K130529

RAUMEDIC
Lifeline to Health

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Ihre Nachricht vom	Sachbearbeiter	H Thiem	Tag
Ihre Zeichen	Unsere Zeichen	thi	16th of October 2013

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

OCT 25 2013

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3. Date of preparation of the summary

October, the 16th 2013

4. Name of the device

The **RAUMEDIC® -PTO-Monitoring-System** is composed of the following components:

- NEUROVENT®-PTO
- NEUROVENT®-TO
- NEUROVENT®-PTO 2L
- EASY logO
- BOLT KIT PTO
- BOLT KIT PTO 2L
- Cable LWL
- Cable PTO
- Cable DATALOGGER GE/MARQUETTE
- Cable DATALOGGER Philips/HP
- Cable DATALOGGER Siemens/Dräger Infinity
- Cable DATALOGGER Datex-Ohmeda
- Cable DATALOGGER Hellige
- Cable DATALOGGER SpaceLabs
- Cable DATALOGGER Nihon Kohden

Device Classification Name:	Device, Monitoring, Intracranial Pressure, Temperature and Oxygen
Classification Panel:	Neurology
CFR Section:	21 CFR §882.1620
Device Class:	Class II
Product Code:	GWM

5. Device Description

The **RAUMEDIC® -PTO-Monitoring-System** determines the level and change in intracranial pressure (ICP) by using semi-conductor pressure sensors, in temperature using thermistors, and in partial oxygen pressure ptiO2 using a luminescence optical sensor fibre.

The PTO-Monitoring-System consists of intracranial catheters, a cranial bolt kit, the user interface unit (EASY logO), cables to connect the catheters to the EASY logO and cables for the EASY logO to send the measurements to specific patient monitoring units.

Three intracranial catheters are provided: NEUROVENT®-PTO, NEUROVENT®-TO and NEUROVENT®-PTO 2L. The NEUROVENT®-PTO measures three physiological parameters – ICP, temperature and partial oxygen pressure. The application has to be made with a single lumen Bolt (BOLT-KIT PTO). The NEUROVENT®-PTO 2L also measures these three parameters, but has to be placed with a multi lumen Bolt (BOLT KIT PTO 2L) or via tunneling process. The NEUROVENT®-TO measures two physiological parameters – temperature and partial oxygen pressure. The application has to be made with a single lumen Bolt (BOLT-KIT PTO).

The NEUROVENT®-PTO or the NEUROVENT®-TO is implanted in the parenchyma using a BOLT KIT PTO. The NEUROVENT®-PTO 2L is implanted in the parenchyma using a BOLT KIT PTO 2L or using a RAUMEDIC® spliceable tunnelling sleeve CH8 (already cleared for market under 510(k) K112017).

For connecting the catheters to the EASY logO two cables – cable PTO and cable LWL - are needed. The cable PTO transfers the electrical signal for ICP and temperature. The cable LWL transfers the optical signal for oxygen pressure.

The EASY logO is the user interface that displays the measurements and alerts the user to the status of the intracranial catheters. The EASY logO displays: oxygen partial pressure pO2, intracranial pressure ICP, pulse amplitude ICPA and temperature T. ICP is a pulsatile signal that consists of the ICP average value and a pulsatile ICPA component, which is superimposed over the ICP average value.

DATALOGGER cables allows the EASY logO to send the measurements to specific patient monitoring units.

6. Indications of Use

The **RAUMEDIC® – PTO-Monitoring-System** measures intracranial pressure, temperature and oxygen and is intended as an adjunct monitor of trends in these parameters, indicating the perfusion status of cerebral tissue local to sensor placement. RAUMEDIC® – PTO-Monitoring-System values are relative within an individual, and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice, in cases where hypoxia or ischemia is a concern.

Use of the parenchymal intracranial pressure monitoring kit with bolt is indicated for children who are at least one year old.

7. Substantial Equivalence Summary

The RAUMEDIC® - PTO-Monitoring-System is substantially equivalent to the DIAMETRIC MEDICAL LTD. NEUROTREND MULTIPARAMETER SENSOR which was cleared for market under 510(k) K980380 on 14th of July 1999, the LICOX Brain Oxygen Monitoring System which was cleared for market under 510(k) K002765 on 24th of November 2000, the RAUMEDIC® ICP-TEMP- MONITORING-SYSTEM which was cleared for market under 510(k) K120252 on 11th of April 2012 and the RAUMEDIC® ICP-MONITORING-SYSTEM which was cleared for market under 510(k) K103206 on 04th of March 2011.

For further information see device comparison tables below.

Table 1: Comparison to Predicate RAUMEDIC® ICP-TEMP- MONITORING- SYSTEM (K120252)

Feature	RAUMEDIC® PTO-MONITORING- SYSTEM	RAUMEDIC® ICP-TEMP-MONITORING- SYSTEM (K120252)	SE?
Trade Name	NEUROVENT®-PTO, NEUROVENT®-PTO 2L, NEUROVENT®-TO	NEUROVENT®-P-TEMP, NEUROVENT®-TEMP-IFD-S, NEUROVENT®-TEMP-IFD-R	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 RAUMEDIC® -ICP-TEMP-Monitoring-System is indicated for use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the parenchyma and in the ventricle and cerebrospinal fluid drainage applications.	YES – for measurement of intracranial pressure and temperature; for oxygen measurement see SE-List with predicate device: K980380
Anatomical Site Catheter	Brain parenchyma	Brain parenchyma / ventricle	YES
Sensors Location	Catheter Tip	Catheter Tip	YES
Tip Diameter	5F	5F	YES
Single-use-Catheter	YES	YES	YES
Sterilization Process	With Ethylene Oxide	With Ethylene Oxide	YES
Bolt	Bolt with compression cap	Bolt with compression cap	YES
Spliceable Tunnelling Sleeve	Spliceable Tunnelling Sleeve with Trocar	Splicable Tunnelling Sleeve with Trocar	YES
Size Of Access Hole	for Bolt: 4.2 mm → NEUROVENT®-PTO, NEUROVENT®-TO 6.3 mm → NEUROVENT®-PTO 2L for Tunnelling: ≥ 6 mm → NEUROVENT®-PTO 2L	for Bolt: 4.2 mm → NEUROVENT®-P-TEMP, 6.3 mm → NEUROVENT®-TEMP-IFD-S, NEUROVENT®-TEMP-IFD-R for Tunnelling: ≥ 6 mm → NEUROVENT®-TEMP-IFD-S, NEUROVENT®-TEMP-IFD-R	YES
Fixation Of Catheter	Fixation wing (sutured to skin)	Fixation wing (sutured to skin)	YES
Non-fluid Coupling Catheter	YES	YES	YES
ICP - Sensor Design Catheter	Piezoresistive pressure sensor (Semi-conductor / Wheatstone Bridge)	Piezoresistive pressure sensor (Semi-conductor / Wheatstone Bridge)	YES
ICP - Pressure Range	-50 to +250 mmHg	-50 to +250 mmHg	YES
ICP - Maximum Pressure	1,250 mmHg	1,250 mmHg	YES
ICP – Accuracy	± 1 mmHg	± 1 mmHg	YES
ICP – Resolution	0.1 mmHg	0.1 mmHg	YES
ICP - Zero Point Stability	Less than 1 mmHg during first 24 ours Less than 2 mmHg during the first 7 days	Less than 1mmHg during first 24 hours Less than 2mmHg during the first 7 days	YES
ICP - Dynamic Response Time	< 5 ms	< 5 ms	YES
ICP - Sensitivity System	5 µV/V/mmHg on the monitor side	5 µV/V/mmHg on the monitor side	YES

Feature	RAUMEDIC® PTO-MONITORING- SYSTEM	RAUMEDIC® ICP-TEMP-MONITORING- SYSTEM (K120252)	SE?
TEMP - Sensor Design	Thermistor	Thermistor	YES
TEMP - Temperature Range	25 °C – 45 °C	25 °C – 45 °C	YES
TEMP – Accuracy	± 0.1 °C	± 0.1 °C	YES
TEMP – Resolution	0.01 °C	0.01 °C	YES
TEMP - Zero Point Stability	± 0.2 °C	± 0.2 °C	YES
TEMP - Dynamic Response Time	< 150 s	< 150 s	YES
TEMP – Adapter	Cable PTO	ICP-TEMP-Adapter ICP-TEMP-Adapter HP / Philips	YES
p_tO_2 - Sensor Design Catheter	Fiber Optic / Quenching → measuring amount of reflected light from sensor tip in comparison to pre-calibrated values with reference solutions (see section "12. Substantial Equivalence Discussion")	---	NO – see SE-List with predicate device: K980380
p_tO_2 - Oxygen Pressure Range	0 to 150 mmHg	---	NO – see SE-List with predicate device: K980380
p_tO_2 – Accuracy	± 3 % or ± 2.5 mmHg of the measured value → the higher value is applicable for p_tO_2 < 120 mmHg; < 10 % of the measured value for p_tO_2 from 120 mmHg to 150 mmHg	---	NO – see SE-List with predicate device: K980380
p_tO_2 – Resolution	0.1 mmHg	---	NO – see SE-List with predicate device: K980380
p_tO_2 - Zero Point Stability	max. 1.5 mmHg in 5 days (at a ptiO2 of ≤ 10 mmHg)	---	NO – see SE-List with predicate device: K980380
p_tO_2 - Dynamic Response Time	< 200 s for p_tO_2-decrease from 150 ± 15 mmHg to 0.0 mmHg	---	NO – see SE-List with predicate device: K980380
p_tO_2 – Adapter	Cable LWL	—	NO – see SE-List with predicate device: K980380
Product Code	GWM	GWM	YES
Registration #	Pending	K120252	N/A
Applicant	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts Germany	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts Germany	N/A

* ICP measurement only with NEUROVENT®-PTO and NEUROVENT®-PTO 2L

Table 2: Comparison to predicate DIAMETRIC MEDICAL LTD.NEUROTREND MULTIPARAMETER SENSOR (K980380)

Feature	**RAUMEDIC® PTO-MONITORING- SYSTEM**	**DIAMETRIC MEDICAL LTD. NEUROTREND MULTIPARAMETER SENSOR (K980380)**	**SE?**
Trade Name	NEUROVENT®-PTO, NEUROVENT®-PTO 2L, NEUROVENT®-TO	Neurotrend™ Multiparameter Sensor (C7004S)	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 Neurotrend Multiparameter Sensor is a disposable, sterile, single-use, device for the continuous measurement of intracranial oxygen, carbon dioxide, pH and temperature that is used in conjunction with a suitable intracranial access device.	YES – for measurement of oxygen; for intracranial pressure and temperature measurement see SE-List with predicate device: K120252
Anatomical Site Catheter	Brain parenchyma	Brain ventricle	NO – see SE-List with predicate device: K120252
Sensors Location	Catheter Tip	Catheter Tip	YES
Tip Diameter	5 F	2 F	NO – see SE-List with predicate device: K120252
Single-use-Catheter	YES	YES	YES
Sterilization Process	With Ethylene Oxide	With Gamma - Radiation	NO – see SE-List with predicate device: K120252
Bolt	Bolt with compression cap	A suitable intracranial access device	NO – see SE-List with predicate device: K120252
Spliceable Tunnelling Sleeve	Spliceable Tunnelling Sleeve with Trocar	A suitable intracranial access device	NO – see SE-List with predicate device: K120252
Size Of Access Hole	for BOLT usage: 4.2 mm → NEUROVENT®-PTO, NEUROVENT®-TO 6.3 mm → NEUROVENT®-PTO 2L for Tunnelling Sleeve usage: ≥ 6 mm → NEUROVENT®-PTO 2L	—	NO – see SE-List with predicate device: K120252
Fixation Of Catheter	Fixation wing (sutured to skin)	—	YES
Non-fluid Coupling Catheter	YES	YES	YES

Feature	RAUMEDIC® PTO-MONITORING- SYSTEM	DIAMETRIC MEDICAL LTD. NEUROTREND MULTIPARAMETER SENSOR (K980380)	SE?
ICP - Sensor Design Catheter	Piezoresistive pressure sensor (Semi-conductor / Wheatstone Bridge)	---	NO – see SE-List with predicate device: K120252
ICP - Pressure Range	-50 to +250 mmHg	---	NO – see SE-List with predicate device: K120252
ICP - Maximum Pressure	1,250 mmHg	---	NO – see SE-List with predicate device: K120252
ICP – Accuracy	± 1 mmHg	---	NO – see SE-List with predicate device: K120252
ICP – Resolution	0.1 mmHg	---	NO – see SE-List with predicate device: K120252
ICP - Zero Point Stability	Less than 1 mmHg during first 24 ours Less than 2 mmHg during the first 7 days	---	NO – see SE-List with predicate device: K120252
ICP - Dynamic Response Time	< 5 ms	---	NO – see SE-List with predicate device: K120252
ICP - Sensitivity System	5 µV/V/mmHg on the monitor side	—	NO – see SE-List with predicate device: K120252
TEMP - Sensor Design	Thermistor	Thermocouple	NO – see SE-List with predicate device: K120252
TEMP - Temperature Range	25 °C – 45 °C	10 °C – 42 °C	NO – see SE-List with predicate device: K120252
TEMP – Accuracy	± 0.1 °C	± 0.1 °C	YES
TEMP – Resolution	0.01 °C	0.01 °C	YES
TEMP - Zero Point Stability	± 0.2 °C	± 0.2 °C	YES
TEMP - Dynamic Response Time	< 150 s	< 150 s	YES
TEMP – Adapter	Cable PTO	PDM Cable	YES

Feature	RAUMEDIC® PTO-MONITORING- SYSTEM	DIAMETRIC MEDICAL LTD. NEUROTREND MULTIPARAMETER SENSOR (K980380)	SE?
p_tO_2 - Sensor Design Catheter	Fiber Optic / Quenching → measuring amount of reflected light from sensor tip in comparison to pre-calibrated values with reference solutions (see section "12. Substantial Equivalence Discussion")	Fiber Optic / Quenching → measuring amount of reflected light from sensor tip in comparison to pre-calibrated values with reference solutions	YES
p_tO_2 - Oxygen Pressure Range	0 to 150 mmHg	10 to 430 mmHg	NO; the lower limit is demonstrated by performance testing
p_tO_2 – Accuracy	± 3 % or ± 2.5 mmHg of the measured value → the higher value is applicable for p_tO_2 < 120 mmHg; < 10 % of the measured value for p_tO_2 from 120 mmHg to 150 mmHg	± 3 % or ± 2.5 mmHg of the measured value → the higher value is applicable for p_tO_2 < 120 mmHg; < 10 % of the measured value for p_tO_2 from 120 mmHg to 200 mmHg	YES
p_tO_2 – Resolution	0.1 mmHg	0.1 mmHg	YES
p_tO_2 - Zero Point Stability	max. 1.5 mmHg in 5 days (at a ptiO2 of ≤ 10 mmHg)	< 0.5 % per hour	YES within the stability range of the NEUROTREND
p_tO_2 - Dynamic Response Time	< 200 s for p_tO_2-decrease from 150 ± 15 mmHg to 0.0 mmHg	< 200 s for p_tO_2-decrease from 150±15 mmHg to 0.0 mmHg	YES
p_tO_2 – Adapter	Cable LWL	PDM Cable	YES
Product Code	GWM	GWM	YES
Registration #	Pending	K980380	N/A
Applicant	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts Germany	Diametrics Medical, Ltd. Short Street High Wycombe Buckinghamshire, UK HP11 2QH	N/A

* ICP measurement only with NEUROVENT®-PTO and NEUROVENT®-PTO 2L

Table 3: Comparison to Predicate LICOX Brain Oxygen Monitoring System (K002765)

Feature	RAUMEDIC® PTO-MONITORING-SYSTEM	RAUMEDIC® ICP-MONITORING-SYSTEM	LICOX Brain Oxygen Monitoring System	SE?
Trade Name	EASY logO	NPS3	CMP® Monitor	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 RAUMEDIC® - ICP-Monitoring-System is indicated for use by a qualified neurosurgeon for direct measurement of intracranial pressure in the parenchyma.	The LICOX Brain Oxygen Pressure Monitoring System directly measures Partial Pressure of Oxygen in the brain. The LICOX system can also utilize brain temperature information for temperature compensation of the pO_2.	YES
ICP Measurement	YES	YES	NO	YES
Temperature Measurement	YES	NO	YES	YES
p_tO_2 Measurement	YES	NO	YES	YES
Pressure Range	-40 to +100 mmHg	-40 to +100 mmHg	---	YES
Temperature Range	15 °C – 45 °C	---	0°C – 46 °C	NO; limits are demonstrated by performance testing in accordance to ASTM E1112
p_tO_2 Range	0 to 150 mmHg	—	0 to 150 mmHg	YES; limits are demonstrated by performance testing
Screen	YES	YES	YES	YES
Monitoring	Continuous	Continuous	Continuous	YES
Power Source	A/C wall outlet	D/C battery	A/C wall outlet	YES
Data Output	Analog / Serial	---	Analog / Serial	YES
Calibration	Auto Zero	Auto Zero	Auto Zero	YES
Alarms	Technical Alarms	Technical Alarms	Technical Alarms	YES
Case Material	Plastic	Plastic	Plastic	YES
Product Code	GWM	GWM	GWM	YES
Registration #	Pending	K103206	K002765	N/A
Applicant	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts Germany	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts Germany	Integra NeuroSciences 5955 Pacific Center Blvd. San Diego, CA 92121 USA	N/A

8. Device Testing

The Biocompatibility studies for the material/components of the medical devices NEUROVENT®-PTO, NEUROVENT®-TO, NEUROVENT®-PTO 2L, BOLT KIT PTO and the BOLT KIT PTO 2L were conducted per ISO 10993 standard.

In the toxicological evaluation reports in accordance to ISO 10993/1 for the tested devices NEUROVENT®-PTO (100801-40-B rev 01), BOLT KIT PTO (101164-40-A rev 01) and BOLT KIT PTO 2L (122471-40) it is stated, that the available test results, because of testing the EO-sterilized devices for cytotoxicity according to ISO 10993/5 and performing additional chemical analysis in accordance to ISO 10993/18, reveal no toxicologically relevant information, considering biological effects like cytotoxicity, tissue irritation (implant reactions), sensitization, systemic, subchronic toxicity and genotoxicity based on the intended use of the devices, that would affect the biological safety of the patient. For test matrix see table below.

The additional component of the BOLT KIT PTO 2L mandrel was also tested for cytotoxicity in accordance to ISO 10993/5. The test report 112078-20 indicate that the mandrels do not release substances in cytotoxic concentration during a permanent 24 h contact of 4.5 cm^2 surface area to 1 ml physiological fluid.

For all tests the material insolubilities are in compliance with the requirements of ISO 10993/1 for the intended use. There is no evidence that any effects hazardous to the patient will arise by leachable ingredients and/or residues.

Table 4: Toxicological tests performed on the devices

Material	Test	Comments	Result
NEUROVENT-PTO	Cytotoxicity ISO 10993-5	4.5 cm²/ml DMEM-FBS, 24 h, 37 °C L 929 cell cultures, quantitative determination of cell proliferation	Moderately cytotoxic (the moderately cytotoxic effects observed are within the typical value range obtained with aliphatic polyurethanes)
	Chemical analysis ISO 10993-18	3 cm²/ml ethanol/water (1:20), 24 h, 37 °C, GC-FID/GC-MS. quantitative and qualitative determination of organic leachables	32.3 µg/cm²/24 h (cyclohexanone) (Cyclohexanone is widely used as solvent, bonding and processing agent for medical devices. The toxicological profile is defined. It has not been classified by EU as carcinogenic, mutagenic or reprotoxic. As well, there is no indication of sensitizing, irritating and/or other toxic properties during application of device)
		3 cm²/ml isopropanol, 24 h, 37 °C, GC-MS characterization of organic extractables	characterized (mainly cyclohexanone)
Intracranial screw (milled) with fixing cap and silicone seal of BOLT KIT	Cytotoxicity ISO 10993-5	4.5 cm²/ml DMEM-FBS, 24 h, 37 °C L 929 cell cultures, quantitative determination of cell proliferation	n.n.
	Chemical analysis ISO 10993-18	3 cm²/ml ethanol/water (1:20), 24 h, 37 °C, GC-FID/GC-MS. quantitative and qualitative determination of organic leachables	n.n. (< 0.3 µg/cm²/24 h)
		3 cm²/ml isopropanol, 24 h, 37 °C, GC-MS characterization of organic extractables	characterized (silicone residues of the seal)
Intracranial screw (injection mouled) of BOLT KIT	Cytotoxicity ISO 10993-5	4.5 cm²/ml DMEM-FBS, 24 h, 37 °C L 929 cell cultures, quantitative determination of cell proliferation	n.n.
	Chemical analysis ISO 10993-18	3 cm²/ml ethanol/water (1:20), 24 h, 37 °C, GC-FID/GC-MS. quantitative and qualitative determination of organic leachables	n.n. (< 0.3 µg/cm²/24 h)
		3 cm²/ml isopropanol, 24 h, 37 °C, GC-MS characterization of organic extractables	n.n.
BOLT KIT PTO 2L*, Patient-contacting surfaces EO sterilized	Cytotoxicity ISO 10993-5	4.5 cm²/ml DMEM-FBS, 24 h, 37 °C L 929 cell cultures, quantitative determination of cell proliferation	n.n.
BOLT KIT PTO 2L* Patient-contacting surfaces	Chemical analysis ISO 10993-18	3 cm²/ml ethanol/water (1:20), 24 h, 37 °C, GC-FID/GC-MS. quantitative and qualitative determination of organic leachables	n.n. (3 µg/cm²/24 h)
		3 cm²/ml isopropanol, 24 h, 37 °C, GC-MS characterization of organic extractables	characterized (mainly adhesive residues

* the inner surfaces of BOLT CH9 were coextracted for technical reasons
n.n. no toxicologically relevant effects observed in comparison to the controls

In addition, Performance testing in accordance to the following standard ANSI/AAMI NS 28:1988/(R) 2006 was performed on the RAUMEDIC® ICP-Monitoring-System (K103206). Table 5 provides the testing performed to evaluate the ICP-Monitoring System.

Since the catheter NEUROVENT®-PTO or NEUROVENT®-PTO 2L is equal in dimension, made from the same materials and used the same ICP measurement properties to the tested catheters, the results of performance testing for the ICP-Monitoring System can be transferred to the NEUROVENT®-PTO or NEUROVENT®-PTO 2L.

Table 5: ICP Performance testing-bench

Performance Testing	**Test conditions; requirements**	**Results**	**Meet Standard?**
ANSI/AAMI NS 28:1988/(R) 2006			
Frequency response	Point 1.2. PB_27.11.09; > 100 Hz	167 Hz	yes
Slew rates	Point 1.2. PB_27.11.09; > 7,500 torr/s	10.000 torr/s	yes
Time constants	Point 3.2. PB_27.11.09; < 5 ms	3 ms	yes
Pressure range	Point 4.1. PB_27.11.09; Min 0 to +100 mmHg	-50 to + 250 mmHg	yes
Accuracy	Point 5.2. PB_27.11.09; -50 to +250 mmHg (catheter alone) -40 to + 100 mmHg in combination with NPS-3 display device	< maximum deviation point 3.2.2_NS 28 < maximum deviation point 3.2.2_NS 28	yes yes
Stability of pressure measurements	Point 6.2. PB_27.11.09; Acc. to guidelines 4.1.2.1 (8), temperature 20 ± 1°C (68 ± 2°F) and 39 ± 1 °C (102 ± 2°F) dPx < 1.52 torr	≤ 1.44 torr	yes
Specific zero-point testing	Point 7.2. PB_27.11.09; drift on a 24-hour basis, < 1 torr; drift and on a 168-hour basis, < 1.5 torr	≤ 0.7 torr and ≤ 1.2 torr	yes yes
Accuracy at 10, 20, 50 and 100 torr	Point 8.2. PB_27.11.09; After least 10 days on 10 torr: < 1.5 torr, 20 torr. < 1,5 torr 50 torr: < 1.5 torr and 100 torr: < 1.5 torr	≤ 0.9 torr ≤ 1.2 torr ≤ 1.1 torr and ≤ 1.2 torr	yes yes yes yes
Risk current	Point 9.2. PB_27.11.09; < 10 µA at 120 V AC	< 0.98 µA at 120 V AC	yes
Maximum temperature	Point 10.2. PB_27.11.09; No temperature increase > 40 °C (104 °F)	max. 39.5 °C	yes

Performance testing in accordance to the following standard ASTM E1112-00 (2006) was performed on the RAUMEDIC® PTO-Monitoring-System. Table 6 provides the testing performed to evaluate the PTO-Monitoring System.

Table 6: Temperature Performance testing-bench

Performance Testing	Test conditions; requirements	Results	Meet Standard?
ASTM E1112-00 (2006)			
Cleaning	Point 5.2 PB_08.12.11 No visible of technical changes	No visible of technical changes	yes
Toxicity	Point 5.3 PB_08.12.11 Toxicity Test	 Toxicity Test	 yes
Accuracy	Point 5.4 PB_08.12.11 No difference between the in vivo and in vitro accuracy	No difference between the in vivo and in vitro accuracy	yes
Operating Environment	Point 5.5 PB_08.12.11 40 °C, 15 % RH < Max. Error Temp.Rang. Table 1 ASTM E1112 40 °C, 80 % RH < Max. Error Temp.Rang. Table 1 ASTM E1112 16 °C, 40 % RH < Max. Error Temp.Rang. Table 1 ASTM E1112 16 °C, 95 % RH < Max. Error Temp.Rang. Table 1 ASTM E1112	 < Max. Error Temp.Rang. < Max. Error Temp.Rang. < Max. Error Temp.Rang. < Max. Error Temp.Rang.	 yes yes yes yes
Storage	Point 5.5.2 PB_08.12.11 above Test point o.k. after storage period of one month on -20 °C, RH not applicable and after storage period of one month on 50 °C, 15 % RH and after storage period of one month on 35 °C, 95 % RH	 o.k.	 yes

Internal Performance testing was performed on the RAUMEDIC® PTO-Monitoring-System. Table 7 provides the testing performed to evaluate the PTO-Monitoring System.

Table 7: Oxygen Performance testing-bench

Performance Testing	**Test conditions; requirements**	**Results**	**DIAMETRIC MEDICAL LTD.NEUROTREND MULTIPARAMETER SENSOR (K980380)**	**SE?**
Drift over 5.5 days	on 2.5 % oxygen saturation < 1.5 mmHg on 10 % oxygen saturation < 1.5 mmHg	≤ 1.2 mmHg ≤ 1.4 mmHg	< 11.9 mmHg < 46.2 mmHg	yes yes
Absolute measurement accuracy of the ptiO2 Range 0....120 mmHg	0+/- 2,5 mmHg	≤ 0.2 mmHg	0+/- 3.0 mmHg	yes
Absolute measurement accuracy of the ptiO2 Range >120 mmHg	150.00+/-15 mmHg	146.9 mmHg ... 152.3 mmHg	135.0 mmHg ... 165.0 mmHg	yes
Response time T90	< 200 s for change 150+/-15 mmHg to 0,0 mmHg	≤ 51 s	≤ 55 s	yes
ptiO2 sensitive surface	> 13 mm^2	≥ 15.1 mm^2	≥ 5 mm^2	yes > 5mm^2 is o.k. in brain
Length of the ptiO2 sensitive area	> 4mm	> 4.9 mm	> 4 mm	yes
Outer catheter diameter	< 1.35 mm	≤ 0.99 mm	≤ 0.5 mm	yes

The oxygen function of NEUROVENT® -PTO is comparable to DIAMETRIC MEDICAL LTD.NEUROTREND MULTIPARAMETER SENSOR (which is cleared to market under 510(k) (K980380) for the test criteria shown in the table above.

9. Conclusion:

The **RAUMEDIC® -PTO-Monitoring-System** is equivalent to the predicate devices 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.
- The devices demonstrate equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 25, 2013

Raumedic AG
c/o TUV SUD America
Mr. Alexander Schapovalov
1775 Old Hwy 8 NW
Suite #104
New Brighton, MN 55112

Re: K130529
Trade/Device Name: Raumedic-PTO-Monitoring System
Regulation Number: 21 CFR §882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: August 22, 2013
Received: August 26, 2013

Dear Mr. Schapovalov:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting 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): K130529

Device Name: RAUMEDIC® -PTO-Monitoring-System

Indications For Use:

The RAUMEDIC® – PTO-Monitoring-System measures intracranial pressure, temperature and oxygen and is intended as an adjunct monitor of trends in these parameters, indicating the perfusion status of cerebral tissue local to sensor placement. RAUMEDIC® – PTO-Monitoring-System values are relative within an individual, and should not be used as the sole basis for decisions as to diagnosis or therapy. It is intended to provide data additional to that obtained by current clinical practice, in cases where hypoxia or ischemia is a concern.

Use of the parenchymal intracranial pressure monitoring kit with bolt is indicated for children who are at least one year old.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S