April 10, 2026

Sophysa
Eugénie Magné
Regulatory Affairs Manager
5 Rue Guy Môquet
Orsay, 91400
France

Re: K252241
Trade/Device Name: Pressio® 3 Multi-parameter Neuromonitoring System
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: July 17, 2025
Received: July 17, 2025

Dear Eugénie Magné:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

JULIA E. SLOCOMB -S

Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.04.10 13:32:34 -04'00'

for Jamie 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)*
K252241

Device Name
Pressio® 3 Multi-parameter Neuromonitoring System

Indications for Use *(Describe)*
The Pressio® 3 System is indicated for continuous invasive monitoring of intracranial pressure by trained personnel in neuro-intensive care units and neurosurgical departments.

Depending on the type of catheter being used, the Pressio® 3 Monitor can also display the intracranial temperature. According to the clinical situation, you can select the appropriate Pressio® catheter:

– Pressio® kit for monitoring intracranial parenchymal pressure and temperature with bolt (PSO-PBT), indicated for use in parenchymal pressure and temperature monitoring.
– Pressio® kit for monitoring intracranial parenchymal pressure and temperature with tunneling (PSO-PTT), indicated for use in parenchymal pressure and temperature monitoring.
– Pressio® kit for monitoring intracranial ventricular pressure and temperature with tunneling (PSO-VTT), indicated for use in intraventricular pressure and temperature monitoring and cerebrospinal fluid drainage application.

The following Pressio® kits for Intracranial Pressure Monitoring are also compatible with the Pressio® 3 Monitor:
– Pressio® kit for monitoring intracranial parenchymal pressure with bolt (PSO-PB), indicated for use in parenchymal pressure monitoring.
– Pressio® kit for monitoring intracranial parenchymal pressure with tunneling (PSO-PT), indicated for use in parenchymal pressure monitoring.
– Pressio® kit for monitoring intracranial ventricular pressure with tunneling (PSO-VT), indicated for use in intraventricular pressure monitoring and cerebrospinal fluid drainage application.

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.

510(k) Summary

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)
Sophysa Person:	Julie LOPEZ Regulatory affairs director regulatory@sophysa.com
Submission contact Person:	Eugénie MAGNÉ Neurocritical care regulatory affairs manager emagne@sophysa.fr
Date Prepared:	06-April-2026

Device Name and Classification

Trade/Proprietary Name:	Pressio®3 Multi-parameter Neuromonitoring System
Common Name:	Intracranial pressure monitoring device
Classification Name	Device, monitoring, intracranial pressure
Regulation:	21 CFR 882.1620
Device Class:	2
Product Code:	GWM

Predicate Device

Predicate:	Pressio® 2 ICP Monitoring System (K162108)

Device Description

The Pressio® 3 Monitor is used in patients requiring continuous invasive monitoring of intracranial pressure and/or intracranial temperature (ICT) by trained personnel in a hospital environment (neurological intensive care unit, operating room).

The Pressio®3 Monitor is designed to measure and display the ICP value and curve, as well as the ICT value determined by the Pressio® catheters:

- PSO-PB, PSO-PT and PSO-VT
- PSO-PBT, PSO-PTT and PSO-VTT

The Pressio® catheter kits are part of the previously cleared 510(k) submission K162108.

To monitor the patient's ICP and ICT, the Monitor must be connected to a Catheter (supplied separately) using the Catheter Extension Cable (PSO-EC30). The Monitor can be connected to a patient bedside monitor (not supplied by Sophysa) which centralizes the measurements from various medical devices. When the Monitor is connected to a patient bedside monitor, the ICP and ICT measurements are transmitted to the patient bedside monitor via the Pressure cable (PSO-MCPxx) and the Temperature cable (PSO-MCT2-y), both supplied separately. Along with ICP and ICT monitoring, the Pressio® 3 Monitor also offers the following features:

Display of Mean Arterial Pressure (MAP) values, that can be recovered from the Bedside Monitor and displayed on the Monitoring screen via the analog blood pressure cable (PSO-MPAxx), supplied separately.

Calculation of Cerebral Perfusion Pressure (CPP) using the MAP values recovered from a Bedside Monitor.

Display of Cerebral Compliance data, that can be assessed by displaying P2/P1 change indicators in the patient being monitored.

Display of Cerebral Autoregulation data, that can be assessed by correlating the ICP and MAP variations, using the PRx (Pressure Reactivity Index) measure

Indications for Use

The Pressio® 3 System is indicated for continuous invasive monitoring of intracranial pressure by trained personnel in neuro-intensive care units and neurosurgical departments.

Depending on the type of catheter being used, the Pressio® 3 Monitor can also display the intracranial temperature. According to the clinical situation, you can select the appropriate Pressio® catheter:

- Pressio® kit for monitoring intracranial parenchymal pressure and temperature with bolt (PSO-PBT), indicated for use in parenchymal pressure and temperature monitoring.
- Pressio® kit for monitoring intracranial parenchymal pressure and temperature with tunneling (PSO-PTT), indicated for use in parenchymal pressure and temperature monitoring.
- Pressio® kit for monitoring intracranial ventricular pressure and temperature with tunneling (PSO-VTT), indicated for use in intraventricular pressure and temperature monitoring and cerebrospinal fluid drainage application.

The following Pressio® kits for Intracranial Pressure Monitoring are also compatible with the Pressio® 3 Monitor:

- Pressio® kit for monitoring intracranial parenchymal pressure with bolt (PSO-PB), indicated for use in parenchymal pressure monitoring.
- Pressio® kit for monitoring intracranial parenchymal pressure with tunneling (PSO-PT), indicated for use in parenchymal pressure monitoring.
- Pressio® kit for monitoring intracranial ventricular pressure with tunneling (PSO-VT), indicated for use in intraventricular pressure monitoring and cerebrospinal fluid drainage application.

Summary of Equivalence to Predicate Device

The Pressio®3 Multi-parameters neuromonitoring system, ICP, ICT, CPP is concluded to be substantially equivalent to the legally marketed predicate device: Pressio®2 ICP monitor as part of the bundled devices approved in K162108. as listed in Table 1.

Table 1: Predicate Devices Comparison

Item	Predicate Device	Proposed device	Discussion
Manufacturer	Sophysa	Sophysa	Same
510k no.	K162108	K252241	N/A
Classification	21 CFR882.1620	21 CFR882.1620	Same
FDA Product code	GWM	GWM	Same
Indication for use	The Pressio® 2 Intracranial Pressure Monitoring system is indicated for continuous invasive monitoring of intracranial pressure by trained personnel of (neuro) intensive care units and neurosurgery	The Pressio® 3 System is indicated for continuous invasive monitoring of intracranial pressure by trained personnel in neuro-intensive care units and neurosurgical departments.	

	departments. Depending the type of catheter used, the Pressio® 2 ICP Monitor can also display the intracranial temperature. According to the clinical situation, users choose the appropriate Pressio® catheters: - Pressio® kit for monitoring intracranial parenchymal pressure and temperature with bolt (PSO-PBT) indicated for use in parenchymal pressure and temperature monitoring. - Pressio® kit for monitoring intracranial parenchymal pressure and temperature with tunneling (PSO-PTT) indicated for use in parenchymal pressure and temperature monitoring. - Pressio® kit for monitoring intracranial ventricular pressure and temperature with tunneling (PSO-VTT) indicated for use in intraventricular pressure and temperature monitoring and cerebrospinal fluid drainage application. The following Pressio® kits for Intracranial Pressure Monitoring are also compatible with the Pressio® 2 ICP Monitor: - Pressio® kit for monitoring intracranial parenchymal pressure with bolt (PSO-PB) indicated for use in	Depending on the type of catheter being used, the Pressio® 3 Monitor can also display the intracranial temperature. According to the clinical situation, you can select the appropriate Pressio® catheter: – Pressio® kit for monitoring intracranial parenchymal pressure and temperature with bolt (PSO-PBT), indicated for use in parenchymal pressure and temperature monitoring. – Pressio® kit for monitoring intracranial parenchymal pressure and temperature with tunneling (PSO-PTT), indicated for use in parenchymal pressure and temperature monitoring. – Pressio® kit for monitoring intracranial ventricular pressure and temperature with tunneling (PSO-VTT), indicated for use in intraventricular pressure and temperature monitoring and cerebrospinal fluid drainage application. The following Pressio® kits for Intracranial Pressure Monitoring are also compatible with the Pressio® 3 Monitor: – Pressio® kit for monitoring intracranial parenchymal pressure with bolt (PSO-PB), indicated for use in parenchymal pressure monitoring.	

	parenchymal pressure monitoring - Pressio® kit for monitoring intracranial parenchymal pressure with tunneling (PSO-PT) indicated for use in parenchymal pressure monitoring. - Pressio® kit for monitoring intracranial ventricular pressure with tunneling (PSO-VT) indicated for use in intraventricular pressure monitoring and cerebrospinal fluid drainage application.	– Pressio® kit for monitoring intracranial parenchymal pressure with tunneling (PSO-PT), indicated for use in parenchymal pressure monitoring. – Pressio® kit for monitoring intracranial ventricular pressure with tunneling (PSO-VT), indicated for use in intraventricular pressure monitoring and cerebrospinal fluid drainage application.	
Users	The PRESSIO®2 is intended for hospital use, particularly in the neuro intensive care and neurosurgery (operating theatre) departments.	The PRESSIO®3 is intended for hospital use, particularly in the neuro-intensive care and neurosurgery (operating theatre) departments.	Same
Compatible device	Monitor is intended to be used in association with sensor to get complete ICP monitoring system: PSO-PB/PBT, PSO-PT/PTT and PSO-VT/VTT	Monitor is intended to be used in association with sensor to get complete ICP monitoring system: PSO-PB/PBT, PSO-PT/PTT and PSO-VT/VTT	Same
Compatible Accessories	Catheter extension cable: PSO-EC30 Patient monitor cables: Pressure: PSO-MCxx, Temperature: PSO-MCTy	Catheter extension cable: PSO-EC30 Patient monitor cables: Pressure: PSO-MCPxx Temperature: PSO-MCT2-y Blood Pressure Cable: PSO-MPAxx Patient Monitor Extension Cable: PSO-MPM01	The 2 plugs to transmit ICP and ICP to bedside monitor on Pressio ®2 were replaced by a unique plug to connect PSO-MPM01, which permit to plug patient monitor cables (PSO-MCPxx and PSO-MCT2-y) which respectively are the same than PSO-MCxx and PSO-MCTy, except that the plug which was connected to Pressio 2 has been replaced by a plug compatible with

			PSO-MPM01. PSO-MCPx cables for Pressio 3 and PSO-MCx cables for Pressio 2 are both cables that enable analog transmission (AAMI BP22) of pressure measurements. Similarly, PSO-MCT2-y and PSO-MCT-y cables are both cables that enable analog transmission of temperature (YSI400). Their lengths (PSO-MCPx and PSO-MCT2-y) are adapted to take into account the additional length of the PSO-MPM01 3-way cable.
Reusable	Yes	Yes	Same
Software functions	1-Measuring and displaying intracranial pressure (ICP) values and curve 2-Measuring and displaying intracranial temperature (ICT) values 3-Displaying ICP and ICT values on patient monitor: ICP history format is 24 h of data in real time + 14 days of average data or 15 days of data in real time. 4-History management (ICP, ICT and events) 5-ICP and ICT alarms management	1-Measuring and displaying intracranial pressure (ICP) values and curve 2-Measuring and displaying intracranial temperature (ICT) values 3-Displaying ICP and ICT values on patient monitor: ICP history format is 24 h of data in real time + 14 days of average data or 15 days of data in real time. 4-History management (ICP, ICT and events) 5-ICP and ICT alarms management 5-Display P2/P1 calculated ratio with	Similar. The Pressio®3 displays additional information due to improvements and ability to obtain mean arterial pressure from a patient bedside monitor.

		range: 0.01 to 5.00 ICP amplitude in mmHg 6-Calculate and display CPP: Range from 0 to +150mmHg 7-Display Pressure time dose of CPP in mmHg-hr 8-Display of the time spent under the threshold with 2 configurable thresholds (high value and low value) 9-Display Pressure Time Dose of ICP in mmHg-hr with configurable thresholds 10-Display the data that helps to monitor cerebral autoregulation and the "U-shape" curve to detect CPP opt value in mmHg 11-Display PRx History management (ICP, ICT, CPP and events)	

Summary of Non-clinical testing

The following bench testing has been performed on representative samples of the Pressio®3 Multi-parameter Neuromonitoring System: simulated measurement verification, battery autonomy, resistance to cleaning agents, functional performance under varying environmental conditions, simulated transport, clamp fixation, connection endurance, disconnection cycles, resistance to bending, resistance to traction, electrical resistance, and resistance to humidity.

EMC, electrical safety and software tests have been performed on the representative samples of the Pressio®3 Multi-parameters neuromonitoring system, ICP, ICT, CPP system, according to design requirements. The proposed device confirms to the following non clinical testing standards :

- IEC 60601-1 : 2005 / AMD1:2012/ AC1: 2014 / A2: 2020 : Medical electrical equipment – Part 1 : General requirements for basic safety and essential performance
- IEC 60601-1-2 : 2014 /A1: 2020 :Medical electrical equipment – Part 1-2 : general requirements for basic safety and essential performance – Collateral standard : electromagnetic compatibility – Requirements and tests
- IEC 60601-1-8 : 2006 + A1:2012 + A11:2017 / A2: 2020 :Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard:

General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

- IEC 80601-2-49: 2018 : Medical electrical equipment - Part 2-49 : Particular requirements for the basic safety and essential performance of multifunction patient monitors
- ISO 80601-2-56 : 2017 / A1 :2020 : Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- IEC 62304 : 2006 + A1 :2015 Medical Device Software - Software Life Cycle Processes
- ISO 10993-1 :2020 :Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 15223-1 :2021 : Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Statement of Substantial Equivalence

The information summarized above demonstrates that Pressio®3 Multi-parameters neuromonitoring system, ICP, ICT, CPP is substantially equivalent to and is as safe and as effective as the legally marketed predicate device Pressio®2 ICP monitor.