



Food and Drug Administration
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January 22, 2016

Medos International SARL
c/o Dr. Elena Jugo
Codman Neuro
325 Paramount Drive
Raynham, MA 02767

Re: K152670

Trade/Device Name: DirectLink ICP Module
DirectLink Extension Cable
Patient Monitor Interface Cables

Regulation Number: 21 CFR 882.1620

Regulation Name: Intracranial pressure monitoring device

Regulatory Class: Class II

Product Code: GWM

Dated: December 18, 2015

Received: December 21, 2015

Dear Dr. Elena Jugo:

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. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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" (21CFR 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 -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

Indications for Use

510(k) Number (if known)
K152670

Device Name

DirectLink™ ICP Module
DirectLink™ ICP Extension Cable
Patient Monitor Interface Cable

Indications for Use (Describe)

The intended use of the DirectLink Module is to enable the connection of Codman intracranial pressure sensors to an available invasive blood pressure input channel on select commercially available third party patient bedside monitor systems.

The DirectLink ICP Extension Cable is intended for use as a connecting cable between the DirectLink ICP Module and a Codman Microsensor ICP Transducer.

The Patient Monitor Interface Cable is intended for use as a connecting cable between DirectLink ICP Module, and selected patient monitors available from third party suppliers.

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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7. 510(k) Summary

I. Submitter Codman Neuro
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CH 2400 LeLocle, Switzerland

Phone: 305-265-6802
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Contact Person: Elena Jugo
Date of Submission: September 16, 2015

II. Device

Name of Device	DirectLink ICP Module DirectLink Extension Cable Patient Monitor Interface Cables
Common Name	Intracranial pressure monitoring device
Classification Name	Intracranial Pressure Monitoring Device (21 CFR 882.1620)
Regulatory Class	II
Product Code	GWM

III. Predicate Device Codman CU-II (ICP Express), K945585

IV. Device Description

DirectLink ICP Module

The DirectLink ICP Module is a direct interface to connect the CODMAN MICROSENSOR® ICP Transducers to a patient bedside monitor, allowing the user to do the following:

- Zero the ICP sensor
- Provide zero reference and calibration signals to the patient bedside monitor
- Transfer the ICP readings to the patient bedside monitor for visualization and data storage/processing.

The module does not have its own source of power, but is powered through connection to the patient monitor.

510(k) Summary (Cont)

**IV. Device
Description
(Cont.)**

In order to connect the DirectLink Module to the Microsensor and to the bedside monitor two cables (the DirectLink ICP Extension Cable and the Patient Monitor Interface Cable) are needed. These cables are described below.

DirectLink ICP Extension Cable

The DirectLink ICP Extension Cable is required to connect the DirectLink ICP Module and the CODMAN MICROSENSOR ICP Transducer. The extension cable is reusable and is supplied non-sterile. The cable can be wiped down before each use with combination wipes (Quarternary Ammonium/Isopropyl Alcohol), or 70% isopropyl alcohol, or can be sterilized by autoclave before each use.

Patient Monitor Interface Cable

The Patient Monitor Interface Cable is used as a connecting cable between the DirectLink ICP Module, and selected patient monitors available from third party suppliers. The interface cable is reusable and is supplied non-sterile. The cable can be wiped down before each use with combination wipes (Quarternary Ammonium/Isopropyl Alcohol), or 70% isopropyl alcohol.

**V. Indications
for Use**

The intended use of the DirectLink ICP Module is to enable the connection of Codman intracranial pressure sensors to an available invasive blood pressure input channel on select commercially available third party patient bedside monitor systems.

The DirectLink ICP Extension Cable is intended for use as a connecting cable between the DirectLink ICP Module, and a Codman Microsensor ICP Transducer.

The Patient Monitor Interface Cable is intended for use as a connecting cable between DirectLink ICP Module, and selected patient monitors available from third party suppliers.

510(k) Summary (Cont)

VI. Comparison to Predicate Device

Based upon the intended use, design, function, comparison to the currently marketed device, and testing performed, it is concluded that the DirectLink ICP Module and related cables are substantially equivalent to the predicate Codman CU-II (ICP Express), and therefore, do not raise any new questions of safety and effectiveness.

VII. Performance Data

The following performance data have been provided in support of the substantial equivalence determination.

Bench Testing

Validation and verification testing were performed on the DirectLink ICP Module, the ICP Extension Cable, and the Patient Monitor Interface Cables. Testing was performed on each individual component, as well as on the entire system. **Table 2** lists the tests performed.

Table 2. Validation and Verification Tests
DirectLink ICP Module
Accuracy Test
Output Impedance, Zero Short Term Drift, Sensor Signal Stability Test
Accuracy and Symmetry of the Pressure Reference Signals Test
Power Consumption and Input Impedance Test
Wiping Test
Hardware Diagnostic Test
DirectLink ICP Extension Cable and Patient Monitor Interface Cables
Cable Baseline Tests (mating and demating force, flex cycles)
Cable Autoclave Tests (autoclave, wiping, flex cycles, operating cycles)
Documents and Drawings Review
Complete System – DirectLink ICP Modules and Cables
Transit Test
Summative Usability Test – Part 1 - Surgeons
Summative Usability Test – Part 2 – Nurses
Functionality and Performance Testing of the DirectLink System Connected to a Patient Monitor including Cables Mating
60601-1 and 60601-1-2 Test
PPQ Validation for DirectLink ICP Module and Cables

510(k) Summary (Cont)

**VII.
Performance
Data, cont.**

Biocompatibility Testing

Biocompatibility testing was not performed as these devices are not intended to contact the patient.

Animal Studies

No animal studies were required as appropriate verification of the new intended use was achieved based on the similarities of the proposed device to the predicate devices, and from results of bench testing.

Clinical Studies

Clinical data are not necessary to demonstrate substantial equivalence of the DirectLink ICP Module and associated cables to the predicate device.

**VIII.
Conclusion**

Based upon the intended use, design, materials, function, comparison to currently marketed device, and testing performed it is concluded that the DirectLink ICP Module and associated cables are substantially equivalent to the predicate Codman CU II (ICP Express) and therefore, do not raise any new questions of safety and effectiveness.
