K023993

DEC 27 2002

510(k) SUMMARY

Submitter's name: Evermed Corporation

Submitter's address: 4999 E. La Palma Ave.
Anaheim, CA 92807

Submitter's phone number: (714) 777-9997

Date summary prepared: November 27, 2002

Proprietary name: Galaxy Series Wheelchair

Common or usual name: Wheelchair

Classification name: Wheelchair, mechanical

Predicate device: Breezy Series Wheelchair manufactured by Sunrise Medical, Inc. (K974820)

Intend use of device:

The Galaxy Series Wheelchair provides enhanced mobility to physically challenged Persons limited to a sitting position.

Technological Characteristics and Substantial Equivalence:

Device description:

The Galaxy Series Wheelchair is manually operated mechanical wheelchair. It is designed to be light in weight with folding frame. The range of sizes and configurations are available to accommodate the needs of each user. The wheelchair is suitable to provide mobility to user for both indoors and outdoors with firm surface that is free of climbing obstacles.

The Galaxy Series Wheelchair consists of typical components found on most manual wheelchair. The wheelchair consists of metal frame constructed of round steel tubing that is welded, seat and back upholsteries, removable footrests/legrests, front casters and rear wheels. The upholstery fabric meets the California Technical Bulletin CAL 117 Standard for flame retardancy.

The users manual of Galaxy Series Wheelchair provides information on warnings, cautions and operation instruction of the wheelchair.

Substantial equivalence:

The Galaxy Series Wheelchair is substantially equivalent to the Breezy Series Wheelchair manufactured by Sunrise Medical, Inc. (K974820). They both have the same technological characteristics and intended use of the device.

Testing conducted:

Required tests for mechanical wheelchair listed in the Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles, July 1995, were conducted and the results are included in the subject 510(k) submission.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2002

Evermed Corporation
Calvin Chang
4999 East La Palma Avenue
Anaheim, California 92807

Re: K023993
Trade/Device Name: Galaxy Series Wheelchair
Regulation Number: 890.3850
Regulation Name: Wheelchair, mechanical
Regulatory Class: Class I
Product Code: IOR
Dated: November 27, 2002
Received: December 3, 2002

Dear Mr. Chang:

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 (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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
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) Number (if known): _____

Device name: Galaxy Series Wheelchair

Indications for Use: The Galaxy Series Wheelchair provides enhanced mobility to physically challenged persons limited to a sitting position.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023993