DB PERKS & ASSOCIATES LTD. K031910
COMMERCIAL AQUATIC SUPPLIES • TEAM AQUATIC SUPPLIES • THE SWIM & FITNESS SHOP
HEAD OFFICE: Unit 201-1305 Welch Street, North Vancouver, BC V7P 1B3
Phone: 604-980-8950 • Fax: 604-980-0196 • E-mail: cas@comm-aquatic.com

JUL 25 2003

510K Summary

Premarket Notification — Stainless Steel Aquatic Wheelchair

Submitters Name: DB Perks & Associates Ltd.

Submitters Address:
#201 – 1305 Welch Street
North Vancouver, BC
Canada
V7P 1B3

Phone: 1-800-663-5905 (Toll Free North America)
Fax: 604-980-0196
Email: jack@comm-aquatic.com

US Agent:
Mr. Ed Oliver
CPCS Inc.
490 NW Datewood Drive
Issaquah, WA
98027

Phone: 425-557-9990
Fax: 425-313-5620
Email: eoliver@columbiapharma.com

Summary Prepared: June 16, 2003

Proprietary Device Name: Stainless Steel Aquatic Wheelchair

Generic Name: Manual Wheelchair (Folding)

Device Name: Mechanical Wheelchair

Models: Available in three seat widths - 16 inch, 18 inch, 20 inch

FDA Product Code: IOR

FDA Classification: Class I

Panel Code: Physical Medicine (89)

Regulation Number 890.3850

COMMERCIAL AQUATIC SUPPLIES
#201 – 1305 Welch Street
North Vancouver, BC, V7P 1B3
Tel: 604-980-2812
1-800-663-5905
Fax: 604-980-0196
cas@comm-aquatic.com

TEAM AQUATIC SUPPLIES
#101 – 1305 Welch St
North Vancouver, BC, V7P 1B3
Tel: 604-980-2805
1-800-234-4833
Fax: 604-980-2814
shark@team-aquatic.com

TEAM AQUATIC SUPPLIES
421 Forge Road S.E.
Calgary, AB, T2H 0S9
Tel: 403-319-2000
1-800-661-7946
Fax: 403-319-2002
calgary@team-aquatic.com

TEAM AQUATIC SUPPLIES
#8–4155 Fairview Street
Burlington, ON, L7L 2A4
Tel: 905-632-2590
1-888-259-7946
Fax: 905-632-0902
east@team-aquatic.com

DB PERKS & ASSOCIATES LTD.
COMMERCIAL AQUATIC SUPPLIES • TEAM AQUATIC SUPPLIES • THE SWIM & FITNESS SHOPS
HEAD OFFICE: Unit 201-1305 Welch Street, North Vancouver, BC V7P 1B3
Phone: 604-980-8950 • Fax: 604-980-0196 • E-mail: cas@comm-aquatic.com

Predicate device:

A) Tracer EX Manual Wheelchair — Invacare granted clearance by FDA March 01, 1994 under 510K # K935398.

B) Silhouette 300 Manual Wheelchair — G Hirsch & Co. granted clearance by FDA August 31, 1998 under 510K # K982607.

Intended Use:

This wheelchair is to provide mobility to persons limited to a sitting position being transported either by an attendant or self-propelled.

This device is designed to be a typical manual wheelchair for use in an aquatic center setting.

Description:

The Stainless Steel Aquatic Wheelchair is a non-rigid style, folding wheelchair. The wheelchair is suitable to provide mobility indoors or in wet conditions on a firm surface free of obstructions.

Construction is typical for this style of wheelchair. Our chair uses a cross-braced, welded, stainless steel frame with slung fabric (seat and back); swing back armrests and removable foot riggings. The chair uses 8-inch caster wheels at the front for steering with rear push handles for attendant assisted propulsion and 24-inch rear drive wheels with hand rims for self-propulsion. Lever style wheel locks are used on this chair.

All parts on our wheelchair are fabricated from stainless steel and selected plastics suitable for use in a swimming pool environment. The chair can be submersed in pool water without any harmful effects.

Upholstery meets California Technical bulletin CAL 117 standard for flame retardancy.

Users manual provides information on warnings, cautions maintenance and operation instructions.

Substantial Equivalence:

The Stainless Steel Aquatic Wheelchair is substantially equivalent to the predicate devices listed above. They both have the same technological characteristics and indications for use. Differences that do exist are in the selection of fabrication materials that allow our chair to operate in a swimming pool environment.

COMMERCIAL AQUATIC SUPPLIES
#201 – 1305 Welch Street
North Vancouver, BC, V7P 1B3
Tel: 604-980-2812
1-800-663-5905
Fax: 604-980-0196
cas@comm-aquatic.com

TEAM AQUATIC SUPPLIES
#101 – 1305 Welch St
North Vancouver, BC, V7P 1B3
Tel: 604-980-2805
1-800-234-4833
Fax: 604-980-2814
shark@team-aquatic.com

TEAM AQUATIC SUPPLIES
421 Forge Road S.E.
Calgary, AB, T2H 0S9
Tel: 403-319-2000
1-800-661-7946
Fax: 403-319-2002
calgary@team-aquatic.com

TEAM AQUATIC SUPPLIES
#8–4155 Fairview Street
Burlington, ON, L7L 2A4
Tel: 905-632-2590
1-888-259-7946
Fax: 905-632-0902
east@team-aquatic.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2003

DB Perks & Associates Ltd.
c/o Mr. Ed Oliver
CPCS, Inc.
490 NW Datewood Drive
Issaquah, WA 98027

Re: K031910
Trade/Device Name: Stainless Steel Aquatic Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: June 16, 2003
Received: July 1, 2003

Dear Mr. Oliver:

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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

DB PERKS & ASSOCIATES LTD.
COMMERCIAL AQUATIC SUPPLIES • TEAM AQUATIC SUPPLIES • THE SWIM & FITNESS SHO
HEAD OFFICE: Unit 201-1305 Welch Street, North Vancouver, BC V7P 1B3
Phone: 604-980-8950 • Fax: 604-980-0196 • E-mail: cas@comm-aquatic.com

INDICATIONS FOR USE:

This wheelchair is to provide mobility to persons limited to a sitting position being transported either by an attendant or self-propelled.

This device is designed to be a typical manual wheelchair for use in an aquatic center setting.

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

510(k) Number K031910

COMMERCIAL AQUATIC SUPPLIES
#201 - 1305 Welch Street
North Vancouver, BC, V7P 1B3
Tel: 604-980-2812
1-800-663-5905
Fax: 604-980-0196
cas@comm-aquatic.com

TEAM AQUATIC SUPPLIES
#101 - 1305 Welch St
North Vancouver, BC, V7P 1B3
Tel: 604-980-2805
1-800-234-4833
Fax: 604-980-2814
shark@team-aquatic.com

TEAM AQUATIC SUPPLIES
421 Forge Road S.E.
Calgary, AB, T2H 0S9
Tel: 403-319-2000
1-800-661-7946
Fax: 403-319-2002
calgary@team-aquatic.com

TEAM AQUATIC SUPPLIES
#8-4155 Fairview Street
Burlington, ON, L7L 2A4
Tel: 905-632-2590
1-888-259-7946
Fax: 905-632-0902
east@team-aquatic.com