JAN 19 1999

K984457

510(k) Summary

510(k) is submitted by Suiter Medical. Contact person is James P. Suiter. Address, 203 West 2nd Street, McCook, NE 69001. Telephone # 1-800-354-3450. Summary was prepared on December 10, 1998.

The name of the device submitted is "World Class Wheeled Chair". The common name for this device is mechanical wheelchair.

The predicate device to which we claim equivalence is the Action Series of Wheelchairs from Invacare. (K914553)

The Suspension Seating of the World Class Wheeled Chair marketed by Suiter Medical is a design that gives the chair user incredible comfort with a multitude of positions for seat, back, leg, and arm supports-independently or in unison. From the suspension pivot points, located just below the arm rests, the chair user can rock, tilt, or recline while maintaining their center of weight forward of the rear wheels. This design serves the need for movement to avoid being drawn into an ever-tightening contracted ball.

The itended use of the device is to provide mobility to the user. Its intended use is the same as the predicate device. Features and charcteristics of both devices are the same in that they both have a reclining back, an adjustable back, provide multiple seating positions, both tilt-in-place.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 1999

Mr. James P. Suiter
Suiter Medical L.L.C.
203 West Second Street
McCook, Nebraska 69001

Re: K984457
Trade Name: World Class Wheeled Chair, Model SS
Regulatory Class: I
Product Code: IOR
Dated: December 11, 1998
Received: December 15, 1998

Dear Mr. Suiter:

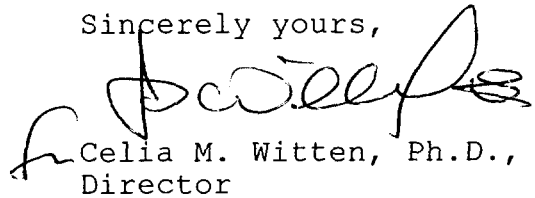
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K984457

DEVICE NAME: WORLD CLASS WHEELED CHAIR

INDICATIONS FOR USE: THE INTENDED USE OF THE DEVICE IS TO PROVIDE MOBILITY TO THE USER. ITS INTENDED USE IS THE SAME AS THE PREDICATE DEVICE. FEATURES AND CHARCTERISTICS OF BOTH DEVICES ARE THE SAME IN THAT THEY BOTH HAVE A RECLINING BACK, AN ADJUSTABLE BACK, PROVIDE MULTIPLE SEATING POSITIONS, BOTH TILT-IN-PLACE.

ABOVE SUBMITTED IN ORIGINAL REPORT ON PAGE E2.

(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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984457