DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 17, 2017

SOPHYSA SA
Etienne Duhot
Quality and Regulatory Affairs Specialist
5, Rue Guy Moquet
Orsay, Cedex, 91400 FR

Re: K162108
Trade/Device Name: Pressio® 2 ICP Monitoring System
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: April 11, 2017
Received: April 14, 2017

Dear Etienne Duhot:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162108

Device Name
Pressio® 2 ICP Monitoring System

Indications for Use *(Describe)*
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 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 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.

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K162108
510(K) SUMMARY

Submitter: SOPHYSA SA
5 rue Guy Moquet
91400 Orsay
FRANCE
Tel: (+33) 1 69 35 35 00
Fax: (+33) 1 69 35 36 90

Contact Person: Etienne DUHOT
Quality and Regulatory Affairs Specialist, SOPHYSA, SA

Date Prepared: April 17, 2017

Proprietary Name: Pressio® 2 ICP Monitoring System

Classification: 21 CFR 882.1620 Intracranial Pressure Monitoring Device
Class II, Product Code GWM

Product Code: GWM

Predicate Devices:

Applicant	Model	Document number	Regulation & Product Code	Review Panel
Integra®	Camino® ICP monitor Camino Parenchymal Bolt ICP Monitoring catheter – 110-4B	K121573 K102875	21 CFR 882.1620 GWM	Ear Nose & Throat Ear Nose & Throat
Raumedic®	Neurovent®-PTO 2L Neurovent®-PTO	K130529	21 CFR 882.1620 GWM	Neurology
	Neurovent®-TEMP IFD-S	K120252	21 CFR 882.1620 GWM	Ear Nose & Throat
Sophysa®	Sophysa® - PSO-PB Sophysa® - PSO-PT Sophysa® - PSO-VT	K062584	21 CFR 882.1620	Neurology

Device:

The Pressio® 2 ICP Monitoring System is composed of the following elements:

- Pressio® 2 ICP Monitor (PSO-4000)
- Pressio® ICP implantable catheters indicated for pressure and temperature monitoring:
    - Implantable catheter for parenchymal pressure and temperature monitoring with bolt (PSO-PBT).
    - Implantable catheter for parenchymal pressure and temperature monitoring with tunneling (PSO-PTT).
    - Implantable catheter for ventricular pressure and temperature monitoring and cerebrospinal fluid drainage application with tunneling (PSO-VTT).
- Pressio® ICP implantable catheters indicated for pressure monitoring (already FDA approved K062584):

  - Implantable catheter for parenchymal pressure monitoring with bolt (PSO-PB).
  - Implantable catheter for parenchymal pressure monitoring with tunneling (PSO-PT).
  - Implantable catheter for ventricular pressure monitoring and cerebrospinal fluid drainage application with tunneling (PSO-VT)
- Catheter extension cable (PSO-EC30).
- Patient Monitor connection cable for ICP (PSO –MCxx), depends on the type of patient monitor available in the hospital. It exists 9 different references (already FDA approved K062584):
  - Patient monitor cable / Philips (Agilent), 12 pins (PSO-MC01)
  - Patient monitor cable / Siemens (Sirecust), 10 pins (PSO-MC02)
  - Patient monitor cable / Spacelab and Mindray, 6 pins (PSO-MC03)
  - Patient monitor cable / GE Datex – Ohmeda, 10 ins (PSO-MC04)
  - Patient monitor cable / GE Solar (Marquette), 11 pins (PSO-MC05)
  - Patient monitor cable / Hellige, 10 pins (PSO-MC06)
  - Patient monitor cable / Siemens, 7 pins (PSO-MC07)
  - Patient monitor cable / Nihon Kohden, 5 pins (PSO-MC08)
  - Patient monitor cable / Datascope, 6 pins (PSO-MC10)
- Patient monitor connection cable for ICT (PSO-MCT-Y), depends on the type of patient monitor available in the hospital. It exists 5 different references :
  - Patient monitor cable – temperature / Philips (Agilent), 2 pins (PSO-MCT-A)
  - Patient monitor cable – temperature / Siemens, 7 pins (PSO-MCT-B)
  - Patient monitor cable – temperature / Spacelabs, 10 pins (PSO-MCT-C)
  - Patient monitor cable – temperature / GE solar (Marquette), GE DATEX-Ohmeda, 11 pins (PSO-MCT-E)
  - Patient monitor cable temperature / HELLIGE, DATEX-Ohmeda, NIHON KOHDEN, MINDRAY & DATASCOPE – JACK 6.35mm (PSO-MCT-F)
- Power supply cable (5C010005).
- Pressio® MRI support (PSO-MRI)

Device Description:

The Pressio® 2 ICP Monitoring System is composed of a monitor (PSO-4000) with accessories and implantable catheters. The PSO-4000 monitor is an electromedical device designed for monitoring patient's intracranial pressure and temperature via catheters implanted in parenchyma (PSO-PBT and PSO-PTT) or in ventricles with drainage of cerebrospinal fluid (PSO-VTT). Previously marketed Pressio® kits (K062584) are also available on the Pressio® 2 ICP Monitor and allows monitoring of intracranial pressure via catheters implanted in parenchyma (PSO-PB and PSO-PT) or in ventricles (PSO-VT) with also drainage of cerebrospinal fluid.

The Pressio® 2 ICP Monitor can also be connected to a patient monitor via a compatible monitor connection cable. This connection is not necessary for Pressio® 2 Intracranial Pressure Monitor functioning. The Pressio® 2 Monitor can also extract data to external computer via a USB cable. The Pressio® 2 ICP Monitoring System is sold as a kit containing a Pressio® 2 ICP Monitor (PSO-4000), a power supply cable (PSO-AC), a catheter extension cable (PSO-EC30).

Intended 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 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 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.

Non-Clinical Testing:

The Pressio® 2 ICP Monitoring System is conform to the following non clinical testing standards:

- ISO 10993-1:2009/(R)2010: Biological evaluation of medical devices – part 1: Evaluation and testing within a risk management process- AAMI ANSI ISO 11135:2014: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ANSI IEC 60601-1 Ed.3, Medical electrical equipment – part 1: general requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 3:2007-03, Medical Electrical Equipment – part 1-2: General Requirements for Safety – collateral standard: Electromagnetic compatibility: Requirements and tests
- IEC 60601-1-8:2006, 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
- AAMI ANSI IEC EN 62304:2006 Medical device software – software life cycle processes
- ISO 80601-2-56:2009, Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
- ISO 15223-1:2012, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
- IEC 62366-1:2007, Medical devices – Part 1: Application of usability engineering to medical devices
- ANSI/AAMI NS28 (2010): Intracranial Pressure Monitoring Devices

Substantial Equivalence: The following tables summarize the predicate devices comparison based on main technological characteristics. These summaries are organized by product code.

ICP Monitors Substantial Equivalence Summary

Devices	*Pressio® ICP Monitoring system*	*K062584Integra® Camino® ICP Monitoring System K121573*	*Pressio® 2 ICP Monitoring System K162108*	*Rationale / Comment*
Applicable product codes	21CFR 882.1620			GWM; Same

Table 1: Predicate comparison: Intended uses and design (ICP Monitors)

Item	**Integra® Camino® ICP Monitoring System K121573**	**Pressio® 2 ICP Monitoring System K162108**	**Comment**
Manufacturer	Integra®	Sophysa®	N/A
510(k) no.	K121573	K162108	N/A
Classification regulation	21 CFR 882.1620	21 CFR 882.1620	Same
Product no.	GWM	GWM	Same
Indications for Use	The Integra® Camino ® ICP Monitoring system is indicated for use by qualified neurosurgeons or neurointensivists for measurement of intracranial pressure and temperature	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 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	Subject device includes the relevant bullet points for each particular catheter.

Item	Integra® Camino® ICP Monitoring System K121573	Pressio® 2 ICP Monitoring System K162108	Comment
		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 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.	
Prescription use	Yes	Yes	Same
Anesthesia required	Yes	Yes	Same
Physician training required	Yes	Yes	Same
System components	Monitor Power cable Battery Patient bedside monitor cables Integra® Catheter Flex extension cable USB adapter cable	Monitor Power cable Battery Patient bedside monitor cables Sophysa® Catheter Catheter extension cable USB adapter cable	Same

Table 2: Predicate comparison: Main functions and technological specifications (ICP Monitors)

Item	Integra® Camino® ICP Monitoring System K121573	Pressio® 2 ICP Monitoring System K162108	Comment
Intracranial Pressure Monitoring	Yes	Yes	Same
Intracranial Temperature Monitoring	Yes	Yes	Same
Output to patient monitor for ICP	Yes	Yes	Same
Output to patient monitor for ICT	Yes	Yes	Same

Externalization to a PC	Yes (USB)	Yes (USB)	Same

Table 3: Predicate comparison, Safety (ICP Monitors)

Safety – ICP Monitor	**Raumedic® ICP-TEMP Monitoring System K120252**	**Pressio® 2 ICP Monitoring System K162108**	**Comment**
Electrical and EMC standards conformity	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Same
Electrical safety - Multifunction patient monitoring equipment	IEC 60601-2-49	IEC 60601-2-49	Same
Electrical safety – Alarm systems	IEC 60601-1-8	IEC 60601-1-8	Same
Software	ISO 62304	ISO 62304	Same

Parenchymal and Ventricular Implantable Catheters Equivalence Summary

Devices	*Pressio® ICP Monitoring system K062584*	*Raumedic® ICP-TEMP Monitoring System K120252*	*Raumedic® PTO Monitoring System K130529*	*Pressio® 2 ICP Monitoring System K162108*	*Comment*
Applicable product codes	21CFR 882.1620				GWM; Same

Table 4: Predicate comparison: Parenchymal Implantable Catheters

Item	**Raumedic® PTO Monitoring System K130529**	**Pressio® ICP Monitoring system K062584**	**Pressio® 2 ICP Monitoring System K162108**	**Comment**
Trade Name	NEUROVENT®-PTO (tunellisable) NEUROVENT®-PTO 2L (with Bolt)	SOPHYSA®-PSO-PT (with tunneling) PSO-PB (with bolt)	SOPHYSA®-PSO-PTT (with tunneling) PSO-PBT (with bolt)	N/A
Indication for use	The Raumedic®-PTO Monitoring System is indicated for use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the parenchyma as well as to determine the partial oxygen pressure PtiO2 of the interstitial fluid.	The Pressio® PSO-PB and PSO-PT Monitoring Kit is indicated for continuous invasive monitoring of intracranial parenchymal pressure (ICP) by trained personnel of (neuro) intensive care units and neurosurgery departments	The Pressio® PSO-PBT and PSO-PTT Monitoring Kit is indicated for continuous invasive monitoring of intracranial parenchymal pressure (ICP) and temperature (ICT) by trained personnel of (neuro) intensive care units and neurosurgery departments	Same – for measurement of intracranial pressure and temperature.
Anatomical Site Catheter	Brain Parenchyma	Brain Parenchyma	Brain Parenchyma	Same
Sensors	Catheter tip	Catheter tip	Catheter tip	Same

Item	Raumedic® PTO Monitoring System K130529	Pressio® ICP Monitoring system K062584	Pressio® 2 ICP Monitoring System K162108	Comment
location				
Single Use catheter	Yes	Yes	Yes	Same
Sterilization process	With ethylene Oxide	With ethylene oxide	With ethylene oxide	Same
Drainage	No	No	No	Same
ICP – sensor design catheter	Piezoresistive pressure sensor	Piezoresistive pressure sensor	Piezoresistive pressure sensor	Same
ICT- sensor design	Thermistor	-	Thermistor	Same – for Raumedic. The Pressio® PSO-PT and PSO-PB do not read intracranial temperature.
MRI conditional	Yes	Yes	Yes	Same
Product code	GWM	GWM	GWM	Same
Biocompatibility of patient contacting components	ISO 10993-1	ISO 10993-1	ISO 10993-1	Same
Sterilization	EN ISO 11135-1 ISO 11607	EN ISO 11135-1 ISO 11607	EN ISO 11135-1 ISO 11607	Same

Table 5: Predicate Comparison: Ventricular Implantable catheters

Item	Raumedic® ICP-TEMP Monitoring System K120252	Pressio® ICP Monitoring system K062584	Pressio® 2 ICP Monitoring System K162108	Comment
Trade Name	NEUROVENT®-TEMP-IFD-S	SOPHYSA®-PSO-VT	SOPHYSA®-PSO-VTT	N/A
Indication for use	The Raumedic®-PTO Monitoring System is indicated for use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the ventricle and cerebrospinal	The Pressio® PSO-VT Intracranial Pressure Monitoring Kit with tunneling is indicated for continuous invasive monitoring of intracranial ventricular pressure (ICP) by trained personnel of (neuro) intensive care units	The Pressio® PSO-VTT Intracranial Pressure Monitoring Kit with tunneling is indicated for continuous invasive monitoring of intracranial ventricular pressure (ICP) and temperature (ICT) by trained personnel of (neuro) intensive care	Same for Raumedic. The PSO-VT does not read intracranial temperature.

Item	Raumedic® ICP-TEMP Monitoring System K120252	Pressio® ICP Monitoring system K062584	Pressio® 2 ICP Monitoring System K162108	Comment
	applications	and neurosurgery departments with cerebrospinal fluid drainage application.	units and neurosurgery departments with cerebrospinal fluid drainage application.	
MRI conditional	Yes	Yes	Yes	Same
Anatomical Site Catheter	Brain ventricle	Brain ventricle	Brain ventricle	Same
Single Use catheter	Yes	Yes	Yes	Same
Sterilization process	With ethylene Oxide	With ethylene oxide	With ethylene oxide	Same
Drainage	Yes	Yes	Yes	Same
ICP – sensor design catheter	Piezoresistive pressure sensor	Piezoresistive pressure sensor	Piezoresistive pressure sensor	Same
ICT- sensor design	Thermistor	-	Thermistor	Same The Pressio® PSO-VT does not read intracranial temperature.
Product code	GWM	GWM	GWM	Same
Biocompatibility of patient contacting components	ISO 10993-1	ISO 10993-1	ISO 10993-1	Same
Sterilization	EN ISO 11135-1 ISO 11607	EN ISO 11135-1 ISO 11607	EN ISO 11135-1 ISO 11607	Same

Table 6: Predicate comparison: Implantable catheters safety (summary)

Safety – Implantable catheters	Pressio®2 ICP Monitoring System	Pressio® ICP Monitoring system K062584	Raumedic® Monitoring system K130529, K120252	Comment
Biocompatibility of patient contacting components	ISO 10993-1	ISO 10993-1	ISO 10993-1	Same
Sterilization	EN ISO 11135-1 ISO 11607	EN ISO 11135-1 ISO 11607	EN ISO 11135-1 ISO 11607	Same

Parenchymal and Ventricular Intracranial and Temperature Monitoring kit accessories Equivalence Summary

Devices	*Raumedic® PTO Monitoring System K130529*	*Pressio® ICP Monitoring system K062584*	*Pressio® 2 ICP Monitoring System K162108*	*Comment*
Bolt for introduction and fixation	21 CFR 882.1620			Same

Table 7: Predicate comparison: Parenchymal and Ventricular Intracranial Pressure and Temperature Monitoring kit accessories (summary)

Item	**Raumedic® PTO Monitoring System K130529**	**Pressio® ICP Monitoring system K062584**	**Pressio® 2 ICP Monitoring System K162108**	**Comment**
ACCESSORIES OF IMPLANTATION				
Type of installation – ICP monitoring with tunneling	Spliceable Tunneling Sleeve CH8: - Trocar - Tunneling sleeve	Monitoring kit with tunneling (PSO-PT) - Trocar - Tunneling needle with stylet - Drill with adjustable stop - Allen key	Monitoring kit with bolt (PSO-PBT): - Trocar - Tunneling needle with stylet - Drill with adjustable stop - Allen key	Similar – for Raumedic kit Same – for Sophysa® monitoring
Type of installation – Ventricular pressure monitoring	Spliceable Tunneling sleeve CH12: - Trocar Tunneling sleeve	Monitoring kit with tunneling (PSO-VT): - Trocar - Tunneling sheath - Drill with adjustable stop - Allen key	Monitoring kit with tunneling (PSO-VT): - Trocar - Tunneling sheath - Drill with adjustable stop - Allen key	Similar – for Raumedic kit Same – for Sophysa® monitoring kit
PERFORMANCE TESTING				
Placement in subdural space - Pressure Measurement	No alteration of pressure measured with a Raumedic® catheter when inserted in a subdural space	No alteration of pressure measured with a Pressio® catheter when inserted in a subdural space	No alteration of pressure measured with a Pressio® catheter when inserted in a subdural space	Same performance results reached.
Biocompatibility of patient contacting components	ISO 10993-1	ISO 10993-1	ISO 10993-1	Same
Sterilization	EN ISO 11135-1 ISO 11607	EN ISO 11135-1 ISO 11607	EN ISO 11135-1 ISO 11607	Same

Table 8: Predicate comparison: Bolt for Introduction and Fixation and Burr with adjustable stop comparison

Devices	*Camino Parenchymal Bolt ICP Monitoring catheter – 110-4B K102875*	*Pressio® 2 ICP Monitoring System K162108*	*Comment*
Implantation	Parenchymal bone	Parenchymal bone	Same
Number of lumens	1	1	Same
Type of catheter used with	Parenchymal catheter for ICP monitoring	Parenchymal catheter for ICP monitoring	Same
Bolt components	Skull screw	Skull screw	Same
	Turning wings	Turning wings	Same
	Compression cap	Wing nut (tab)	Same
	Spacer ring	Spacer ring	Same
Piercing guide	Stylet	Stylet	Same
Drilling way	Parenchymal bone	Parenchymal bone	Same
Piercing kit composition	Drill	Drill	Same
	Adjustable safety stop	Adjustable Drill stopper	Same
	Hex wrench for adjustable safety stop	Allen key for adjustable Drill stopper	Same

Conclusion

The Pressio® 2 ICP Monitoring System (K162108) is substantially equivalent to the Integra® Camino® ICP Monitoring system (K121573), Integra® Camino® Parenchymal Bolt ICP Monitoring catheter (K102875), the Raumedic® Monitoring System (K130529 and K120252) and Pressio® ICP Monitoring System (K062584) in terms of intended uses, materials, design, functions and operating characteristics. Additionally, the same technology is used in order to perform intracranial pressure and temperature monitoring.