November 28, 2025

SOPHYSA
Lucie Dubois
Regulatory Affairs Manager, CSF
5 Rue Guy Moquet
Orsay, 91400
France

Re: K250636
Trade/Device Name: Sophy Mini Monopressure Valve
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: March 3, 2025
Received: October 31, 2025

Dear Lucie Dubois:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the QS regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

XIAOLIN
ZHENG -S

For Jaime Raben, Ph.D.
Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250636

Device Name
Sophy Mini Monopressure Valve

Indications for Use *(Describe)*
The Sophy Mini Monopressure Valve is designed for the treatment of hydrocephalus by shunting cerebrospinal fluid (CSF) to the abdominal cavity or right atrium of the heart.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

1. 807.92(a)(1) Sponsor Information

Applicant Name: Sophysa

Address: 5 Rue Guy Moquet
ORSAY, FRANCE, 91400

Phone and Fax Number: +33 (0)1 69 35 35 00 (phone)
+33 (0)1 69 35 36 90 (fax)

Contact Person: Julie LOPEZ
QMS & Regulatory Affairs Director
jlopez@sophysa.fr

Date Prepared: 2025-November-26

2. 807.92(a)(2) Device Name and Classification

Trade/Proprietary Name: Sophy® Mini Monopressure Valve

Common Name: Hydrocephalus Shunt System

510(k) Submitter: Sophysa

Device Class: Class II

Product code: JXG

Regulation: 21 CFR 882.5550

There are 15 different Sophy SM1 valve references as listed in the table below:

Product Reference	Designation
SM1-H	Sophy® Mini Monopressure valve HP
SM1-L	Sophy® Mini Monopressure valve LP
SM1-M	Sophy® Mini Monopressure valve MP
SM1-2010H	Sophy® HP kit preattached with BO19-10
SM1-2010L	Sophy® LP kit preattached with BO19-10
SM1-2010M	Sophy® MP kit preattached with BO19-10
SM1A-2010H	Sophy® HP kit preattached with BO19-10

Product Reference	Designation
SM1A-2010L	Sophy® LP kit preattached with BO19-10
SM1A-2010M	Sophy® MP kit preattached with BO19-10
SM1A-H	Sophy® HP valve with antechamber
SM1A-L	Sophy® LP valve with antechamber
SM1A-M	Sophy® MP valve with antechamber
SM1B-H	Sophy® HP valve with burr hole reservoir
SM1B-L	Sophy® LP valve with burr hole reservoir
SM1B-M	Sophy® MP valve with burr hole reservoir

3. 807.92(a)(3) Predicate Device

Predicate: Polaris® Adjustable Pressure Valve, Sophysa (K141227)

4. 807.92(a)(4) Device Description

The Sophy® Mini Monopressure Valve is intended for the treatment of hydrocephalus by shunting the cerebrospinal fluid (CSF) to the abdominal cavity or right atrium of the heart.

The complete CSF shunting system provides shunting of CSF from the ventricular cavities in the brain to another part of the body where the CSF can be absorbed in blood.

At the minimum, a complete CSF shunt consists of:

- A proximal catheter to drain CSF from either lateral brain ventricles;
- A distal catheter to drain CSF to a body cavity where it can be absorbed in blood (most often, the peritoneal cavity or the right atrium of the heart so respectively called peritoneal or atrial catheter also);
- Between the two, a valve which regulates the flow of CSF.

5. 807.92(a)(5) Indications for Use

The Sophy® Mini Monopressure Valve is designed for the treatment of hydrocephalus by shunting the cerebrospinal fluid (CSF) to the abdominal cavity or right atrium of the heart.

6. 807.92(a)(5) Intended Population

This device can be used on patients of all ages, excluding pre-term infants.

7. 807.92(a)(6) Comparison of Technological Characteristics with the Predicate Device

The Sophy® Mini Monopressure Valve is substantially equivalent to Polaris® Adjustable Pressure Valve, Sophysa (K141227) according to Table 1.

Table 1 : Predicate Device Comparison

	Predicate: Polaris Valve 510(k): K031097, K042481, K090342, K141227	**Subject Device: Sophy Mini Monopressure Valve (SM1) K250636**	**Rationale of Why No New Issues of Safety and Effectiveness**
Clinical equivalence:			
Intended use	The treatment of hydrocephalus by shunting the cerebrospinal fluid (CSF) to the abdominal cavity or right atrium of the heart.	The treatment of hydrocephalus by shunting the cerebrospinal fluid (CSF) to the abdominal cavity or right atrium of the heart.	Same
Single use	Single use	Single use	Same
Sterility status	Sterile	Sterile	Same
Sterilization method	EO sterilization	EO sterilization	Same
Re-sterilization status	Cannot be resterilized	Cannot be resterilized	Same
Technical equivalence:			

		Predicate: Polaris Valve 510(k): K031097, K042481, K090342, K141227	Subject Device: Sophy Mini Monopressure Valve (SM1) K250636	Rationale of Why No New Issues of Safety and Effectiveness
Principle mode of action		"Ball-in-cone" design. The pressure is based on the pressure variation exerted on a ruby ball by the spring.	"Ball-in-cone" design. The pressure is based on the pressure variation exerted on a ruby ball by the spring.	Same
Product composition & design	Magnets	Two micro magnets enclosed in polysulfone shuttles located on rotor.	No magnets	Adjustment by magnetism implies the presence of magnets inside the predicate Polaris valve.The SM1 valve has no magnets, and therefore reduce artifact and induced heating during MRI compared with the predicate Polaris valve.
	Rotor design	Rotor has two radially movable magnets englobed in shuttle (providing magnetic lock function) and can rotate when shuttle is influenced by magnetic force (of the setting tool).	Fixed rotor	SM1 is a single-pressure valve, so there is rotor, but it is fixed because it is not an adjustable valve like the predicate Polaris. Therefore, there is no impact on the safety and effectiveness because both have a rotor inside but the rotor for SM1 is

		Predicate: Polaris Valve 510(k): K031097, K042481, K090342, K141227	Subject Device: Sophy Mini Monopressure Valve (SM1) K250636	Rationale of Why No New Issues of Safety and Effectiveness
				fixed and the rotor for Polaris is movable.
	Shuttle	Shuttle can move radially to lock/unlock the rotor.	No shuttle	SM1 is a single-pressure valve; it is not possible to vary pressure by rotating a rotor, and it has no magnets for rotation. This means that it has no shuttles for locking these magnets and has no impact on the absence of these shuttles because it is in accordance with the operating principle of SM1.
	Spring fixation	Spring fixed on rotor by ultrasonic welding.	Spring fixed on rotor by ultrasonic welding.	Same
	Pressure determinants	Pressure varies when the ruby ball is at different points on the spring's curvature.	SM1 has the same mechanism as Polaris with the ruby ball on the spring's curvature. But SM1 is a single-pressure valve therefore there is no pressure adjustment.	There is no pressure adjustment because SM1 is a single-pressure valve and is available in 3 variant pressure positions included in the pressure range of the Polaris SPV valve. The pressure determinant

		Predicate: Polaris Valve 510(k): K031097, K042481, K090342, K141227	Subject Device: Sophy Mini Monopressure Valve (SM1) K250636	Rationale of Why No New Issues of Safety and Effectiveness
				stays the same because it is also the ruby ball on the spring's curvature.
Shape/dimension	Shape	The valve is a teardrop shaped valve with slight curve to fit the skull.	The valve is a teardrop shaped valve with slight curve to fit the skull.	Same
	Dimension	16 mm in diameter, 32.5 mm in length and 5 mm in thickness	16 mm in diameter, 32.5 mm in length and 4.9 mm in thickness	Similar SM1 valve is identical in diameter and length to Polaris but is 0.1 mm thinner. Since the SM1 valve is thinner than Polaris, there are no additional risks compared to those associated with Polaris.
Compatible products	Adjustment kits	**References**: PAK2, PAK2-LI, PAK2-RI, PAK2-SI **510K Number**: K141227	Not necessary	Similar SM1 is a single-pressure valve, it does not need an adjustment kit.
	Catheters	**References**: B905S, BO19-10 **510K Number**:	**References**: B905S, BO19-10 **510K Number**:	Same

		Predicate: Polaris Valve 510(k): K031097, K042481, K090342, K141227	Subject Device: Sophy Mini Monopressure Valve (SM1) K250636	Rationale of Why No New Issues of Safety and Effectiveness
		K141227	K141227	
	Anti-siphon	**Reference**: SX-200 **510K Number**: K091328	**Reference**: SX-200 **510K Number**: K091328	Same The connection between the valve and the anti-siphon is identical for SM1 and the predicate SPV. The Sophy Mini Monopressure Valve does not include a shunt kit reference with the anti-siphon SX-200, unlike the predicate Polaris® valve. The anti-siphon SX-200 is compatible with the Sophy Mini Monopressure Valve.
Functional characteristics	Pressure program	Non-invasive reading and adjustment transcutaneously.	Calibration pressure easily identifiable to the naked eye in all phases of deconditioned valve handling and no adjustment possible. Easily identifiable after implantation by radiography.	SM1 is a single-pressure valve and is available in 3 variant pressure positions included in the pressure range of the Polaris SPV valve.

		Predicate: Polaris Valve 510(k): K031097, K042481, K090342, K141227	Subject Device: Sophy Mini Monopressure Valve (SM1) K250636	Rationale of Why No New Issues of Safety and Effectiveness
	Operating pressure	4 models providing 4 operating pressure ranges (10-140, 30-200, 50-300, 80-400 mmH_2O), each with 5 pressure settings	3 models providing 3 operating pressures (50, 110, 170 mmH_2O) with 1 pressure setting	SM1 is a single-pressure valve and is available in 3 variant pressure positions included in the pressure range of the Polaris SPV valve.
	Lock up design	Magnetic lock, maintain the pressure by resisting daily shock, daily magnetic field and MRI exposure.	There is no rotor with magnets in the SM1; therefore, no pressure variation and the lock up design is not necessary.	The valve contains no magnets and no movable rotor.
	MRI safety information	MR Conditional	MR Conditional	Same
	Radiopaque marks	Marking points (made with titanium) plotted alongside the valve body.	Marking points (made with titanium) plotted alongside the valve body.	Same
Applicable standards		ISO 7197	ISO 7197	Same
Shelf life		5 years	5 years	Same
Primary packaging system		Double tray + Tyvek	Double tray + Tyvek	Same

8. 807.92(b)(1) Performance Data

The biological safety of the Sophy® Mini Monopressure Valve has been established through the demonstration of equivalency with the predicate Polaris® Adjustable Pressure Valve, Sophysa (K141227) in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). The following performance testing has been conducted in support of the substantial equivalence determination. The testing was performed according to FDA-recognized consensus standards and internal test methods according to Table 2.

Table 2: Performance bench test results

Test	Test Method Summary	Results
Radiopacity per ISO 7197, ASTM F647 and ASTM F640.	To verify whether the entire shunt is visible on X-ray and to differentiate between all variants of a product range and the direction of shunt implantation.	Pass
Resistance to leakage per ISO 7197 and ASTM F647.	To check the shunt's air and water tightness.	Pass
Functional property pressure flow characteristics per ISO 7197.	To evaluate if the pressure range of the shunt corresponds to the pressure range of the SM1.	Pass
Dynamic breaking strength per ISO 7197 and ASTM F647.	To verify the tensile and flexion fatigue resistance of shunt connectors.	Pass
Functional property reflux performance per ISO 7197 and ASTM F647.	To check the anti-reflux performance of the shunt.	Pass
Shock resistance test per ISO 7197 and ASTM F647.	To verify whether the device's performance remains compliant after drops.	Pass
Dimensional control.	Check the dimensional conformity of products.	Pass
Long term stability per ISO 7197 and ASTM F647.	To verify whether the device's performance remains compliant after prolonged use.	Pass
Functional property influence of the changed posture on the valve performance per ISO 7197.	Measure the flow rate and pressure of the shunt in the vertical and horizontal positions.	Pass
Bursting pressure per ISO 7197 and ASTM F647.	To verify whether the device's performance remains compliant after burst pressure.	Pass
Overpressure per ISO 7197 and ASTM F647.	To verify whether the device's performance remains compliant after overpressure.	Pass
MRI compatibility – magnetic displacement force, induced torque, induced heating per ASTM F2052, ASTM F2213 and ASTM F2182.	To verify the shunt's compatibility with an MRI scan.	Pass

Test	Test Method Summary	Results
Visual control per ISO 20698 and ASTM F647.	To check for surface defects.	Pass
Resistance to dynamic breaking of the complete shunt system per ISO 7197 and ASTM F647.	To verify the resistance to dynamic breaking of the complete shunt system.	Pass
Hydrodynamic resistance catheters per ISO 7197.	To measure flow rate and pressure and calculate the hydrodynamic resistance of the catheter.	Pass

9. 807.92(b)(3) Summary of Non-clinical testing

Bench testing has been performed on the representative samples of the Sophy® Mini Monopressure Valve, according to design requirements. All tests have passed the acceptance criteria.

The information summarized above demonstrates that the Sophy® Mini Monopressure Valve is substantially equivalent to and is as safe and as effective as the legally marketed predicate device. Due to the high similarity to the predicate device (design, material, catheter, reservoir), most non-clinical performance test results are identical between SM1 and the predicate device. Only the MRI test results are better due to the absence of magnets.