



July 6, 2017

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Raumedic AG
% Dawn Tibodeau
Third Party 510(k) Project Coordinator
TUV SUD America Inc.
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

Re: K171666
Trade/Device Name: MPR2 logO DATALOGGER
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: March 22, 2017
Received: June 5, 2017

Dear Dawn Tibodeau:

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.
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510(k) Number (if known)

K171666

Device Name

MPR2 logO DATALOGGER

Indications for Use (Describe)

The RAUMEDIC® MPR2 is indicated for use by qualified neurosurgeons or neurointensivists for measurement of intracranial pressure, temperature as well as to determine the partial oxygen pressure ptiO₂ of the interstitial fluid.

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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Ihre Nachricht vom
Ihre Zeichen

Sachbearbeiter H Thiem
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Tag
30th of August 2016

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.

1. Name, address, phone and fax number of the applicant

RAUMEDIC AG
Hermann-Staudinger-Straße 2
95233 Helmbrechts
D - Germany
Tel.: 0049 9252 359-0
Fax: 0049 9252 359-1000

2. Contact person

Mr. Reiner Thiem
Head of Regulatory Affairs
Hermann-Staudinger-Straße 2
95233 Helmbrechts
D – Germany
Tel.: 0049 9252 359-2782

3. Date of preparation of the summary

August, the 30th 2016

4. Name of the device

Device Classification Name:	MPR2 logO DATALOGGER
Classification Panel:	Neurology
CFR Section:	21 CFR §882.1620
Device Class:	Class II
Product Code:	GWM

5. Device Description

The MPR2 is a small bedside monitor for measuring, displaying and monitoring of physiological parameters in the human brain which is used only in conjunction with RAUMEDIC® -catheters. Analog signals can be relayed to a series-connected bedside monitor via its 2 analog outputs. Optionally, the device can be operated in stand-alone mode. The power is supplied by either the internal rechargeable battery or by an external, medically approved wide range wall plug transformer.

The MPR2 is a diagnostic device with physiological limit value monitor for measuring, displaying and monitoring the following physiological parameters: oxygen partial pressure (pO₂), intracranial pressure (ICP) and brain temperature (T). These parameters are determined exclusively by connecting RAUMEDIC® catheters for single channel ICP measurement or with RAUMEDIC® multi-parameter catheters for combined measurement of ICP, pO₂ and temperature (thermistor-based with YSI400 characteristic) or combinations derived from them such as pO₂ and temperature. Optionally the pO₂ and ICP signals can be relayed via the 2 analog outputs to a bedside monitor with limit value monitoring.

6. Device Intended Use

The RAUMEDIC® MPR2 is indicated for use by qualified neurosurgeons or neurointensivists for measurement of intracranial pressure, temperature as well as to determine the partial oxygen pressure ptiO₂ of the interstitial fluid.

7. Substantial Equivalence Summary

The MPR2 logO DATALOGGER is substantially equivalent to those of the legally marketed predicate devices, the EASY logO as part of the RAUMEDIC® -PTO-Monitoring-System which was cleared to market under 510 (k) K130529 on 25th of October 2013 and the INTEGRA CAMINO ICP MONITOR which was cleared to market under 510 (k) K121573 on 10th of September 2012.

For further information see device comparison tables attached.

Based on performance testing and the available information concerning the referenced comparison devices, the **MPR2 logO DATALOGGER** is equivalent in that:

- The devices have the same intended use and indication for use.
- The devices are made of the same materials or substantially equivalent materials.
- The devices have equivalent form, function, procedures and features.
- Performance characteristics are suitable for designated indications for use



Based on this, the anticipated clinical performance of the **MPR2 logO DATALOGGER** is equivalent to the referenced systems.

8. Device Testing

The mentioned MPR2 logO DATALOGGER was subjected to extensive performance testing. Results of the testing showed that the MPR2 logO DATALOGGER is safe for its intended use.

Finally, the manufacturing process of the MPR2 logO DATALOGGER complies with the United States Food and Drug Administration and European Standards for the manufacturing of medical devices.

See attachment 2: Device comparison tables.

Table 1:

Feature	RAUMEDIC® MPR2 logO	RAUMEDIC® EASY logO (The RAUMEDIC® EASY logO is a component of the RAUMEDIC®-PTO- Monitoring-System) K130529	Integra® Camino® ICP Monitor K121573	SE?
Trade Name	MPR2 logO	EASY logO	Integra Camino ICP Monitor	N/A
Indications for Use	The RAUMEDIC® MPR2 is indicated for use by qualified neurosurgeons or neurointensivists for measurement of intracranial pressure, temperature as well as to determine the partial oxygen pressure p_tO_2 of the interstitial fluid.	The RAUMEDIC® EASY logO 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 p_tO_2 of the interstitial fluid.	The Integra® Camino® ICP Monitor is indicated for use by qualified neurosurgeons or neurointensivists for measurement of intracranial pressure and temperature.	NO – see SE-discussion 1 below table
ICP Measurement	YES	YES	YES	YES
Pressure Measurement Range ICP	-20 to +100 mmHg	-40 to +100 mmHg	-10 to 125 mmHg	NO – see SE-discussion 2 below table
Accuracy of ICP Measurement	<ul style="list-style-type: none"> • Accuracy -20 to 20 mmHg: ± 1 mmHg for measuring instrument and ± 1 mmHg for catheter • Accuracy <-20 mmHg and >20 mmHg: $\pm 5\%$ for measuring instrument and $\pm 5\%$ for catheter 	<ul style="list-style-type: none"> • Accuracy -20 to 20 mmHg: ± 1 mmHg for measuring instrument and ± 1 mmHg for catheter • Accuracy <-20 mmHg and >20 mmHg: $\pm 5\%$ for measuring instrument and $\pm 5\%$ for catheter 	<ul style="list-style-type: none"> • Range -10 to 10 mmHg: ± 2 mmHg • Range 11 to 33 mmHg: ± 3 mmHg • Range 34 to 125 mmHg: $\pm (6\% + 1 \text{ mmHg})$ 	YES
Temperature Measurement	YES	YES	YES	YES
Temperature Measurement Range	15°C - 45°C	15°C - 45°C	15°C - 45°C	YES
Accuracy of Temperature Measurement	15 ... 25°C: ± 0.2 K (plus ± 0.2 K of the sensor) 25 ... 45°C: ± 0.1 K (plus ± 0.1 K of the sensor) 37 ... 39°C: ± 0.05 K (plus ± 0.05 K of the sensor) 39 ... 45°C: ± 0.1 K (plus ± 0.1 K of the sensor)	15 ... 25°C: ± 0.2 K (plus ± 0.2 K of the sensor) 25 ... 45°C: ± 0.1 K (plus ± 0.1 K of the sensor) 37 ... 39°C: ± 0.05 K (plus ± 0.05 K of the sensor) 39 ... 45°C: ± 0.1 K (plus ± 0.1 K of the sensor)	± 0.3 °C	YES

Feature	RAUMEDIC® MPR2 logO	RAUMEDIC® EASY logO (The RAUMEDIC® EASY logO is a component of the RAUMEDIC®-PTO- Monitoring-System) K130529	Integra® Camino® ICP Monitor K121573	SE?
p_tO_2 Measurement	YES	YES	---	YES
p_tO_2 Measurement Range	0 to 150 mmHg	0 to 150 mmHg	---	YES
Accuracy of p_tO_2 Measurement	<ul style="list-style-type: none"> $\pm 3\%$ of the measured value or ± 2.5 mmHg – the higher value is applicable for the partial oxygen pressure < 120 mmHg < 10 % of the measured value for the partial oxygen pressure 120 mmHg to 150 mmHg 	<ul style="list-style-type: none"> $\pm 3\%$ of the measured value or ± 2.5 mmHg – the higher value is applicable for the partial oxygen pressure < 120 mmHg < 10 % of the measured value for the partial oxygen pressure 120 mmHg to 150 mmHg 	---	YES
User interface	Multi Parameter Monitor with graphic display, Membrane Buttons	Multi Parameter Monitor with alphanumeric display, Membrane Buttons	Multi Parameter Monitor with graphic display, Touch screen	YES
Monitoring	Continuous	Continuous	Continuous	YES
Data Storage	YES	NO	YES	YES
Power Source	A/C wall outlet or D/C battery	A/C wall outlet	A/C wall outlet or D/C battery	YES
Battery operating time	Min. 4 hours	---	1.5 hours	NO – see SE-discussion 3 below table
Analog Output to Bedside Monitor	2 pcs. analog outputs for ICP and p_tO_2	2 pcs. analog outputs for ICP and p_tO_2	2 pcs. analog outputs for ICP and Temperature	YES
Digital Interface	RS 232	RS 232 (intern)	RS 232	YES
Data Extraction (for connection with other devices, such as PC, and further Software)	USB 1.1	---	USB 1.1	YES
Calibration of the analog signal inputs	Auto Zero	Auto Zero	Auto Zero	YES
Alarms	Technical Alarms and Physiological Alarms for ICP, Temperature and p_tO_2	Only Technical Alarms	Technical Alarms and Physiological Alarms for ICP	NO – see SE-discussion 4 below table

Feature	RAUMEDIC® MPR2 logO	RAUMEDIC® EASY logO (The RAUMEDIC® EASY logO is a component of the RAUMEDIC®-PTO- Monitoring-System) K130529	Integra® Camino® ICP Monitor K121573	SE?
Safety Measures (electrical safety)	Defibrillation-proof type CF applied parts	Defibrillation-proof type CF applied parts	Defibrillation-proof type CF applied parts	YES
Safety Measures (functional safety)	Control system and 2 watchdog timers	Control system and 2 watchdog timers	unknown	YES
Accessories	All cables and catheters listed in chapter 9 of the IFU zwo-459	All cables and catheters listed in chapter 9 of the IFU zwo-380	unknown	NO – see SE-discussion 5 below table
Case Material	Plastic	Plastic	Plastic	YES
Product Code	GWM	GWM	GWM	YES
Registration #	Pending	K130529	K121573	N/A
Applicant	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts Germany	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts Germany	Integra LifeSciences Corporation 311 Enterprise Drive Plainsboro NJ 08536 USA	N/A

SE-Discussion:

- 1) A) The indications for use of the MPR2 logO and the Integra Camino are identical and therefore substantial equivalent, with the following differences:
- "as well as to determine the partial oxygen pressure $ptiO_2$ of the interstitial fluid": Integra Camino is not able to determine the partial oxygen pressure, therefore a second predicate device (Easy logO) was selected (see below).

- B) The indications for use of the MPR2 logO and the Easy logO are identical and therefore substantial equivalent, with the following differences:
- "indicated for use by qualified neurosurgeons or neurointensivists": the indications for use of the Easy logO do not mention neurointensivists. Both devices are to be applied by trained healthcare professionals as defined in the relevant IFUs. This includes both neurosurgeons and neurointensivists. Therefore the two devices are substantial equivalent also in this point.
 - "for measurement of intracranial pressure, temperature": the indications for use of the Easy logO state "for direct measurement" instead. Further it says "temperature in the parenchyma" there. The principles of the measurements (direct and in the parenchyma) are the same for MPR2 and Easy logO as the applied catheters, which perform the actual measurement, are the same for both devices. Therefore the two devices are substantial equivalent also in these points.

- 2) The pressure-range of the RAUMEDIC® MPR2 logO covers the physiological intracranial pressure-range measurable in the brain ($0 < ICP < 100$ mmHg, see literature) and is within the range of the RAUMEDIC® EASY logO.

Literature 1: "3.2 Safety and Performance Requirements

3.2.1 Pressure Range

The minimum pressure range of the ICP monitoring system and of the pressure display module shall be 0 to 100 torr or 0 to 140 cm of water.."

ANSI/AAMI NS28:1988/(R)2010

Intracranial pressure monitoring devices

AAMI Association for the Advancement of Medical Instrumentation

- 3) The Battery operating time of both devices are similar. Both devices use a rechargeable battery, and the battery operating time is greater than 1.5 hours. Both devices are used in a professional health care environment. There is no normative requirement from a standard. The Battery operating must be sufficient for operation of the device during transport within the specified operating environment. This requirement is met by the MPR2 logO.

- 4) All 3 devices have an alarm system for technical alarms.

Only the MPR2 logO and the Integra Camino ICP monitor additionally have physiological alarms. The physiological alarms of both devices are similar but not identical. The physiological limit values can be set for both devices. Both devices have the possibility of monitoring the alarm limit value of the ICP for example and therefore both devices are substantial equivalent on the alarm system.

- 5) All accessories for the EASY logO (exception: the respective main power adapter) can be used without limitation as accessories for the MPR2 logO and are therefore listed as accessories for the MPR2 logO (cf. IFU zwo-459 chapter 9. Accessories and IFU zwo-380 chapter 9). In addition, there are the following accessories for the MPR2 logO which are not accessories for the EASY logO:

094268-002 NEUROVENT-P-TEMP ¹⁾

094278-002 NEUROVENT-TEMP ¹⁾

094288-002 NEUROVENT-TEMP-IFD-S ¹⁾

095327-002 NEUROVENT-TEMP-IFD-R ¹⁾

094323-001 ICP-TEMP-Adapter; length 0.70 m ¹⁾

094328-001 ICP-TEMP-Cable; length 2.00 m ²⁾

¹⁾ This accessory has already been tested within 510 (k) –registration K120252 RAUMEDIC® -ICP-TEMP-Monitoring-System.

²⁾ This accessory has already been tested within 510 (k) –registration K03206 RAUMEDIC® -ICP-Monitoring System.

The accessories for the MPR2 logO are either identical to the accessories of the EASY logO or they were already accessories of earlier RAUMEDIC 510 (k) registrations and have therefore already been cleared. Therefore the accessories of the MPR2 logO and the EASY logO are substantial equivalent.