RENISHAW mayfield

K132755

510(k) SUMMARY

APR 2 9 2014

1. SUBMITTER:

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Preparation date: July 11, 2013

2. DEVICE NAME:

Trade name: neuromate Frameless Gen II

Common name: Stereotactic neurological system

Classification name: Stereotaxic Instrument (HAW)

3. PREDICATE DEVICE(s):

K991081 - Frameless Neuromate – Integrated Surgical Systems Inc

4. 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 and utilizes ultrasonic registration. The system is intended for use by neurosurgeons to guide standard neurosurgical instruments.

5. INTENDED 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.

6. COMPARISON TO PREDICATE DEVICE:

6.1 Similarities

The neuromate system is a technical update of the cleared Frameless NeuroMate. It has the same intend and is similar in all the following respects:

- the patient benefits
- the architecture of the product
- the materials and components used
- the construction and method of manufacture
- the embedded software
- the planning and imaging software
- the operational modes offered
- the attachments used

6.2 Differences

The only areas of difference between the neuromate and the cleared Frameless NeuroMate are:

a. The new neuromate system is type BF applied part while the cleared Frameless NeuroMate is type B applied part.

Note: The terms "Type BF applied part" and "Type B applied part" are used in the IEC60601-1 standard (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance) to define the level of electrical isolation of an electrical medical equipment that has a part(s) in contact with a patient under normal use. The electrical isolation is between the patient and an external electrical source. In the IEC60601-1 standard, a "Type BF applied part" has a higher degree of electrical isolation compared to a "Type B applied part".

b. The neuromate system uses absolute digital encoders to control the position of the axis of the robot arm of the system while the cleared Frameless NeuroMate uses analogical ones.

c. The image-feedback sensor has been removed from the standard tool-holder, thereby removing the image-feedback functionality of the system

6.3 Conclusion

Except for the above stated changes, the proposed Neuromate is identical in design, intended use, construction and operation to the predicate K991081.

The itemised comparison between the device and its predicate is provided in paragraph 10 (Substantial Equivalence Summary) of this document.

7. NONCLINICAL DATA:

Bench and performance testing showed that neuromate performed as designed and intended. The neuromate was tested to and found compliant with the requirements of IEC 60601-1 and IEC 60601-1-2.

Software was developed in compliance with FDA software guidance and IEC 62304.

8. CLINICAL DATA:

No clinical data are submitted.

9. CONCLUSIONS DRAWN FROM TESTING:

The testing showed that the neuromate performs as designed and intended, and is equivalent in design and performance to the predicate device.

10. SUBSTANTIAL EQUIVALENCE SUMMARY

Device	neuromate Frameless Gen II (this submission)	Frameless Neuromate (510(k) K991081)	SE
Manufacturer	Renishaw Mayfield	Integrated Surgical Systems Inc	SE
Intended Use/Indications for Use			
Intended 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.	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
Clinical application	Neurological surgery	Neurological surgery	Same
Sites of use	Operating rooms	Operating rooms	Same
User	Neurosurgeon	Neurosurgeon	Same
Anatomical site	Head	Head	Same
Technical Characteristics			
General device description	Computer-controlled electromechanical multi-jointed arm	Computer-controlled electromechanical multi-jointed arm	Same
Principle of Operation	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. The data is communicated to the robot which locates the tool holder accordingly and accurately.	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. The data is communicated to the robot which locates the tool holder accordingly and accurately.	Same

Device	neuromate Frameless Gen II (this submission)	Frameless Neuromate (510(k) K991081)	SE
	The surgeon performs the procedure by inserting tools through the tool-holder, the robot ensuring the continued stability of the position. Patient registration uses an ultrasound system.	The surgeon performs the procedure by inserting tools through the tool-holder, the robot ensuring the continued stability of the position. Patient registration uses an ultrasound system.	
May be used in frame-based mode	Yes: the patient wears a stereotactic frame and the frame is attached to the robot (mechanical registration)	Yes: the patient wears a stereotactic frame and the frame is attached to the robot (mechanical registration)	Same
May be used in frameless mode	Yes: the patient wears a light-weight microphone frame and the registration is made by ultrasound.	Yes: the patient wears a light-weight microphone frame and the registration is made by ultrasound.	Same
Image feedback	No: the surgeon controls the depth of insertion of a biopsy needle through the rule on the cannula.	Yes: the position of the tool's extremity is shown superposed to the brain scan image. However, the surgeon is advised not to use this information to control tool depth (use instead the rule on the cannula)	SE
System Architecture	• a robot, made of a computer-controlled articulated motorized arm and the base that supports it and contains the control electronics; • a workstation on which runs software for scanned image processing, procedure planning, robot configuration, robot control and system diagnostic; • a series of attachments to connect the robot to the patient, to perform patient registration and to support the tools used by the surgeon	• a robot, made of a computer-controlled articulated motorized arm and the base that supports it and contains the control electronics; • a workstation on which runs software for scanned image processing, procedure planning, robot configuration, robot control and system diagnostic; • a series of attachments to connect the robot to the patient, to perform patient registration and to support the tools used by the surgeon	Same
Attachments	• remote control handset • standard tool-holder • tool laser holder • frame adapter • head-holder • ultrasound tool-holder • microphone frame • temporary implant insert • CT image localizer • MRI image localizer • angiographic module localizer	• remote control handset • standard tool-holder • tool laser holder • frame adapter • head-holder • ultrasound tool-holder • microphone frame • temporary implant insert • CT image localizer • MRI image localizer • angiographic module localizer	Same

Device	neuromate Frameless Gen II (this submission)	Frameless Neuromate (510(k) K991081)	SE
Construction	• Mechanical arm in four parts with 5 joints (5 degrees of freedom) • Rigid fixation between the stereotactic ring attachment or head holder attachment and the neuromate robot • Each arm joint is an electrome-chanical subassembly composed of a motor; planetary reducer; gear reducer; and worm-wheel adjustment system with variable backlash, providing non-reversible motion and guaranteeing rigid position locking.	• Mechanical arm in four parts with 5 joints (5 degrees of freedom) • Rigid fixation between the stereotactic ring attachment or head holder attachment and the neuromate robot • Each arm joint is an electrome-chanical subassembly composed of a motor; planetary reducer; gear reducer; and worm-wheel adjustment system with variable backlash, providing non-reversible motion and guaranteeing rigid position locking.	Same
Axis control technology	Incremental digital encoders Absolute digital encoders	Incremental digital encoder Absolute analogical encoder	SE
Software/firmware / microprocessor control	Yes	Yes	Same
- **Controller S/W**	Main Controller	Main Controller	Same
- **Planning S/W**	VoXim neuromate 6.4	VoXim 1.0	SE
- **Imaging S/W**	VoXim neuromate 6.4	VoXim 1.0	SE
Compliance with voluntary standards	Yes IEC 60601-1:2005 + AC1 + AC2 IEC 60601-1-2:2007 IEC 60601-1-4:2000 IEC 62366: 2007 ISO 14971: 2007 IEC 62304: 2006 DICOM 3 ISO 17665-1:2006	Yes EN 55011, Group 1, Class B EN 50082-1 (IEC 801-2) EN 50082-1 (IEC 801-3) EN 50082-1 (IEC 801-4) IEC 601.1	SE

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

April 29, 2014

Renishaw Mayfield Sarl
Mr. Stephane Vinot
Quality Assurance & Regulatory Affairs Manager
31 Rue Ampere
Chassieu, France 69680

Re: K132755
Trade/Device Name: Neuromate Frameless Gen II
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: January 21, 2014
Received: January 29, 2014

Dear Mr. 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.

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 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,

Felipe Aguel -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 on last page.

510(k) Number *(if known)*
K132755

Device Name
Neuromate Frameless Gen II

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.04.29 18:06:23 -04'00'

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