ATTACHMENT 2. 510(k) SUMMARY K090342

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

3.1 Name, Address, Phone and Fax Number of the Applicant

AUG 11 2009

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3.2 Contact Person

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3.3 Date Prepared

February 6, 2009

3.4 Device Name

Polaris® Adjustable Pressure Valve (Models SPV, SPVA, and SPVB), and

Polaris® Adjustable Pressure Valve System (Models SPV-140, SPV-300, and SPV-400)

3.5 Device Description

The Polaris® Adjustable Pressure Valve 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® Valve Models SPV, SPVA, and SPVB are 30, 70, 110, 150 and 200. Adjustments to intermediate pressures are made manually in 40-50 mm H_20 increments (decrements) in three operating ranges, low pressure (LP =30 mm H_20), medium pressure (MP = 110 mm H_20), and high pressure (HP = 200 mm H_20).

The basic settings of the Polaris® SPV-140 Valve are 10, 40, 80, 110 and 140 mm H_20; adjustments to intermediate pressures are made manually in 30-40 mm H_20 increments (decrements).

The basic settings of the Polaris® SPV-300 Valve are 50, 100, 150, 220 and 300 mm H_20; adjustments to intermediate pressures are made manually in 50-80 mm H_20 increments (decrements).

The basic settings of the Polaris® SPV-400 Valve are 80, 150, 230, 330 and 400 mm H_20; 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.

3.6 Indications for Use

The Polaris® Adjustable Pressure Valves are indicated to drain cerebrospinal fluid (CSF) for the management of hydrocephalus.

3.7 Description of Modifications

There have been no changes to the device design. The changes involve labeling changes to upgrade the MRI characteristics of the valves for use in an MRI environment from 1.5 Tesla to up to 3 Tesla. Additional changes were made to the IFU to update instructions for the Polaris Adjustment Kit (PAK) handling procedure as well as numerous other minor changes for clarification of to the procedures.

3.8 Verification & Validation Testing of Changes

Testing was conducted to evaluate the presence of magnetic filed interactions, heating, and artifacts for the Polaris Adjustable Pressure Valves after exposure to a 3-Tesla MRI environment; and to determine if exposure to a 3-Tesla MRI environment alters the functional aspects of Polaris Adjustable Pressure Valves. The results supported the MRI labeling statements for exposure of the Polaris Adjustable Pressure Valves to a 3-Tesla MRI environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Sophysa SA
c/o Jean-Christophe Audras
Director, Regulatory Affairs
22 Rue Jean Rostand
Parc Club Orsay Université
91893 Orsay Cedex France

AUG 11 2009

Re: K090342
Trade/Device Name: Polaris® Adjustable Pressure Valve (Models SPV, SPVA, and SPVB), and Polaris® Adjustable Pressure Valve System (Models SPV-140, SPV-300, and SPV-400)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: II
Product Code: JXG
Dated: June 5, 2009
Received: June 10, 2009

Dear Mr. Audras:

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 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/ucm115809.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" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090342

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

Indications For Use:

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

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kristen Bowsher

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K090342