



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

December 18, 2015

Möller Medical GmbH
Ms. Juliane Dragon
Regulatory Affairs Manager
Wasserkuppenstr. 29-31
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Re: K150898

Trade/Device Name: LiquoGuard 7
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: November 12, 2015
Received: November 20, 2015

Dear Ms. Dragon:

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,

Carlos L. Peña -S

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)

K150898

Device Name

LiquoGuard 7

Indications for Use (Describe)

The LiquoGuard 7 is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intrathecal pressure. The LiquoGuard 7 controls CSF pressure using pressure sensors and a pump and also monitors CSF pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions.

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

1. Submitter

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Date Prepared: March 24, 2015

2. Device

Trade name: LiquoGuard 7
Consists of: LiquoGuard 7 pump and LiquoGuard 7 disposable drainage tube sets

Common or Usual Name: External CSF Drainage System
Classification Name: Shunt, Central Nervous System and Components (21 CFR 882.5550)

Regulatory Class: II
Product Code: JXG

3. Predicate Device

The Möller Medical LiquoGuard 7 is substantially equivalent to the LiquoGuard CSF System listed below with regard to intended use, design, operating principles, materials, CSF pressure monitoring, semiconductor sensor principle, display, alarm functions and data recording.

LiquoGuard CSF System: K121248

4. Device Description

Cerebrospinal fluid (CSF) drainage and pressure monitoring in lumbar and ventricular applications is the “gold standard” for cases involving trauma, post-operation, shunt infection, subarachnoid hemorrhage (SAH) therapy, neurophysiological monitoring during vascular surgery (e.g. TAA and TAAA) and normal-pressure hydrocephalus (NPH) diagnosis.

The LiquoGuard 7 CSF Drainage System consists of a pump and a corresponding disposable drainage tube set, including two pressure sensors. The dynamic range of this system is from -75 mmHg to +100 mmHg. The drainage tube set is inserted into the pump, connected to the intrathecal drainage catheter (not part of the product) via a 3-way stopcock and the LiquoGuard 7 device via cable connector. The device continuously measures the pressure of CSF due to the fluid column inside the tube and operates the peristaltic pump of LiquoGuard 7 whenever the current patient's CSF pressure is higher than a preselected target pressure. Thus the LiquoGuard 7 combines CSF drainage and intracranial pressure (ICP) monitoring like the predicate device, the LiquoGuard CSF System, with integrated alarm and documentation/data logging functions, improving safety, simplifying the handling and enhancing patient's mobility.

5. Indications for Use

The LiquoGuard 7 is indicated for the external drainage of cerebrospinal fluid (CSF). It connects to any drainage catheter (not part of the product) which is usually inserted by the doctor into the lateral or third ventricle of the brain or lumbar subarachnoid space in selected patients to reduce intrathecal pressure. The LiquoGuard 7 controls CSF pressure using pressure sensors and a pump and also monitors CSF pressure and cerebrospinal fluid flow during CSF drainage, and provides many alarm functions.

6. Comparison of Technological Characteristics with the Predicate Device

The LiquoGuard 7 is working equivalently to the predicate device, with the additional safety that, using LiquoGuard 7, a bleeding or swelling of the brain may be detected in many cases (flow control and alarm). The principles of measurement are exactly the same as both systems measure the pressure of the surrounding liquid.

The LiquoGuard 7 behaves comparable to the predicate device. It is able to sound and display alarms to operators, is portable, can be used while not connected to the mains, records and stores data and can be connected to bedside monitoring systems.

The LiquoGuard 7 and its predicate device both utilize components such as sterile tubing's, pressure sensors, CSF drainage bags, microcontroller and interfaces. The LiquoGuard 7 tubing set is made from polyvinyl chloride, the same material that the predicate devices tubing sets are made of, along with numerous marketed IV administration tubing sets. The LiquoGuard 7 tubing set has two pressure transducers, such as the predicate device tubing's. Both systems include CSF drainage bags to collect drained CSF.

Both systems display values, curves and trends on a built in monitor, sound alarms via speaker and light emitting LED, are operated by pressing foil keypad buttons or a touch display and are basically computer and software controlled.

Both systems measure intrathecal pressure the same way; critical intrathecal pressure increase in the patient can be recognized, thereby enabling the required diagnostic and treatment steps to be taken. Since the pressure measurement in systems is done via piezo-resistive pressure sensors that are attached at reference height to the patient, there is no difference in intrathecal pressure measurement. Additional details for comparing these CSF Systems are contained in Table 1 and Table 2.

Table 1: System Comparison

Product Component	Predicate device (LiquoGuard CSF System)	LiquoGuard 7
Tube set disposable	•	•
CSF drainage bag	•	•
Pressure transducer	•	•
Micro controller	•	•
Software operated	•	•
Data storage	•	•
Screen	•	•
Ports	•	•
Casing	•	•
Power supply	•	•

Table 2: Device Comparison

	Predicate device	LiquoGuard 7
Indication	External drainage of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to reduce intracranial pressure and measurement of CSF pressure.	External drainage of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to reduce intracranial pressure and measurement of CSF pressure.
CSF sterile tubing set with pressure sensor and drainage bag	Tubing material: Polyvinyl chloride (PVC). Pressure sensor: Dual transducers. CSF Collection Bag: 500ml.	Tubing material: Polyvinyl chloride (PVC). Pressure sensor: Dual transducers. CSF Collection Bag: 500ml.
Pressure controlling mechanism	Based on pressure equivalence (Pascal's law of fluid statics) between patient and pressure sensors inside the tubing. From the sensor location, drainage is performed using a peristaltic pump controlled by the sensed pressure inside the tubing.	Based on pressure equivalence (Pascal's law of fluid statics) between patient and pressure sensors inside the tubing. From the sensor location, drainage is performed using a peristaltic pump controlled by the sensed pressure inside the tubing.
Height alignment of patient and device	Device can be positioned arbitrarily, only the pressure sensor needs to be aligned.	Device can be positioned arbitrarily, only the pressure sensor needs to be aligned.
Device adjusting fluid flow	LiquoGuard CSF System peristaltic pump controlled by pressure at sensor location.	LiquoGuard 7 peristaltic pump controlled by pressure at sensor location.

	Predicate device	LiquoGuard 7
Monitoring functions	Drained volume and pressure curve inside tubing (equal to intracranial pressure unless blockage) are monitored and recorded by LiquoGuard CSF System.	Drained volume and pressure curve inside tubing (equal to intracranial pressure unless blockage) are monitored and recorded by LiquoGuard 7.
Alarm functions enhancing patient safety	<p>Many alarm functions integrated in the system:</p> <ul style="list-style-type: none"> * Pressure too high. * Pressure too low. * Physiological pressure pulsation lost. * Pressure remains constant for too long. * Dual sensors deviate in readings (defective sensor). * Watchdog or main controller does not respond to each other's requests (device or software malfunction). * Battery low 	<p>Many alarm functions integrated in the system:</p> <ul style="list-style-type: none"> * Pressure too high. * Pressure too low. * Physiological pressure pulsation lost. * Pressure remains constant for too long. * Dual sensors deviate in readings (defective sensor). * Watchdog or main controller does not respond to each other's requests (device or software malfunction). * Battery low * Sensor difference ICP vs. PCSF * No ICP sensor connected * High Flow Alarm * Low Flow Alarm
Measured pressure range	-15mmHg to +75mmHg.	-75mmHg to +100mmHg
Physical dimensions	315mm x 210 mm x 280 mm (H x W x D). 4.8 kg.	145mm x 238.1mm x 212.8mm (H x W x D). 3.7 kg.
Displayed parameters	Actual ICP value, ICP waveform, ICP trend. Display resolution of 1 mmHg.	Actual ICP and PCSF value, ICP and PCSF waveform, ICP and PCSF trend. Display resolution of 1 mmHg.
Sensor type	Dual transducer.	Dual transducer.
Scheduled preventive maintenance	Every 12 months	Every 12 months
Battery	Rechargeable sealed lead acid. Operation time: 3h.	Rechargeable Lithium Ion. Operation time: 2h.

7. Performance Data

The LiquoGuard 7 has the same indication for use as the predicate devices (measurement and drainage of CSF). In addition, the LiquoGuard 7 tubing set is made from the same materials as the predicate devices, and because the risks associated with the surgical insertion of a CSF drain are not dependent on the CSF drainage system chosen, no new safety or effectiveness concerns are introduced over the predicate devices. Please refer to Table 3 for the list of bench tests – there you find a list of all bench tests that have been performed.

The test series exhibits a very wide range of performance tests and all necessary and required tests for the LiquoGuard 7 were appropriately performed and all tests passed according to the predetermined pass/fail criteria. Particularly highlighting are tests which serve to check the pressure and alarm systems. For this purpose, a plurality of measurements has been carried out to verify the critical components.

Table 3: List of bench test

Test	Test method summary	Results
Accuracy of measured and displayed pressure	Verify precision of displayed pressure at various pump rates and pressure loads. Criterion: Deviation of displayed pressures less than ± 2 mmHg to water column.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
Endurance test with in-vitro simulated patient	Verify long term stability of the device with simulated patient > 30 days (includes 3 tube set changes). Criterion: No malfunction of the device.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
Verify pump stopping	Verify reliability of pump stopping with negative pressure at different flow rates. Criterion: Pump stops at the predefined pressure level P_{min} .	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
Pressure stability while patient movement	Verify device function depending of pressure sensor position. Criterion: Displayed pressure changes with a deviation of ± 1 mmHg while movement.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
Minimum and maximum flow rate and accuracy of the measured and displayed volume at adjusted flow rate	Verify accuracy of the total volume measurement at different pump rates. Deviations of the real flow from the adjusted flow and deviations of the displayed flow and the actual flow are measured. Criterion: Deviations are smaller than $\pm 15\%$.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
AAMI NS28:1988 (Revision 2010)	Verify all applicable requirements of AAMI NS28:1988 (3.1.2.1, 3.1.2.2, 3.1.2.3, 3.1.3 and 3.2). Criterion: According to AAMI NS28:1998 (Revision 2010).	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.

Test	Test method summary	Results
Alarm: pressure too low	Verify pressure alarms: P_{CSF} stays below the defined limit of P_{LOW} an alarm has to activate. Increase of $P_{CSF} > P_{LOW}$ alarm has to deactivate automatically. Criterion: Alarm is issued reliably after intentional delay of 20 seconds.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
Alarm: pressure too high	Verify pressure alarms: P_{CSF} stays over the defined limit of P_{HIGH} an alarm has to activate. Increase of $P_{CSF} < P_{HIGH}$ alarm has to deactivate automatically. Criterion: Alarm is issued reliably after intentional delay of 20 seconds.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
Alarm: pressure too constant	Verify pressure alarms: P_{CFS} is too constant within the defined limits of P_{max} and P_{min} and the pulse rate is below the defined limit an alarm has to activate. Criterion: Alarm is issued reliably after intentional delay of 120 seconds.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
Alarm: pulsation is lost	Verify pressure alarms: If P_{CSF} shows no pulsation and the motor test shows a substantial drop of P_{CFS} an alarm has to activate. Criterion: Alarm is issued reliably after intentional delay of 30 seconds.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
Alarm: tip sensor disconnected	Verify pressure alarms: Tip sensor is connected no alarm activates and tip sensor is disconnected an alarm has to activate. Criterion: Alarm is issued reliably with no intentional delay.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
Alarm: tube set disconnected	Verify pressure alarms: Tube set is connected no alarm has to activate and tube set is disconnected an alarm has to activate. Criterion: Alarm is issued reliably with no intentional delay.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
Alarm: tube is malfunction	Verify pressure alarms: Simulated tube set malfunction an alarm has to activate, stop simulation of tube set malfunction the alarm has to stop. Criterion: Alarm is issued reliably after intentional delay of 10 seconds.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
Alarm: Main battery	Verify main battery alarms: Starting device without main battery, main battery with low capacity and main battery failure an error message is visible or an alarm has to activate. Criterion: Error message or alarm is issued reliably.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.

Test	Test method summary	Results
Alarm: main battery low	<p>Verify main battery alarms: Alarm is active while device is running on battery charged < 20%. Alarm is inactive while device is running on battery charged ≥ 20 %.</p> <p>Criterion: Main battery capacity alarm is issued reliably after intentional delay of 10 seconds.</p>	<p>All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.</p>
Alarm: emergency battery behavior	<p>Verify emergency battery behavior: Remove emergency battery and start device an error message has to be visible and an alarm has to activate.</p> <p>Criterion: Error message and alarm is issued reliably.</p>	<p>All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.</p>
Alarm: communication motor controller	<p>Verify alarm functions: When application is running (1) simulate motor controller malfunction the application has to stop, an alarm has to activate and an error message has to be visible and (2) simulate watchdog malfunction the application has to stop, an alarm has to activate and an error message has to be visible.</p> <p>Criterion: Alarms are issued reliably and application stops.</p>	<p>All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.</p>
Alarm: watchdog audio	<p>Verify device function alarms: When application is running with removed speaker cable: (1) produce any alarm the watchdog activates an alarm and (2) malfunction of watchdog device stops application and shows error message.</p> <p>Criterion: Alarm is issued reliably after intentional delay of 20 seconds.</p>	<p>All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.</p>
Alarm: tube set usage time expires	<p>Verify device function alarms: Simulation of the maximum usage time an alarm activates the tube set is about to expire.</p> <p>Criterion: Alarm is issued reliably for various tube set conditions.</p>	<p>All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.</p>
Tube Set usage time expires	<p>Verify single use and shelf life of tube set: Reconnection of an already used tube set and connection of an expired tube set to the device the application must not start.</p> <p>Criterion: Re-use of a tube set is not accepted.</p>	<p>All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.</p>
Detection of opening and closing the cover	<p>Verify the angle of the opened and closed pump cover for starting and stopping the pump.</p> <p>Criterion: The angle to stop and start the pump is ≤ 10°.</p>	<p>All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.</p>

Test	Test method summary	Results
Device operation continues while removing mains power	Verify automatic switching to battery upon power failure: Device has to continue operation without any disturbance or abnormal behavior. The power plug icon has to be visible on the screen. Criterion: Device continues operation without any disturbances.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
Tube Set Durability	Verify functionality after double sterilization and accelerated aging of 4 years. Criterion: Functionality of tube set must be fulfilled.	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.
Safety patient monitor output	Verify external connectivity: Start device and connect to patient monitor. Pressure simulation test with various values. Criterion: Deviation of device and monitor values < 5% or < 2 mmHg	All samples passed the acceptance criteria. In relevancy of the test results the substantial equivalence is verified.

8. Conclusion

The LiquoGuard 7 is a tube system with integrated redundantly designed pressure sensors, as well as a peristaltic pump device, into which a part of the tube system is inserted in order to perform pressure or volume-controlled CSF drainage. The intrathecal CSF drain is used independent of the LiquoGuard 7, and the products approved for intrathecal CSF drainage can be connected to the LiquoGuard 7 (but are not part of the system). The indication for insertion of intrathecal drainage will not be affected by using the LiquoGuard 7.

The control parameters for the CSF drainage (target pressure, CSF flow) are identically between the predicate device and the LiquoGuard 7. The effective mechanism and the function of the CSF extraction by means of a target value-controlled peristaltic pump in the LiquoGuard 7 is also used in the predicate device, the LiquoGuard CSF System. Therefore, the LiquoGuard 7 offers comparable effectiveness to the predicate device.

The measuring sensor is also identically to the ones used in the predicate device, as well as many functions (ICP value display, trend analysis, etc.) and alarm settings (e.g. high pressure).

The LiquoGuard 7 is equivalent to the predicate devices in that:

- The devices have the same intended use and indication for use.
- The devices have equivalent design, function, procedures and features.
- The devices demonstrate equivalent performance.