DEC 1 4 2004

K042481

10. SMDA Summary of Safety and Effectiveness SMDA Summary of Safety and Effectiveness

510(k) Summary
Polaris® SPV-140, SPV-300, SPV-400 Pressure Adjustable Valve

A. Submittor Information

Sponsor:

SOPHYSA SA
C/o Interactive Consulting Inc.
70 Walnut Street
Wellesley, MA 02481
Tel: (781) 239-8108
Fax: (781) 239-8005

Manufacturer:

SOPHYSA SA
22 rue Jean Rostand
Parc Club Orsay Université
91893 ORSAY Cedex, France
Tel: 011-331-69 35 35 00
Fax: 011 331 69 35 36 90
Website : www.sophysa.com

Contact Person: Jean-Christophe Audras, Regulatory Affairs

Date Prepared: September 10, 2004

B. Device Identification

Common/Usual Name:	Hydrocephalus Shunt
Proprietary Name:	Polaris® SPV-140, SPV-300, SPV-400 Pressure Adjustable Valve System
Regulatory Class:	Class II by 21 CFR 882.5550

C. Identification of Predicate Device(s)

The Polaris® Pressure Adjustable Valve models SPV-140, SPV-300, SPV-400 is substantially equivalent to the SOPHYSA Sophy® Polaris® SPV Valve (K031097) previously cleared and currently marketed.

D. Device Description

The Polaris® Pressure Adjustable Valve models SPV-140, SPV-300, SPV-400 is an implantable device designed for the treatment of hydrocephalus in adult and pediatric patients by shunting, thereby providing continuous, controlled intraventricular pressure and CSF drainage from the cerebral ventricles. Intraventricular pressure is maintained at a constant level by the device's ball-in-cone valve seat design, and the value is pressure-adjustable transcutaneously. Drainage is directed to the abdominal cavity or to the right atrium of the heart.
The basic settings of the Polaris® SPV-140 Valve are 10, 40, 80, 110 and 140 mm H_2O; adjustments to intermediate pressures are made manually in 30 mm H_20 increments (decrements).
The basic settings of the Polaris® SPV-300 Valve are 50, 100, 150, 220 and 300 mm H_2O; adjustments to intermediate pressures are made manually in 50-70 mm H_20 increments (decrements).
The basic settings of the Polaris® SPV-400 Valve are 80, 150, 230, 330 and 400 mm H_2O; adjustments to intermediate pressures are made manually in 70-100 mm H_20 increments (decrements).

The specific feature of the self-locking rotor-shuttle micro-magnet system of the passive Polaris® SPV Valve is that the adjustment position of each pressure setting cannot be changed by a unidirectional magnetic field. A domestic magnetic field or an exposure to MRI attracts the

shuttles in the same direction and thus cannot unlock them simultaneously, therefore the rotor cannot be mobilized and the pressure setting remains fixed and constant.

E. Substantial Equivalence

The Polaris® Pressure Adjustable Valve models SPV-140, SPV-300, SPV-400 is substantially equivalent to the Polaris® SPV Pressure Adjustable Valve System (K031097) in terms of intended use, materials, biocompatibility, design, performance, function, and operating characteristics.

F. Indications for Use

To drain cerebrospinal fluid (CSF) for the management of hydrocephalus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2004

Sophysa SA
c/o Ms. Jackie Masse
Interactive Consulting, Inc.
70 Walnut Street
Wellesley, Massachusetts 02481

Re: K042481
Trade/Device Name: Polaris® Pressure Adjustable Valve System
Models Polaris® SPV-140, SPV-300, SPV-400
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: November 8, 2004
Received: November 9, 2004

Dear Ms. Masse:

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,

Miriam C Provost

for 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

Indications for Use

510(k) Number (if known): K042481

Device Name: Polaris® Pressure Adjustable Valve System
Models Polaris® SPV-140, SPV-300, SPV-400

Indications For Use:

To drain cerebrospinal fluid (CSF) for the management of hydrocephalus

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K042481