K051709

AUG 15 2005

# 510(k) Summary
# for
# Vipamat Technologie Hippocampe Wheelchair

## 1. SPONSOR

Vipamat Technologie
ZA La Vraie Croix
56270 Ploeumer
France

Contact Person: Franck Coeudo
Telephone: 33 2 97 86 24 87

Date Prepared: June 23, 2005

## 2. DEVICE NAME

| | |
|---|---|
| Proprietary Name: | Hippocampe Wheelchair |
| Common/Usual Name: | Mechanical Wheelchair |
| Classification Name: | Mechanical Wheelchair |

## 3. PREDICATE DEVICES

| | |
|---|---|
| DB Perks and Associates Stainless Steel Aquatic Chair | K031910 |
| Landeez All-Terrain Sport Chair | K031342 |

## 4. DEVICE DESCRIPTION

The Hippocampe Wheelchair is an all terrain wheelchair suitable for use on various terrains and in water. It can be used on surfaces such as the beach, seaside, snow, mountain pathways, forest, hiking paths, gardens and grass. The Hippocampe Wheelchair is a versatile durable wheelchair that is comprised of the following components.

- Wheel chair
- Pushbar
- Trunk harness (optional)
- Armrest (optional)

- Headrest (optional)
- Skiing kit (optional)
- Traction kit
- Transport bag (optional)

The Hippocampe is available in small, medium, large and extra large configurations which all vary in length but have the same seat width, total width and seat height dimensions. Two versions of the Hippocampe, standard and pool, are available. The standard Hippocampe is intended for use in natural water (beaches, ponds, lakes). The pool Hippocampe is only intended for pool use by children and thin adults and is only available in a small size.

## 5. INTENDED USE

The Hippocampe Wheelchair is a versatile, mechanical, wheelchair intended for use on various terrains including sand, grass, gravel, snow, foot/hiking paths, and in water.

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The overall design of the Hippocampe and the predicate wheelchairs are similar in that they are all low to the ground wheelchairs made of rugged metals and flame retardant materials. They are all compatible with various types of water (pool, oceans, lakes etc). All of these devices consist of 3 or 4 wheels with a chassis and pushbar. One minor difference is that the Hippocampe Wheelchair is comprised of three wheels whereas the predicate devices have a four wheel configuration. This difference does not affect safety or effectiveness since safety testing (stability testing) has been completed successfully using the Hippocampe. The technological characteristics are similar in that both the proposed and predicate devices are compatible with various terrains and water. Like the small-pool Hippocampe Wheelchair, the DB Perks Chair is intended only for pool water whereas the standard Hippocampe and Landeez Chairs are intended for either pool water or natural water (ocean, lakes, and ponds) and various terrains.

## 7. PERFORMANCE TESTING

Testing has been performed to evaluate the overall stability, dimensions and mechanics of the Hippocampe Wheelchair. The testing showed that the Hippocampe is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2005

Vipamat Technologie
c/o Ms. Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K051709
Trade/Device Name: Hippocampe Wheelchair
Regulation Number: 21 CFR 890.3880
Regulation Name: Special grade wheelchair
Regulatory Class: II
Product Code: IQC
Dated: June 23, 2005
Received: June 28, 2005

Dear Ms. McNamara-Cullinane:

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 (240) 276-0115. 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,

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

Enclosure

510(k) Number (if known):

Device Name: Hippocampe Wheelchair

Indications For Use:

The Hippocampe Wheelchair is a versatile, mechanical wheelchair intended for use on various terrains including sand, grass, gravel, snow, foot/hiking paths, and in water.

Prescription Use _____ AND/OR Over-the-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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