K060212

MAR 7 2006

9.0 510(K) Summary

"510(k) SUMMARY"

9.1 Trade/Proprietary Name: Merits Model E Series Lift Chair
9.2 Common/Usual Name: Lift Chair
9.3 Classification Name: Chair, Electric, Positioning
9.4 Comparison to Currently Marketed Devices

The Merits Health Products Model E Series Lift Chairs are substantially equivalent to the GOLDEN POWER LIFT CHAIR Model PR355M (K880800).

9.5 Device Description

The Merits Pioneer Model E Series Lift Chair operates using standard AC Power from a wall outlet. All models consist basically of an upholstered chair assembly, which is constructed of fabric, and fastened to a lower frame, lifting assembly, which is constructed of welded steel. Additionally, all include one/or two motorized linear actuators which are used to position the chair assembly, and a hand held, push button type pendant control, which is used to engage actuator motion and vary the chair's position.

9.6 Intended use

The Merits Model E Series Lift Chairs are intended to assist elderly and/or physically challenged persons, who have difficulty rising from a seated position to a standing position.

9.7 Technological Characteristics

Merits Model E Series Lift Chairs are equivalent in functions to the legally marketed predicate device. The devices both use motorized linear actuator which is used to position the chair assembly, and a hand held, push button type pendant control, which is used to engage actuator motion and vary the chair's position. This technology is well established and has been used in other legally marketed products. There are no major technological differences.

9.8 Performance Data

The results of the testing confirm that the device meets specifications and is substantially equivalent to the predicate device.

9.9 Conclusion

Based on the design, performance specifications and testing and intended use, the Merits Model E Series Lift Chairs are substantially equivalent to the currently marketed device, GOLDEN POWER LIFT CHAIR Model PR355M. (K880800)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 2006

Merits Health Products Co., Ltd.
C/O Mr. Steve Chao
Chief Executive Officer
9, Road 36
Taichung Industrial Park
Taichung, Taiwan R.O.C

Re: K060212
Trade/Device Name: Merits Health Products Model E series Lift Chair
Regulation Number: 21 CFR 890.3110
Regulation Name: Electric Positioning Chair
Regulatory Class: II
Product Code: INO
Dated: January 26, 2006
Received: January 30, 2006

Dear Mr. Chao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) File Number: K060212

Device Name: Merits Health Products Model E Series Lift Chair

Indications For Use: The Merits Model E Series Lift Chairs are intended to assist elderly and/or physically challenged persons, who have difficulty rising from a seated position to a standing position.

Prescription Use _____ (Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ✓ (Per 21 CFR 801 Subpart C)

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, and Neurological Devices

510(k) Number K060212