



Food and Drug Administration
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October 20, 2016

Innerspace Neuro Solutions, Inc.
Gary Frugard
VP, Regulatory Affairs
1622 Edinger Ave Suite C
Tustin, California 92780

Re: K161010

Trade/Device Name: HICP200 Patient/monitor Interconnect Cable
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: April 9, 2016
Received: September 19, 2016

Dear Gary Frugard:

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 yours,

William J.
Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HH5,
ou=NIH, ou=People,
0.9.2342.19200300.100.1.1=0010149848,
cn=William J. Heetderks -A
Date: 2016.10.20 12:27:38 -0400

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

Indications for Use

510(k) Number (if known)

K161010

Device Name

HICP 200 Patient/Monitor Interconnect Cable

Indications for Use (Describe)

The HICP200 is designed for use with any Hummingbird catheter. Together, they comprise a system that is indicated for use in those conditions where continuous monitoring of ICP is required. As dictated by clinical judgment, direct measurement of ICP may be obtained from the subdural, parenchymal, or intraventricular locations.

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
for the
HICP200 Patient/Monitor Interconnect Cable

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

I. SUBMITTER

Company: InnerSpace Neuro Solutions, Inc.
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Tel: 877-486-2473 ext. 108
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Company Representative: Gary G. Frugard
VP, Regulatory Affairs/Quality Assurance
Contact phone: 949-683-1642
Email: GGFandA@msn.com

Date 510(k) Prepared: April 9, 2016

II. DEVICE

Trade Name: HICP200 Patient/Monitor Interconnect Cable

Common Name: Patient/Monitor Interconnect Cable

Classification Name: Device, Monitoring, Intracranial Pressure

Classification Panel: Neurology

Product Code: GWM

CFR Section: 882.1620

Classification: Class II

III. PREDICATE DEVICE

HICP200 Patient/Monitor Interconnect Cable is substantially equivalent to the following currently marketed devices:

- InnerSpace Medical Air Management System (AMS) as described in the Trilogy, K083378¹
- Aesculap-Spiegelberg Brain Pressure Monitor, K003759

These predicates have not been subject to a design-related recall.

IV. *DEVICE DESCRIPTION*

The HICP200 is a reusable patient/monitor interconnect cable with integrated Control and Catheter-Connect Modules. The principle of operation of the HICP200 and Hummingbird intracranial pressure catheter system is air-coupled pressure transduction.

The HICP200 Catheter-Connect Module houses the pressure transducer and provides a high-reliability pneumatic connection to the Hummingbird ICP catheter. The connector provides for audible and tactile feedback indicating a secure connection. The Intracranial Pressure (ICP) waveform is transduced in the Catheter-Connect Module and the analog signal is transmitted to the patient monitor, according to AAMI BP-22 standard protocol of $5\mu\text{V/V/mmHg}$.

The HICP200 Control Module monitors the same ICP signal transmitted to the monitor to control and implement system air priming cycle requirements and user interface audio/visual system status.

The HICP200 is configured with a user-specified connector to interface with the patient monitor.

V. *INDICATIONS FOR USE:*

The HICP200 is designed for use with any Hummingbird catheter. Together, they comprise a system that is indicated for use in those conditions where continuous monitoring of intracranial pressure (ICP) is required. As dictated by clinical judgment, direct measurement of ICP may be obtained from the subdural, parenchymal, or intraventricular locations.

VI. *COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE*

The HICP200 is substantially equivalent to the AMS (Air Management System) cable component of the Trilogy (K083378). Both are air-coupled pressure transduction devices, which require precise control of the system air volume. This is usually controlled by a priming mechanism that first evacuates the system and then introduces a defined volume of air. The HICP200 automates the priming process, whereas the AMS requires manual priming which is performed by hospital personnel on a periodic basis. The electromechanical priming mechanism is housed in the Control Module of the cable. The HICP200 is also substantial equivalent to the Aesculap-Spiegelberg Brain Pressure Monitor (K003759), which is also an air-coupled pressure transduction device; however with the Aesculap-Spiegelberg device, the priming mechanism is located in the monitor housing.

¹ In K083378 the Trilogy catheter is also referred to as the Synergy catheter.

A detailed listing of substantially equivalent elements are provided in the table below.

**Summary of Technological Characteristics, Including the Related Components
that Comprise the ICP Pressure Monitoring System**

	Predicate Device, AMS (Air Management System) (Trilogy K083378)	Predicate Device, Aesculap-Spiegelberg Brain Pressure Monitor (K003759)	HICP200	S/E
Indication for Use	ICP Monitoring	ICP Monitoring	ICP Monitoring	YES
Principle of Operation	Air coupled pressure transduction	Air coupled pressure transduction	Air coupled pressure transduction	YES
Mechanism of Control	Electromechanical	Electromechanical with software control	Electromechanical with software control	YES
Intracranial Access	Parenchymal catheters: H110MR, K083378 H510MR, K083378 H710MR, K083378 Ventricular catheters: H210MR, K083378 H310, K013705 H410MR, K083378 H610MR, K083378 Subdural catheter: H910MR, K113088	Probes numbered 1 through 3 for subdural, parenchymal and intraventricular access	Parenchymal catheters: H110MR, K083378 H510MR, K083378 H710MR, K083378 Ventricular catheters: H210MR, K083378 H310, K013705 H410MR, K083378 H610MR, K083378 Subdural catheter: H910MR, K113088	YES
ICP Display	Hospital Monitor	Aesculap-Spiegelberg Monitor	Hospital Monitor	YES
Transducer Location	Main cable housing	Aesculap-Spiegelberg Monitor	Catheter-Connect Module	YES
Priming Actuator Location	Main cable housing	Aesculap-Spiegelberg Monitor	Control Module	YES
Sensor Location	Air bladder located on the body of the catheter	Air-pouch located on the tip of the probe	Air bladder located on the body of the catheter	YES
Precise Priming Volume	Yes (.03 cc)	Yes (.05-.1 cc)	Yes (.1 cc)	YES
Reference to a Set Pressure	Yes – Relative to Atmospheric	Yes – Atmospheric	Yes – Atmospheric	YES
Priming Actuation	Manual	Automatic, Electronic	Automatic, Electronic	YES
Priming Frequency	Manual, per IFU	Once every hour	Once every hour	YES
System Leak Detection	Yes	Yes	Yes	YES

VII. PERFORMANCE DATA

The HICP200 design (including software) reflects the distillation of documented requirements analyses, including hazard analysis and the identification of risk mitigations. The hazard analysis was performed consistently with the company's risk

management procedures. The software that controls the function of the device was developed according to the company's software development procedure RD-004, Software Lifecycle Process, which is based on the IEC 62304:2006 and FDA software-related guidance documents. The HICP200 was subjected to extensive design verification and validation testing, including functional and performance testing, to demonstrate its ability to perform effectively as a component of the system employed in the measurement of intracranial pressure (ICP). The HICP200 summary V&V test reports contain trace matrices linking individual test reports that contain evidence that the HICP200 conforms to product specifications and that demonstrate risk mitigation schemes have been implemented successfully. Included in these reports are the results of an independent laboratory testing for conformance with the requirements of IEC 60601, including electrical safety and electromagnetic compatibility. The HICP200 has been subjected to testing and demonstrates conformance with the requirements of AAMI NS 28, including absolute accuracy, accuracy over time, and the labeling requirements contained in the standard. The standards to which the HICP200 conforms are referenced below.

- IEC 60601-1-2:2007 + ISH1:2010 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests*
- EN 60601-1-2:2007 + CORR1:2010 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests*
- IEC 60601-1:2005 + A1:2012 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
- AAMI/ANSI ES 60601-1:2005/(R)2012 + A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- EN 60601-1:2006 + A1:2013 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- ANSI/AAMI NS 28:1988/(R)2010 *Intracranial Pressure Monitoring Devices*

The results indicate that the HICP200 presents no new issues of safety when compared to the predicate devices.

VIII. CONCLUSIONS

Evaluation of Substantial Equivalence Conclusion: Based on the principles of operation and the information contained in the Summary of Technological Characteristics table and performance data described above, it is concluded that:

- The devices have the same intended use and indications for use.
- The devices employ comparable air management either by manual actuation or automatically by electromechanical means controlled by software.
- The HICP200 and the AMS are components of a system that use the same catheters and that system is substantially equivalent to the Aesculap-Spiegelberg system.

- The devices perform in a similar manner and are suitable for the designated indications for use.

The sponsor believes that the data submitted for the HICP200 constitutes valid scientific evidence to support the determination that the HICP200 is as safe and effective as the predicate devices.