K112017

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Lifeline to Health

OCT 11 2011

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RAUMEDIC AG · Postfach 5 01 · D - 95205 Münchberg

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Forschung & Entwicklung

Telefon: (0 92 52) 359-0
Telefax: (0 92 52) 359-10 00
info@RAUMEDIC.com
www.RAUMEDIC.de

Direktkontakt:
Telefon: (0 92 52) 359-2782

Reiner.Thiem@RAUMEDIC.com

Ihre Nachricht vom	Sachbearbeiter	H Thiem	Tag
Ihre Zeichen	Unsere Zeichen	thi	03.06.2011

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

June, the 03rd 2011

Device #:_____

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4. Name of the device

The **RAUMEDIC® -ICP-Monitoring-System ventricular** is composed of the following elements:

- NEUROVENT®
- NEUROVENT® IFD-S
- NEUROVENT® IFD-R
- Spliceable tunneling sleeve CH8
- Spliceable tunneling sleeve CH12
- BOLT KIT CH9
- DRILL KIT CH9

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

5. Device Description

The **RAUMEDIC® -ICP-Monitoring-System ventricular** determines the level and change in intracranial pressure (ICP) by using semi-conductor pressure sensors.

The NEUROVENT®, NEUROVENT® IFD-S and NEUROVENT® IFD-R are indicated for use in ventricular pressure monitoring and cerebrospinal fluid drainage applications.

The NEUROVENT® IFD-S is implanted in the ventricle by using a soft mandrel and the spliceable tunneling sleeve CH12 or via a RAUMEDIC® - BOLT KIT CH9.
The NEUROVENT® IFD-R is implanted in the ventricle only by using a rigid mandrel and a RAUMEDIC® - BOLT KIT CH9.
The NEUROVENT® is implanted in the ventricle by using the spliceable tunneling sleeve CH12 and a stylet.

In addition to the catheters used for pressure monitoring a zero point module NPS2 x (already cleared to market under 510 (k) K103206) is needed. "x" depends on the type of patient monitor available in the hospital - there are 20 different references. To the equipment also belongs an ICP-Temp-Cable (already cleared to market under 510 (k) K103206).

The **RAUMEDIC® -ICP-Monitoring-System ventricular** is composed of the following elements:

- NEUROVENT®
- NEUROVENT® IFD-S
- NEUROVENT® IFD-R
- Spliceable tunneling sleeve CH8
- Spliceable tunneling sleeve CH12
- BOLT KIT CH9
- DRILL KIT CH9

Device #:_____

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6. Device Intended Use

The **RAUMEDIC® -ICP-Monitoring-System ventricular** is indicated for use in ventricular pressure monitoring and cerebrospinal fluid drainage applications. It can be used for the measurement of the intra-cranial pressure (ICP) as well as of the cerebral perfusion pressure (central arterial blood pressure minus ICP) which is the essential pre-requisite for an effective treatment of patients suspected of suffering from intra-cranial pressure increases (such as cranio-cerebral traumas, GCS ≤ 8; malignant medial cardiac infarctions; hepatic encephalopathy; SAB Hunt / Hess IV + V; cerebral edema; hydrocephalus) or of patients whose clinical picture may be linked to an increase of the ICP and cerebrospinal fluid drainage applications.

7. Substantial Equivalence Summary

The **RAUMEDIC® -ICP- Monitoring-System ventricular** is substantially equivalent to those of the legally marketed predicate devices, the RAUMEDIC® -ICP-Monitoring-System which was cleared to market under 510 (k) K103206 on 04th of March 2011 and the Pressio® ICP MONITORING SYSTEM, which was cleared to market under 510 (k) K062584 on July 5 2007.

Fur further information see device comparison tables attached.

Based on performance testing and the available information concerning the referenced comparison device, the **RAUMEDIC® -ICP-Monitoring-System ventricular** is similar in that:

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

Based on this, the anticipated clinical performance of the **RAUMEDIC® -ICP-Monitoring-System ventricular** is equivalent to the referenced systems.

8. Device Testing

Biocompatibility studies were conducted per ISO 10993 standard and have demonstrated that the materials used to manufacture the **RAUMEDIC® -ICP- Monitoring-System ventricular** are safe for its intended use.

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

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

Device #:_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

TUV SUD America, Inc.
c/o Mr. Olaf Teichert
Foreign Affairs
1775 Old Highway 8 NW
Suite 104
New Brighton, MN 55112-1891

OCT 11 2011

Re: K112017
Trade/Device Name: Raumedic ICP Monitoring System
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: July 11, 2011
Received: July 14, 2011

Dear Mr. Teichert:

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.

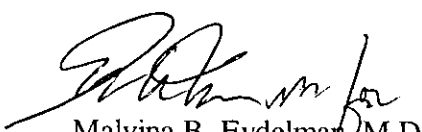
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112017

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Indications for Use

510(k) Number (if known): K_____

Device Name: Device, Monitoring, Intracranial Pressure

Indications for Use:

The **RAUMEDIC® -ICP-Monitoring-System ventricular** is indicated for use in ventricular pressure monitoring and cerebrospinal fluid drainage applications.

Use of the ventricular intracranial pressure monitoring kit with bolt is contra-indicated in children under one year old.

The RAUMEDIC® catheters are MR Unsafe.

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)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112017