February 2, 2023

Sophysa
Zheng Xue
Consultant
05 Rue Guy Moquet
Orsay, Essonne 91400
France

Re: K222422
Trade/Device Name: Polaris Valve Electronic Reading Instrument
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: December 30, 2022
Received: December 30, 2022

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 (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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 2023.02.02 15:22:38 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222422

Device Name
Polaris Valve Electronic Reading Instrument

Indications for Use *(Describe)*
The Electronic Reading Instrument is intended to locate and read the operating pressure of a Polaris valve.
It is specifically designed to be combined with the Locator from a compatible Polaris Adjustment Kit (PAK2).

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.

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510(k) Summary

1. Sponsor Information

Applicant Name:	Sophysa SA
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:	Zheng XUE Consultant z.xuecazenave@sophysa.fr
Date Prepared:	February 23, 2023

2. Device Name and Classification

Trade/Proprietary Name:	Polaris Valve Electronic Reading Instrument
Common Name:	Accessory to Hydrocephalus shunt system
510(k) Submitter:	Sophysa
Device Class:	Class II
Product code:	JXG
Regulation:	21 CFR 882.5550

3. Predicate Device

Predicate:	POLARIS® PRESSURE ADJUSTABLE VALVE SYSTEM/POLARIS® ADJUSTABLE VALVE WITH SIPHONX (Sophysa SA), K141227, Product code: JXG

4. Device Description

The Polaris® valve electronic reading instrument (PAK3-ERI) is intended to non-invasively locate and read the operating pressure of a Polaris® valve before and after implantation in the treatment of hydrocephalus. It should be inserted into the PAK2-LI locator tool (identical to the locator tool part as in the predicate device cleared via K141227) in order to read the valve's pressure position.

5. Intended Use

The Electronic Reading Instrument is intended to locate and read the operating pressure of a Polaris® valve.

It is specifically designed to be combined with the Locator from a compatible Polaris® Adjustment Kit (PAK2).

6. Summary of Equivalence to Predicate Device

The Polaris® valve electronic reading instrument (PAK3-ERI) is substantially equivalent to the Polaris® pressure reading instrument (PAK2-RI) in the bundled submission of K141227 as listed in Table 5-1.

Table 5-1: Predicate Devices Comparison: PAK2-RI vs. PAK3-ERI

Item	**Polaris® pressure reading instrument in the bundled submission of K141227 (predicate device)**	**The Polaris® valve electronic reading instrument (subject device)**
INTENDED USES AND DEVICE DESIGN		
Intended Use	designed for reading the operating pressure of a Polaris®valve	designed for reading the operating pressure of a Polaris®valve.
Indications for use	Same as above	Same
Prescription use	Prescription use only	Same
Operating Principle	After that the locator identifies the valves axis, the PAK2-RI is inserted in the locator. PAK2-RI incorporates an indicator that aligns with the valve's magnetic field to display the valve pressure position.	Similar, After that the locator identifies the valves axis, the PAK3-ERI is inserted in the locator. PAK3-ERI incorporates an indicator light that measures the valve's magnetic field and display the valve pressure position.
Energy type	Mechanical, not battery operated	Battery operated
Location/indication feedback	Location: No location feedback; the user is required to manually palpate to determine the valve location	Location: display screen with a Ball to aid the localization of valve's magnetic center. Indication: display a light indicator to the valve pressure

Item	Polaris® pressure reading instrument in the bundled submission of K141227 (predicate device)	The Polaris® valve electronic reading instrument (subject device)
	Indication: display a mechanical indicator to the valve pressure position on the locator tool (PAK2-LI)	position on the locator tool (PAK2-LI)
Materials – not patient contacting	No patient contact. ABS	No patient contact ABS, PBT, Polycarbonate
Software	No	Yes
Sterilization	NA, non-sterile	NA, non-sterile

7. Summary of Non-clinical testing

Performance testing included design verification tests, software tests, electrical safety test, EMC safety test, simulated use test, use life test and transit test.

8. Statement of Substantial Equivalence

The information summarized above demonstrates that the Polaris® valve electronic reading instrument is substantially equivalent to and is as safe and as effective as the legally marketed predicate device.