K981557

Section III -- Summary under 21 CFR 807.92

Submitter: Richvale Ltd d/b/a MyCycle
885 N. LaSalle Street
Chicago, Illinois 60610
(312) 867-7065
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Goran Rajsic

Date: April 30, 1998

Name of the device: MyCycle Handmaster Victory Wheelchair

Identification of predicate device: Quickie 2hp Titanium Wheelchair and Wijit manual power attachment

Description of the device: The MyCycle Handmaster Victory wheelchair comprises a wheelchair and a drive unit for powering the wheelchair. The wheelchair comprises a substantially identical device as the Quickie 2hp Titanium Wheelchair. The measurements of each dimension, as well as the construction materials, and the type of welding techniques utilized are substantially identical, based on the documentation available to applicant regarding this wheelchair. The only difference is that the MyCycle device is not of Titanium but of conventional metal materials. However, the maximum weight bearing capacity, the tiltover testing, the dimensions and the weight of the device are identical.

Intended use of the device: The intended devices comprises a wheelchair. The wheelchair empowers physically challenged persons by providing a means of mobility. This includes temporary and permanent conditions in all ages, including but not limited to Arthritis, paraplegic, Quadriplegic, Multiple Sclerosis and other immobilizing or debilitating conditions. Our device and the predicate device provide the same function for occupants who are unable to move due to injuries or other medical conditions.

Comparison of device characteristics to predicate: This device has similar technological characteristics as the predicate devices. It utilizes the same manufacturing techniques and materials for the

construction of the wheelchair itself. In addition, it utilizes a drive system which under the FDA definitions is a substantially equivalent device.

Testing: Inasmuch as the device is substantially identical in every dimension to the Quickie 2hp Titanium Wheelchair, the same test results that are exhibited by the Quickie 2hp Titanium Wheelchair are applicable to the MyCycle Handmaster Light Wheelchair.

510(k) number: not assigned at the time of writing of the summary.

Conclusion: The MyCycle Handmaster Victory Wheelchair is substantially equivalent to the predicated devices listed in this 510(k) and the technology and construction of the device does not raise any new issues of safety and effectiveness.

Section II. Device Descriptive Information

Section A.

Intended Use

The intended devices comprises a wheelchair. The wheelchair empowers physically challenged persons by providing a means of mobility. This includes temporary and permanent conditions in all ages, including but not limited to Arthritis, paraplegic, Quadriplegic, Multiple Sclerosis and other immobilizing or debilitating conditions. Our device and the predicate device provide the same function for occupants who are unable to move due to injuries or other medical conditions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 1998

Ms. Susan Mays
Managing Director
Richvale Limited
120 East 87th Street
Suite P8I
New York, New York 10128

Re: K981557
Trade Name: MyCycle, Handmaster, Victory
K981558
Trade Name: MyCycle, Handmaster, Light
Regulatory Class: I
Product Code: IOR
Dated: April 30, 1998
Received: May 1, 1998

Dear Ms. Mays:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) to 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). You may, therefore, market the devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 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 devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Date: July 1, 1998

Re: K981557
MyCycle Handmaster Victory

Indications for Use:
(Intended Use:)

The intended use of the device is as a wheelchair. The wheelchair and drive system empower physically challenged persons by providing a means of mobility. This includes temporary and permanent conditions in all ages, including but not limited to Arthritis, paraplegic, Quadriplegic, Multiple Sclerosis and other immobilizing or debilitating conditions. Our device and the predicate device provide the same function for occupants who are unable to move due to injuries or other medical conditions.

[redacted]

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981557

Over-the-Counter Use X