distribution & Supply, Inc.  
701 West Harvard Street  
Glendale, CA 91204  
Phone (818) 246-4624  
Contact: Arthur Keshishyan  
Prepared 10/28/1999

(2) Propriety Name: SIGMA MANUAL WHEELCHAIR  
Common Name: Manual Wheelchair  
Classification Name: Manual, wheelchair

(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 Wheelchairs, K35398  
Bantex Brand Wheelchairs, K915262

(4) The device consists of a chromed steel frame with cross bars, 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 FOSHAN DONGFANG MEDICAL EQUIPMENT MANUFACTORY compared with the dimensions 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. Further the fabric of the submitted wheelchair meets the NFPA 701-89 Flame Resistant Textile and Films test.

Our Submitted Wheelchair      Invacare Tracer Wheelchair (510(k) #K935398)

1. Seat Ht.	20"	20"
2. Widths	14"-22"	14"-22"
3. Rear Wheels	24"	24"
4. Front Casters	8"	8"
Product Wt.	43lbs	44lbs
Weight Limit:	250 lbs.	250 lbs.



JAN 13 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Arthur Keshishyan  
Sigma Distribution & Supply, Inc.  
701 West Harvard Street  
Glendale, California 91204

Re: K993963  
Trade Name: Sigma Manual Wheelchair  
Regulatory Class: I  
Product Code: IOR  
Dated: November 8, 1999  
Received: November 22, 1999

Dear Mr. Keshishyan:

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.

Page 2 - Mr. John T. Mogensen

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) 594-4595. 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,

  
for

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

Enclosure

510(k) Number : ~~K992389~~ K993963

Device Name: SIGMA MANUAL WHEELCHAIR

Indication For Use:

For transportation of disabled persons.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

OR

Over the Counter Use X

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K993963