



April 24, 2018

Renishaw Mayfield Sarl  
Stéphane Vinot  
Quality Assurance & Regulatory Affairs Manager  
31, Rue Ampère  
Chassieu, 69680 Fr

Re: K180206  
Trade/Device Name: neuromate Gen III  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic Instrument  
Regulatory Class: Class II  
Product Code: HAW  
Dated: January 4, 2018  
Received: January 24, 2018

Dear Stéphane Vinot:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

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

## Indications for Use

510(k) Number (if known)

K180206

Device Name

neuromate Gen III

Indications for Use (Describe)

Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments.

neuromate Gen III has been validated with the Leksell Stereotactic System Type G (comprising of head frame and CT Localizer).

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

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### 1. SUBMITTER:

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 Quality Assurance & Regulatory affairs Manager  
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Preparation date: January 4<sup>th</sup>, 2018

### 2. DEVICE NAME:

Trade name: neuromate<sup>®</sup> Gen III  
 Common name: neuromate Gen III stereotactic system  
 Classification : Regulation: 882.4560 Stereotaxic Instrument  
 Product Code: HAW – Neurological Stereotaxic Instrument

### 3. PREDICATE DEVICE(s):

K132755 – neuromate Frameless Gen II – RENISHAW Mayfield S.A.R.L.

### 4. REFERENCE DEVICE:

K163666 - neuro | inspire<sup>™</sup> - Renishaw plc.

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## 5. DEVICE DESCRIPTION:

A stereotactic system with an electromechanical, multi jointed arm for spatial positioning and orientation of an instrument holder or tool-guide. Guidance is based on a preoperative plan developed with three-dimensional imaging software. The system is intended for use by neurosurgeons to guide standard neurosurgical instruments.

## 6. INDICATION FOR USE:

Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments.

neuromate Gen III has been validated with the Leksell Stereotactic System Type G (comprising of head frame and CT Localizer).

## 7. COMPARISON WITH PREDICATE DEVICE:

The neuromate Gen III system (this submission) has the same intended use and the same fundamental scientific technology as the predicate device cleared under K132755.

The differences between the two devices are about the use of a new planning software named neuro|inspire (reference device K163666).

- Substitution of neuro|inspire planning software in the system:

The predicate device used a software package called VoXim as the planning software application. The neuromate Gen III (this submission) uses a planning software package called neuro|inspire (replacing Voxim). neuro|inspire contains a subset of functionalities of Voxim.

Moreover, the PC provided with the workstation has been changed to support the neuro|inspire software.

**The proposed neuromate Gen III (this submission) is identical in design, intended use, construction and operation to the predicate K132755.**

The itemised comparison between the device and its predicate is provided in the following paragraph 7 (Substantial Equivalence Summary) of this document.



### 8. SUBSTANTIAL EQUIVALENCE SUMMARY:

Device	neuromate Gen III (this submission)	neuromate Frameless Gen II (510(k) K132755)	SE
<b>Manufacturer</b>	RENISHAW mayfield	RENISHAW mayfield	Same
<b>Intended Use</b>			
<b>Intended Use</b>	Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments.	Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments.	Same
<b>Indication for use</b>			
<b>Indication for use</b>	Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments.  neuromate Gen III has been validated with the Leksell Stereotactic System Type G (comprising of head frame and CT Localizer).	Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments.	SE
<b>Clinical application</b>	Neurological surgery	Neurological surgery	Same
<b>Sites of use</b>	Operating rooms	Operating rooms	Same
<b>User</b>	Neurosurgeon	Neurosurgeon	Same
<b>Anatomical site</b>	Head	Head	Same

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<b>Principle of operation</b>	<p>Patient imaging data is visualized on the supplied workstation running neuro inspire software. It is the surgeon who chooses the tool, trajectory, point of access and orientation.</p> <p>The data is communicated to the robot which located the tool holder accordingly and accurately.</p> <p>The surgeon performs the procedure by inserting tools through the tool-holder, the robot ensures the continued stability of the position.</p>	<p>Patient imaging data is visualized on the supplied workstation running the VoXim software. It is the surgeon who chooses the tool, trajectory, point of access and orientation.</p> <p>The data is communicated to the robot which located the tool holder accordingly and accurately.</p> <p>The surgeon performs the procedure by inserting tools through the tool-holder, the robot ensures the continued stability of the position.</p>	SE
<b>Registration methods</b>	<p>Framebased mode: the patient wears a stereotactic frame and the frame is attached to the robot (mechanical registration)</p>	<p>Framebased mode: the patient wears a stereotactic frame and the frame is attached to the robot (mechanical registration)</p> <p>Frameless mode: The patient wears a light-weight microphone frame and the registration is made by ultrasound.</p>	SE
<b>Frame type indicated</b>	<p>Leksell Stereotactic System Type G (head ring and CT localizer).</p>	<p>Leksell Stereotactic System Type G (head ring, CT and MRI localizers from Elekta)</p> <p>+ CRW (head ring with MRI and CT localizers from Integra)</p> <p>+ Fischer (head ring with CT localizer from Inomed)</p>	SE
<b>Technical Characteristics</b>			
<b>General device description</b>	<p>Computer-controlled electromechanical multi-jointed arm</p>	<p>Computer-controlled electromechanical multi-jointed arm</p>	Same
<b>System</b>	<ul style="list-style-type: none"> <li>A robot, made of a computer-controlled</li> </ul>	<ul style="list-style-type: none"> <li>A robot, made of a computer-controlled articulated</li> </ul>	Same

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<b>Architecture</b>	<p>articulated motorized arm and the base that supports it and contains the control electronics;</p> <ul style="list-style-type: none"> <li>• A workstation on which runs software for scanned image processing, procedure planning, robot configuration, robot control and system diagnostic;</li> <li>• A series of attachments to connect the robot to the patient, to perform patient registration and to support the tools used by the surgeon.</li> </ul>	<p>motorized arm and the base that supports it and contains the control electronics;</p> <ul style="list-style-type: none"> <li>• A workstation on which runs software for scanned image processing, procedure planning, robot configuration, robot control and system diagnostic;</li> <li>• A series of attachments to connect the robot to the patient, to perform patient registration and to support the tools used by the surgeon.</li> </ul>	
<b>Axis control technology</b>	<p>Incremental digital encoders Absolute digital encoders</p>	<p>Incremental digital encoders Absolute digital encoders</p>	Same
<b>Compliance with voluntary standards</b>	<p>Yes IEC 60601-1: 2005 + AC1 + AC2 + A1: 2012 IEC 60601-1-2: 2007  ISO 14971: 2007 IEC 62304: 2006 IEC 62366: 2007 ISO 17665-1: 2006 DICOM 3</p>	<p>Yes IEC 60601-1: 2005 + AC1 + AC2 + A1: 2012 IEC 60601-1-2: 2007 IEC 60601-1-4: 2000 ISO 14971: 2007 IEC 62304: 2006 IEC 62366: 2007 ISO 17665-1: 2006 DICOM 3</p>	SE
<b>Maximum instrument payload</b>	<p>Maximum useful load: 5 kg (11 lb) 1 kg (2.2 lb) for maximum accuracy</p>	<p>Maximum useful load: 5 kg (11 lb) 1 kg (2.2 lb) for maximum accuracy</p>	Same
<b>Working volume</b> (subset of the above in which the positioning accuracy is achieved)	<p>20 cm (~8") long, 18 cm (7") diameter horizontal cylinder oriented along the robot axis and with its centre 81 cm (~32") from the base.</p>	<p>20 cm (~8") long, 18 cm (7") diameter horizontal cylinder oriented along the robot axis and with its centre 81 cm (~32") from the base.</p>	Same





<b>Overall positioning accuracy</b> (including imaging)	In Frame-based mode: < 2 mm (5/64"). maximum error: 2 mm (0.079") and 2° between the position reached by the instrument carried by the arm and the actual target.	In Frame-based mode: < 2 mm (5/64"). In Frameless mode: < 3 mm (1/8")	SE
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## 9. NO CLINICAL TESTING

<b>Software Verification and Validation</b>	The neuromate Gen III software including neuro inspire planning were designed, verified and validated in accordance with IEC 62304: 2006 and <i>General Principles of Software Validation; Final Guidance for Industry and FDA Staff</i> .  Verification and validation confirmed that the neuromate Gen III software are safe and effective.
<b>Electrical Safety Verification</b>	The neuromate Gen III system was tested in accordance with IEC 60601-1:2005 + AC1 + AC2 + A1: 2012.  Test results confirmed that the neuromate Gen III complies with this standard.
<b>Performance Validation</b>	The neuromate Gen III system was validated with the Leksell Stereotactic System Type G (comprising of head frame and CT Localizer).  The result of this validation confirmed that the accuracy of the system complies with its claimed performances and is equivalent to those of the predicate system.
<b>Usability Validation</b>	The neuromate Gen III interface including neuro inspire was validated in accordance with Usability Engineering standard IEC 62366: 2007.  This validation confirmed that the use of the neuromate Gen III does not pose an unacceptable risk.

## 10. CONCLUSIONS FROM TESTING

Verification and validation activities were conducted to establish the performance and safety characteristics of the neuromate Gen III system.



The results of these activities demonstrate that the neuromate Gen III is safe and effective and performs at least as safely and effectively as the predicate marketed device.

Therefore, the neuromate Gen III is considered substantially equivalent to the predicate device.