K021866

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JUN 14 2002

510(k) Summary

Karma 800 Series Manual Wheelchair

Intended Use

The intended use of the Karma 800 Series Manual Wheelchair is to provide mobility to persons limited to a sitting position.

Technological Description

Device Description:

The Karma 800 Series Manual Wheelchair is a user propelled mechanical wheelchair. Its intended function and use is to provide mobility to persons limited to a sitting position.

The product is designed to be a lightweight, everyday wheelchair for both indoor and outdoor use. It is a folding, or non-rigid type of wheelchair. The product consist primarily of an aluminum alloy frame with cross braces, large rear wheels with hand rims for propelling the chair, and smaller front pivoting casters for steering and turning.

The frame is constructed of round, aluminum alloy tubing that is welded. The seat-to-floor heights are adjustable via dual rear axle positions. The slung fabric seat and back meets the requirements of California 117 specifications for flame retardancy. Swing back armrest and swing away footrest are standard features.

Substantial Equivalence

The product that is substantially equivalent to the Karma 800 Series Manual Wheelchair is Karma Manual FoldingWheelchair (K950195).

Each of these products is a manually operated, manual mechanical wheelchair with the same intended function and use which is to provide mobility to persons limited to a seated position. All products consist basically of an aluminum alloy folding frame with braces to support the wheelchair, large rear wheels, and smaller front pivoting casters for turning and steering.

Performance Data

NA

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510(k) Summary

Vestil Manufacturing Corporation's 510(k) Premarket Notification Karma 800 Series Manual Wheelchair

Submitter's Name, Address, Telephone, Fax Number, and Contact Name

Karma Medical Products, Co., LTD.
No. 2363 Section 2, Da-Shiue Road
Min-Hsiung Shiang
Chia-Yi Hsien, 621. Taiwan
Phone: 886 5 206 6688 Fax: 886 5 206 7788

Manufacturer's Name, Address, Telephone, and Fax Number

Same as Above

Name of Device
Karma 800 Series Manual Wheelchair

Name of Applicant/Submission Correspondent, Address, Phone, Fax Number, and Contact Name

Vestil Manufacturing Corporation
900 Growth Parkway
Angola, IN 46703
Phone 260.668.5677 Fax: 260.668.8967
Rick Michael – rick@vestil.com

Date Prepared

May 2002

Common or Usual Name

Manual Wheelchair

Classification

Wheelchair, Mechanical 89IOR

Predicate Device
The product that is substantially equivalent to the Karma 800 Series Manual Wheelchair is the Karma Manual Folding Wheelchair (K950195).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2002

Mr. Rick Michael
North America Sales Manager
Vestil Manufacturing Company
900 Growth Parkway
Angola, IN 46703

Re: K021866
Trade Name: Karma 800 Series
Regulatory Number: 890.3850
Regulatory Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: June 6, 2002
Received: June 6, 2002

Dear Mr. Michael:

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 and additionally 21 CFR Part 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" (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 Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page____of____

510(k) Number (if known): K021866

Device Name: KARMA 800 SERIES

Indications For Use:

THE INTENDED USE OF THE KARMA 800 SERIES MANUAL WHEELCHAIR IS TO PROVIDE MOBILITY TO PERSONS LIMITED TO A SITTING POSITION.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021866