June 20, 2025

Sophysa
Zheng XUE
Consultant
5 Rue Guy Moquet
Orsay, 91400
France

Re: K242974
Trade/Device Name: External CSF drainage
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: Class II
Product Code: JXG
Dated: May 21, 2025
Received: May 21, 2025

Dear Zheng XUE:

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 quality systems (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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.06.20 15:27:32 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
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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)*
K242974

Device Name
External CSF Drainage

Indications for Use *(Describe)*
The Sophysa external CSF drainage catheters are intended to temporarily drain the Cerebrospinal Fluid (CSF), for less than 30 days (up to 29 days maximum).

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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510(k) Summary

510(k) Number: K242974

Sponsor Information

Applicant Name:	Sophysa
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Phone and Fax Number:	+33 (0)1 69 35 35 00 (phone) +33 (0)1 69 35 36 90 (fax)
Sophysa Person:	Julie LOPEZ Regulatory affairs director Jlopez@sophysa.com
Submission contact Person:	Zheng XUE Consultant: Zheng.xuecazenave@gmail.com
Date Prepared:	05-June-2025

Device Name and Classification

Trade/Proprietary Name:	External CSF Drainage
Common Name:	Central nervous system fluid shunt and components.
Classification Name	Shunt, Central Nervous System and Components
Regulation:	21 CFR 882.5550
Device Class:	2
Product Code:	JXG

Predicate Device

Predicate:	Phoenix Neuro Catheters FVPC2 and FVPC4, Sophysa (K853365) Lumbar Drainage Catheter Kit, Codman (K964923)

Device Description

The Sophysa external CSF drainage catheters are intended to temporarily drain the Cerebrospinal Fluid (CSF), for less than 30 days.
There are two types of external CSF drainage catheters:

- Ventricular catheters
- Lumbar catheters

The catheter is provided sterile and with accessories to facilitate the surgical procedures and connectors. The external CSF drainage catheters need to be connected to collection systems.

Indications for Use

The Sophysa external CSF drainage catheters are intended to temporarily drain the Cerebrospinal Fluid (CSF), for less than 30 days (up to 29 days maximum).

Summary of Equivalence to Predicate Device

The External CSF drainage is substantially equivalent to Phoenix Neuro Catheters FVPC2 and FVPC4, Sophysa (K853365) and Lumbar Drainage Catheter Kit, Codman (K964923).

Table 1 : Predicate Devices Comparison

	Predicates	Proposed Devices	Rational of why no new issues of safety and effectiveness
Clinical Equivalence			
Indications for use	K853365: Temporary, external drainage of CSF following placement in the ventricles. K964923: The Lumbar Drainage Catheter Kit is indicated for temporary access to the lumbar subarachnoid region and, when used with other Codman devices, is designed to drain cerebrospinal fluid (CSF) as a means of reducing increased intracranial volume and pressure	The Sophysa external CSF drainage catheters are intended to temporarily drain the Cerebrospinal Fluid (CSF), for less than 30 days (up to 29 days maximum).	Substantially Equivalent
Single use	Single use	Single use	Same
Sterility status	Supplied sterile	Supply sterile	Same
Re-sterilization status	Cannot be re-sterilized	Cannot be re-sterilized	Same
Technical Equivalence			
Principle mode of action	K853365: The catheter is inserted into the ventricular space and fixed under the scalp by suturing. CSF flow is diverted into a compatible collection system. K964923: The catheter is inserted into the subarachnoid space and fixed to the subcutaneous tissue by suturing. CSF flow is diverted into a compatible collection system.	Same	Same
Shape/Dimension	K853365: 23.5 cm long, 1.5 mm ID. K964923: 80 cm long, 0.76 mm ID.	Ventricular: 29-35cm long, 1.5- 2.3 mm ID Lumbar: 90 cm long, 0.76 mm ID	Substantially Equivalent
Accessories	K853365: Stylet, luer lock connector, compression hub, K964923: Guidewire, Tuohy needle, luer adapter, suture tab	Ventricular: Stylet, trocar, luer-lock connector, suture tab Lumbar: Guidewire, Tuohy needle, suture tab, compression hub	Substantially Equivalent
Performance Standards	-	ISO 7197, ISO 20697, ISO 20698, ISO 11070	Substantially Equivalent

	Predicates	Proposed Devices	Rational of why no new issues of safety and effectiveness
MRI compatibility	MRI Safe	Ventricular: MR Safe Lumbar: MR Conditional due to the presence of metallic parts within the Compression Hub which connects to an external CSF drainage collection system.	Substantially Equivalent
Shelf life	-	5 years	Target shelf life
Biological Safety/Compatibility			
Biocompatibility	Biocompatible materials	Biocompatible materials established by a combination of testing and rationale for the following: Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Material-Mediated Pyrogenicity, Subacute/ Subchronic Toxicity, Genotoxicity, Implantation (brain, 4 weeks, muscle 4 weeks), Indirect Hemolysis, Neurotoxicity	Substantially Equivalent
Sterilization method	Ethylene Oxide	Ethylene Oxide	Same
Primary packaging system	Tyvek pouch	Double peel-off packaging Tyvek pouch	Substantially Equivalent

Summary of Non-clinical testing

The following bench testing has been performed on the representative samples of the External CSF drainage product line: Visual Inspection, Dimensional Analysis, Radiopacity, Pressure / Flow Characteristics, Blockage / Hemorrhagic CSF Exposure, Air and Water Tightness, Dynamic Breaking Strength, Catheter Tensile Strength, Kink Resistance, Catheter Fixation, Corrosion Resistance, Guidewire Tensile Strength, Guidewire Bending Strength, Guidewire Breakage, Tuohy Needle/Hub Connection Strength.

Statement of Substantial Equivalence

The information summarized above demonstrates that External CSF drainage is substantially equivalent to and is as safe and as effective as the legally marketed predicate device.