



Food and Drug Administration  
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September 15, 2017

Renishaw plc  
% Roberto Liddi  
Head of Regulatory Affairs and Quality Assurance  
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Wotton-under-edge,  
Gloucestershire, GL12 8JR GB

Re: K163666

Trade/Device Name: neuro | inspire  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic Instrument  
Regulatory Class: Class II  
Product Code: HAW  
Dated: August 21, 2017  
Received: September 11, 2017

Dear Dr. Liddi:

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,

**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)

K163666

Device Name

neuro | inspire

Indications for Use (Describe)

neuroinspire is a stereotactic software application intended to allow trained clinicians to plan surgical trajectories for neurological procedures. neuroinspire defines a stereotactic region for this planning based on fiducial markers in CT images. neuroinspire reports specific surgical trajectories intended to be manually set on head frame systems validated for use with neuroinspire. neuroinspire has been validated with the Leksell Stereotactic System Type G (comprising of head ring, head frame and CT Localizer). No other components of the Leksell Stereotactic System should be used. No other stereotactic system should be used. The user should consult Section 1.7 Accuracy of these Instructions for Use to assess if the accuracy of neuroinspire is suitable for their needs.

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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## **4: 510(k) Summary**

### **1. Submitter:**

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Preparation date: 14<sup>th</sup> September 2017

### **2. Device:**

Trade name: neuro | inspire™      Common name: *neuroinspire*  
Classification regulation: 21 CFR 882.4560      Stereotaxic instrument  
Product code: HAW

### **3. Predicate device:**

Brainlab AG      iPlan Stereotaxy      K101627  
Device Classification Name: Stereotaxic Instrument  
Regulatory Class: Class II

#### 4. Device description:

*neuroinspire* surgical planning software is an application that enables the viewing of medical images to support the image based neurosurgery. It may be used by neurosurgeons to reconstruct and display multiple image sets to facilitate 2D and 3D targeting and trajectory planning in relation to an intended neurological surgical procedure. It allows the neurosurgeon to download and integrate MRI and CT DICOM (digital imaging communication) images of a patient's brain onto a PC-based platform. The neurosurgeon can then virtually slice the brain into sections, zoom in for close-ups and rotate images in order to visualize and analyze the patient's brain prior to surgery.

*neuroinspire* has been validated with the Leksell Stereotactic System Type G (comprising of head ring, head frame and CT Localizer).

*neuroinspire* surgical planning software allows a neurosurgeon to:

- load data acquired from an MRI scanner
- load data acquired from a CT scanner;
- manually reconstruct target anatomy using multi-planer views;
- calculate target coordinates;
- plan trajectories;
- print a surgical plan.

#### 5. Indications for Use:

*neuroinspire* is a stereotactic software application intended to allow trained clinicians to plan surgical trajectories for neurological procedures. *neuroinspire* defines a stereotactic region for this planning based on fiducial markers in CT images. *neuroinspire* reports specific surgical trajectories intended to be manually set on head frame systems validated for use with *neuroinspire*. *neuroinspire* has been validated with the Leksell Stereotactic System Type G (comprising of head ring, head frame and CT Localizer). No other components of the Leksell Stereotactic System should be used. No other stereotactic system should be used. The user should consult Section 1.7 *Accuracy* of these Instructions for Use to assess if the accuracy of *neuroinspire* is suitable for their needs.

**6. Comparison to Technological Characteristics with Predicate Device:**

<b>Function</b>	<b>Predicate Description of BrainLab iPlan Stereotaxy K101627</b>	<b>Comparison of Predicate to <i>neuroinspire</i></b>	<b>Equivalence</b>
Intended Use	The viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion, atlas assisted visualization and segmentation, intraoperative functional planning where the output can be used e.g. with stereotactic image guided surgery or other devices for further processing and visualization	Software application running on a standard computer workstation for viewing and presentation of medical images. It provides the capability for processing of patient images and the planning of surgical procedures for any medical condition in which the use of stereotactic image guide brain based neurosurgery is considered appropriate	<u>Same</u>
AC/PC Localization	This planning task allows the definition of AC/PC co-ordinate system	This planning task allows the definition of AC/PC co-ordinate system	<u>Same</u>
Localization	Assign a localizer frame for CT or MRI localization Perform automatic detection of localizer rods	Assign a localizer frame for CT localization Perform automatic detection of localizer rods	<u>Substantially Equivalent</u>
Trajectory Planning	Plan pathways for surgical instruments or resection, definition of entry, target points and diameter for trajectories	Plan pathways for surgical instruments or resection, definition of entry, target points and diameter for trajectories	<u>Same</u>
Stereotactic planning	Planning of stereotactic trajectories Usage of AC/PC coordinates and Schaltenbrandt-Wahren atlas. Calculation of stereotactic arc settings for planned trajectories	Planning of stereotactic trajectories Usage of AC/PC coordinates and Shaltenbrandt-Wahren atlas. Calculation of stereotactic arc settings for planned trajectories	<u>Same</u>

Function	Predicate Description of BrainLab iPlan Stereotaxy  K101627	Comparison of Predicate to <i>neuroinspire</i>	Equivalence
Load and Import	Load existing treatment data from different data sources, import patient data from DICOM or other archive types, manage (delete/copy/move) patient folders	<i>neuroinspire</i> imports patient data in DICOM form. It manages patient data locally (on the PC) but does not modify or delete the source hospital data. This is a safety measure as the original data cannot be altered through the use of <i>neuroinspire</i> .	<u>Substantially Equivalent</u>
View and Adjustment	Review patient data in various reconstructions or overlay, side-by-side comparison of different modalities, aligning the data set orientation, import or export screenshot images	<i>neuroinspire</i> allows the review of patient data in various reconstructions or overlay, side-by-side comparison of MRI and CT modalities, alignment of datasets and export of screenshots, but there is no import of screenshot data.	<u>Substantially Equivalent</u>
Image Fusion	Align available image sets automatically, manually or using landmarks for various combinations of images sets and modalities such as CT MRI, PET and SPECT. Visual verification of alignment.	<i>neuroinspire</i> aligns available image sets automatically, manually or using landmarks for various combinations of images sets and modalities but only MRI and CT modalities are supported. MRI and CT are the most common imaging modalities used in neurosurgery.	<u>Substantially Equivalent</u>

Function	Predicate Description of BrainLab iPlan Stereotaxy  K101627	Comparison of Predicate to <i>neuroinspire</i>	Equivalence
Object Creation	Outline anatomical structures using manual or automatic segmentation methods. Advanced manipulation for 3D objects with scaling, logical operations and object splitting. Volumetric measurements based on the created 3D objects	With <i>neuroinspire</i> the user can manually segment anatomical structures using manual segmentation methods. There are no automatic segmentation functions but the volume of a segmented features is reported.	<u>Substantially Equivalent</u>
Save and Export	Save the current treatment plan to the patient folder. Export the results to the navigation, as DICOM or STL format	The <i>neuroinspire</i> user can save and export the treatment plans in a proprietary format, not in DICOM or STL and does not export the results to a navigation system.	<u>Substantially Equivalent</u>
Registration Points	Automatic detection of CT or MR registration markers for navigation, manual placement of markers and anatomical landmarks	<u>No equivalence is claimed</u>	<u>No equivalence is claimed</u>
Advanced Object Planning	Mirror and split segmented structures	<u>No equivalence is claimed</u>	<u>No equivalence is claimed</u>
BOLD MRI mapping	Processing of blood oxygen level dependent (BOLD) MRI data. Definition of block design functional task, calculation of activation areas based on BOLD MRI data, time series view for activation signal, creation of 3D objects from activation areas	<u>No equivalence is claimed</u>	<u>No equivalence is claimed</u>

Function	Predicate Description of BrainLab iPlan Stereotaxy  K101627	Comparison of Predicate to <i>neuroinspire</i>	Equivalence
Fiber Tracking	Processing of diffusion tensor imaging (DTI) using various ways to define and combine seed regions of interest. Definition of multiple fiber bundles and creation of 3D objects from fiber bundles. Volumetric measurements and detailed fiber information	<u>No equivalence is claimed</u>	<u>No equivalence is claimed</u>
Electrode recording	Planning of parallel electrode tracks. Enter and display microelectrode recording and stimulation results, display information stepwise along tracks	<u>No equivalence is claimed</u>	<u>No equivalence is claimed</u>

**a. Conclusion**

Except for the differences stated above, the proposed *neuroinspire* software is similar in design, intended use and operation to the predicate, K101627. The last five functions in the above table are specific areas of functionality that extend the scope of BrainLab’s iPlan Stereotaxy device beyond the scope of *neuroinspire*.

**7. Performance Data:**

**a. Nonclinical Data**

Verification and validation of this device was conducted and documentary evidence has been provided as part of this submission. The software is considered as a “major” level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

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

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Human factors studies have been carried out to validate the safe and effective user experience, the documentary evidence of these studies has been provided as part of this submission.

A ground truth measurement of a CT phantom mimicking a human skull and containing a number of representative brain targets was established using a portable CMM system. Testing was performed and demonstrated that the positional and angular accuracy of transferring the trajectory information from *neuroinspire* to the Leksell stereotactic system is <2 mm and <2° respectively. The documentary evidence of this measurement has been provided as part of this submission, results are summarized below:

Specification for maximum Euclidean positional error: **<2 mm**

Mean: **0.96 mm**

ST Dev: **0.42 mm**

99% CI: **0.130 mm**

99% CI upper bound: **1.090mm**

Specification for maximum angular error: **<2°**

Mean: **0.45°**

ST Dev: **0.29°**

99% CI: **0.089°**

99% CI upper bound: **0.539°**

**b. Clinical Data**

No clinical data has been submitted.

**8. Conclusions:**

The conclusions drawn from the nonclinical tests demonstrate that the device, when used as intended, is as safe, as effective, and performs as well as or better, than the legally marketed device identified in section 3 of this summary.