SEP 21 2000

10. SMDA Summary of Safety and Effectiveness

K992465

510(k) Summary
Sophy® Pressure Adjustable Valve System

A. Submittor Information

Sponsor:

SOPHYSA SA
c/o Interactive Consulting Inc.
70 Walnut Street
Wellesley, MA 02481
Tel: (781) 239-8108
Fax:(781) 863-6497

Manufacturer:

SOPHYSA SA
22 rue Jean Rostand
Parc Club Orsay Université
91893 ORSAY Cedex, France
Tel: 011-331-69-41-3500

Contact Person: Jean-Christophe Audras, Regulatory Affairs

Date Prepared: July 21, 1999

B. Device Identification

Common/Usual Name	Hydrocephalus Shunt
Proprietary Name:	Sophy® Pressure Adjustable Valve System
Regulatory Class:	Class II by 21 CFR 882.5550

C. Identification of Predicate Device(s)

The Sophy® SU8 is substantially equivalent to the following previously cleared and currently marketing devices Johnson & Johnson Hakim Programmable Valve (K974739) and Cordis Standard/Pediatric Valve (K861377).

D. Device Description

The Sophy® Pressure Adjustable Valve System SU8 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 valve is pressure-adjustable transcutaneously. Drainage is directed to the abdominal cavity or to the right atrium of the heart. The Sophy® Pressure Adjustable Valve System SU8 technology allows for the non-invasive manual adjustment of the operating pressure via 8 pressure settings, ranging from 50 mm H_20 to 170 mm, as follows: 50 = Low, 110 = Medium (intermediate 65,80,95), and 170 = High (intermediate 130, 150).

The principle of the Sophy® Pressure Adjustable Valve System SU8, identical to that of several existing FDA cleared hydrocephalus valves, is based on the pressure change exerted on a synthetic ruby ball by a semi-circular spring at different points of its curvature. This spring is connected to a magnetic rotor whose position can be adjusted non-invasively by using a programming magnet oriented at different angles with selected orientations corresponding to different pressures. Radio-opaque identification dots indicate three main positions of the rotor corresponding to Low, Medium, and High operating pressures. For pressure setting, a specific programming kit is necessary, including a compass, magnet, and pressure selector.

E. Device Testing Summary

- Performance Testing

  Performance testing was conducted per and complies with the applicable sections of *ASTM F647-94 Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Applications.* Performance testing included the following areas: Material and Corrosion, Diffusion of Samarium and Cobalt into the Valve, Sensitivity to Angular Accelerations and Shocks, Pressure-Flow Studies, Pressure-Adjustment and Rotor Programming, Magnetic and MRI Tests, Testing results demonstrated that the device was suitable for its intended used.

- Biocompatibility Testing

  Biocompatibility tests were performed per the *Tripartite Biocompatibility Guidance for Medical Devices* and *ISO 10993 Biological Evaluation of Medical Devices.* Testing results demonstrated that the device materials are biocompatible.

- Clinical Evaluation

  A retrospective clinical study of 43 consecutive patients (25 pediatric, 18 adults) was conducted to support a claim of substantial equivalence. One year follow-up data was obtained in 93% of the patients, and 2 year follow-up was achieved in 59% of the patients. Results indicated that the Sophy ® Pressure-Adjustable Valve System SU8 performs as well as, and is safe and effective as currently marketed hydrocephalus shunts.

F. Substantial Equivalence

The Sophy ® Pressure-Adjustable Valve System SU8 is substantially equivalent to the Cordis Standard/Pediatric Shunt (K861377) and to the Hakim Programmable Valve (K974739) in terms of intended use, materials, design, function, and operating characteristics. All three devices utilize the same ball-in-cone mechanism to maintain intraventricular pressure. The valve design maintains intraventricular pressure at a constant selected level. Depending on the CSF flow rate and/or viscosity, the ball moves up or down within the cone under the control of the calibrated stainless steel spring to maintain the selected pressure. While the pressure regulating mechanism is identical in all 3 devices, the variable pressure adjustment capability is only available with the Hakim Programmable Valve and the Sophy® Pressure-Adjustable Valve System SU8. In the case of the Cordis Standard/Pediatric Valve, pressure selection is available in five fixed pressure ranges. The non-invasive transcutaneous pressure adjustment capability together with the ability to monitor the pressure setting in-situ is available in the Hakim Programmable Valve (K974739) and the Sophy® Pressure-Adjustable Valve System SU8, with near identical performance. The Sophy® Pressure-Adjustable Valve System SU8 is thus determined to be Substantially Equivalent to the Cordis Standard/Pediatric Shunt (K861377) and the Hakim Programmable Shunt (K974739).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2000

Sophysa SA
c/o Jean-Luc Boulnois, Ph.D.
President
Interactive Consulting, Inc.
70 Walnut Street
Wellesley, Massachusetts 02481

Re: K992465
Trade Name: Sophy® Pressure Adjustable Valve System
Regulatory Class: II
Product Code: JXG
Dated: July 14, 2000
Received: July 17, 2000

Dear Dr. Boulnois:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) 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 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 (Premarket Approval), 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 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 device 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 device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, 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,

Donna R. Lochner.

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

510(k) Number (if known): K992465

Device Name: SOPHY® Pressure-Adjustable Valve System

Indications For Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992465

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)