JUL 3 1 2003

K032123

510(K) Summary

Submitter

Per4maX Medical, LLC
2550 114th Street
Suite 190
Grand Prairie, Texas 75050
Phone: (972) 641-6773
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Tim Criswell

Date

June 20,2003

Name of Device

Shockwave Suspension Wheelchair

Predicate Devices

Invacare Top End Terminator SS
Sunrise Medical Quickie Suspension Wheelchair Series Model XTR
Colours Boing

Description of Device

Shockwave Suspension Wheelchair is a self-propelled, rigid frame, mechanical wheelchair consisting of components typical of most manual wheelchairs. It has large rear wheels with push rims for self-propulsion and small front pivoting casters for turning and stability. It is a lightweight, user adaptable, everyday chair for use both indoors and outdoors.

Intended Use

The intended use of Shockwave Suspension Wheelchair is to provide mobility to persons with physical limitations limited to a sitting position.

Substantial Equivalence

The Per4maX Shockwave Wheelchair is substantially equivalent to the listed predicate devices in its specifications, performance and use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 2009

Per4maX Medical, LLC
% Mr. Tim Criswell
2550 114th Street, Suite 190
Grand Prairie, Texas 75050

Re: K032123
Trade Name: Shockwave Suspension Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Names: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: June 20, 2003
Received: July 10, 2003

Dear Mr. Tim Criswell:

This letter corrects our substantially equivalent letter of July 31, 2003.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K032123

Intended Use Device

The intended use of the Shockwave Suspension Wheelchair is to provide mobility to persons with physical limitations limited to a sitting position. It is intended for indoors and outdoor use by individuals of all ages who are physically challenged.

for Mark N Milhern

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

510(k) Number K032123