

510(k) Summary

Submitted by:

Future Mobility HealthCare Inc.
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Contact:

Mr. Abdul Panchbhaya
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Date: October 11, 2010

Trade Name: Super Chair for Kids by Orion Tilt in Space mechanical wheelchair

Common Name: Manual Wheelchair

Classification Name: Wheelchair, Mechanical

Predicate Devices:

LEGALLY MARKETED PREDICATE DEVICES	MANUFACTURER NAME	REGULATORY CLASS AND PRODUCT CODE	510(K) REGISTRATION NUMBER
Zippie TS	Sunrise Medical	Class I/IOR	K890050 K973673
ORION II	Future Mobility Healthcare, Inc.	Class I/IOR	K061010

The rationale of declaring the Future Mobility Healthcare Super Chair for Kids by Orion is substantially equivalent to the above predicate devices is based on the following:

- ✓ Same Indications for use: providing mobility to persons limited to a sitting position.
- ✓ Similar key design technical characteristics- The ORIONII, Zippie TS and Super Chair for Kids by Orion are mechanical wheelchairs which have technical similarities.
- ✓ The ORION II, Zippie TS and Super Chair for Kids by Orion tilt in space wheelchairs are manually operated, self propelled mechanical wheelchairs, and may also be used as attendant propelled transport devices. They consist of mechanical steel frames for use by patients weighing up to 150 lbs.
- ✓ The Zippie TS and the Super Chair for Kids by Orion are designed with motor vehicle transport tie down systems that satisfy safety standard in accordance with procedures set forth in Annex A of Section 19, ANSI/RESNA WC/Vol.1 *Wheelchairs Used as Seats in Motor Vehicles*.

Conclusion:

Future Mobility HealthCare Super Chair for Kids by Orion folding mechanical wheelchair was developed in accordance with ISO 7176, parts 1, 5, 7, 8, 11 and 19. It is the conclusion that the Future Mobility HealthCare Super Chair for Kids by Orion is safe and effective, as well as substantially equivalent to the legally marketed device identified as the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Future Mobility Healthcare, Inc.
% Mr. Abdulsamad Panchbhaya
3223 Orlando Drive
Mississauga, Ontario
Canada L4V 1C5

JAN - 3 2010

Re: K103073

Trade/Device Name: Future Mobility Healthcare Inc. Super Chair for Kids by Orion
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: October 11, 2010
Received: October 18, 2010

Dear Mr. Panchbhaya:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

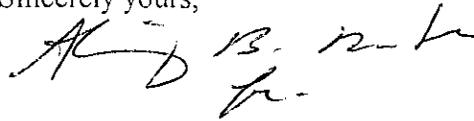
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

JAN - 3 2010

510(k) Number (if known): K103073

Device Name: Future Mobility Healthcare Inc. Super Chair for Kids by Orion

Indication for Use:

The Future Mobility Healthcare Inc. Super Chair for Kids by Orion Wheelchair is intended to provide mobility to persons limited to a sitting position.

Prescription Use _____

AND/OR

Over-The-Counter Use X

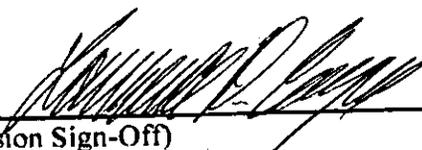
(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103073