K062584

JUL - 5 2007

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

3.1 Name, Address, Phone and Fax Number of the Applicant

Sophysa SA
22 rue Jean Rostand
Parc Club Orsay Université
91893 ORSAY Cedex, France
Tel: 011-331-69 35 35 00
Fax: 011 331 69 35 36 90

3.2 Contact Person

Jean-Christophe Audras
22 rue Jean Rostand
Parc Club Orsay Université
91893 ORSAY Cedex, France
Tel: 011-331-69 35 35 06

3.3 Date Prepared

June 19, 2007

3.4 Device Name

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

- Pressio® ICP Monitor (PSO-3000)
- Pressio® ICP Catheters (PSO-VT, PSO-PT, PSO-PB): there are four available types of implantable catheters:
  - Catheter implanted in ventricles via tunnelling (PSO-VT)
  - Catheter implanted in parenchyma via tunnelling (PSO-PT)
  - Catheter implanted in parenchyma via a bolt (PSO-PB)
- Pressio® Serial Transmitter Model (PSO-TX00)
- Pressio® Intracranial Pressure Interface Control Unit (PSO-IN00)
- Catheter Extension Cable (PSO-EC20)
- Monitor connexion cable (PSO-MCxx): "xx" depends on the type of patient monitor available in the hospital, it exists 9 different references
- Power Supply Cable (PSO-AC)
- Pressio® Pole Clamp (PSO-CL)
- Pressio® Disposable Hand Drill (PSO-DR)

3.5 Device Description

The Pressio® ICP Monitoring System (PSO-3000) is an electromedical device designed for the monitoring of a patient's intracranial pressure (ICP) via a catheter implanted in the parenchyma (PSO-PB or PSO-PT) or in the ventricles (PSO-VT). The Pressio® ICP Monitoring System is sold as a kit containing a Pressio® ICP Monitor (PSO-3000), a Power Supply Cable (PSO-AC) and the Catheter Extension Cable (PSO-EC20).

The Pressio® ICP Monitor can be connected to a patient monitor via a compatible monitor connection cable (PSO-MCxx). This permits medical staff to display intracranial pressure curves on the patient monitor. This connection is not necessary for Pressio™ Intracranial Pressure Monitor functioning. The calibration of patient monitor is performed via a host monitor calibration key on Pressio™ Intracranial Pressure Monitor.

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

- Pressio® ICP Monitor (PSO-3000)
- Pressio® ICP Catheters: there are three available types of implantable catheters:
    - Catheter implanted in ventricles via tunnelling (PSO-VT)
    - Catheter implanted in parenchyma via tunnelling (PSO-PT)
    - Catheter implanted in parenchyma via a bolt (PSO-PB)
- Pressio® Serial Transmitter Model (PSO-TX00)
- Pressio® Intracranial Pressure Interface Control Unit (PSO-IN00)
- Catheter Extension Cable (PSO-EC20)
- Monitor Connexion Cable (PSO-MCxx): "xx" depends on the type of patient monitor available in the hospital, it exists 9 different references
- Power Supply Cable (PSO-AC)
- Pressio® Pole Clamp (PSO-CL)
- Pressio® Disposable Hand Drill (PSO-DR)

3.6 Device Intended Use

The Pressio® Ventricular Intracranial Pressure Monitoring Kit with Tunneling, Model PSO-VT, is indicated for use in intraventricular pressure monitoring and cerebrospinal fluid drainage applications.

The Pressio® Intracranial Parenchymal Pressure Monitoring Kit with Tunneling, Model PSO-PT, is indicated for use in subdural or parenchymal pressure monitoring.

The Pressio® Intracranial Parenchymal Pressure Monitoring Kit with Bolt, Model PSO-PB, is indicated for use in parenchymal pressure monitoring.

3.7 Substantial Equivalence Summary

The Pressio® ICP monitoring system is substantially equivalent to the Codman® ICP express monitoring system (K945585, K914479, K991222 and K974088) in terms of intended use, materials, design, function and operating characteristics. The two monitoring systems utilize the same technology (strain gauge) to monitor Intracranial pressure (ICP).

3.8 Device Testing

Biocompatibility studies were conducted per ISO 10993 standard and have demonstrated that the materials used to manufacture the Pressio® ICP monitoring system are safe for its intended use.

In addition, the three Implantable catheters were subjected to extensive performance testing. Results of the testing showed that the catheter designs are safe for their intended uses.

The Pressio® Intracranial Pressure Monitor, the Pressio® Interface Control Unit and the Pressio® Serial Transmitter underwent numerous safety tests, including testing to IEC 60601-1 and UL 2601.

Finally, the manufacturing process of the Pressio® ICP Monitoring System complies with the United States Food and Drug Administration and European Standards for the manufacturing of medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2007

SOPHYSA
% Mr. Jean-Christophe Audras
Director, Regulatory Affairs
22 rue Jean Rostand
Parc Club Orsay Universite
91893 ORSAY Cedes - France

Re: K062584/S2
Trade/Device Name: Pressio® ICP Monitoring System
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: June 25, 2007
Received: June 26, 2007

Dear Mr. Audras:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anastacia M Bibb

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix E. Indications for Use

510(k) Number (if known): K062584

Device Name: Pressio® Intracranial Pressure Monitoring System

Indications for Use:

The Pressio® Ventricular Intracranial Pressure Monitoring Kit with Tunneling, Model PSO-VT, is indicated for use in intraventricular pressure monitoring and cerebrospinal fluid drainage applications.

The Pressio® Intracranial Parenchymal Pressure Monitoring Kit with Tunneling, Model PSO-PT, is indicated for use in subdural or parenchymal pressure monitoring.

The Pressio® Intracranial Parenchymal Pressure Monitoring Kit with Bolt, Model PSO-PB, is indicated for use in parenchymal pressure monitoring.

Prescription Use ____√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1_ of _1__

(Posted November 13, 2003)

Anastasia M Boles

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062584