

K963256

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9. SMDA Summary of Safety and Effectiveness - 510(k) Summary

A. Sponsor Information

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President

B. Device Identification

Common/Usual Name: Stereotactic Instrument  
Proprietary Name: NeuroMate Stereotactic System

C. Identification of Predicate Device(s)

The NeuroMate Stereotactic System is substantially equivalent to the following previously cleared and currently marketed devices:

- BRW Stereotactic System (Radionics; K811452)
- COMPASS Stereotactic System (Stereotactic Medical Systems; K871046)

D. Device Description

The NeuroMate Stereotactic System is a computer controlled image-guided electro-mechanical multijointed arm. NeuroMate is intended to be used in a stereotactic neurosurgical operating room for the spatial positioning and orientation of an instrument holder or tool guide to be used by the surgeon to manually guide standard neurosurgical instruments (Figure 1).

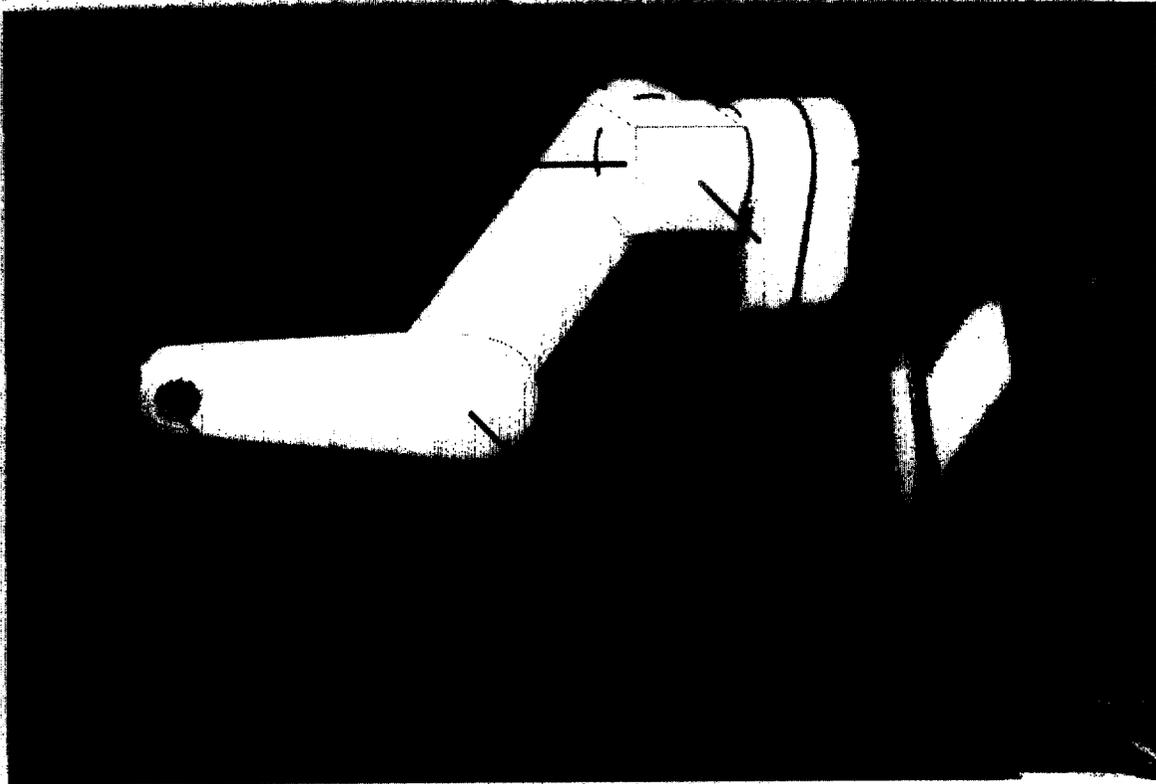
NeuroMate assists the surgeon in its operating tasks by providing a stable, accurate, and reproducible mechanical guidance for surgical instruments, while not directly entering in contact with the patient's head. The instrument holder's stereotactic spatial positioning and orientation are determined by the neurosurgeon using an "external" (i.e., not provided by IMMI Inc.) imaging software for stereotactic planning and specific to the intended clinical application.

The NeuroMate Stereotactic System acts like a motorized stereotactic frame driven by the external imaging software supported by a PC or a computer workstation providing visualization of anatomical structures and brain targets specific for the intended application (e.g., 3-D image databases from CT, MR, DSA, PET, SPECT).

Following a carefully prepared stereotactic treatment plan, at the neurosurgeon request, the NeuroMate Stereotactic System slowly moves and subsequently rigidly maintains an instrument holder proximal to the patient's head: NeuroMate automatically and accurately insure the correct stereotactic angular and spatial positioning of surgical instruments, thereby reducing potential human errors. During most of the duration of a neurosurgical procedure, NeuroMate is motionless and the instrument holder rigidly holds the surgical instrument chosen by the neurosurgeon prior to initiating stereotactic surgery. Only when changing spatial position and/or orientation does NeuroMate actually move. Finally, NeuroMate must be used in conjunction with a stereotactic head ring.

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—— Joint Axis

Figure 1 : NeuroMate Stereotactic System Geometry

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The treatment strategy, including the choice of the entry point on the patient's head and the associated rectilinear route to reach a pre-selected brain target, are entirely left under the neurosurgeon's control. NeuroMate enables the surgeon to spatially position a surgical instrument along a virtually infinite number of angular orientations centered onto a pre-selected brain target point.

The device operates from a 110V supply, with all of its structure grounded; the device is equipped with a double-insulation 110V/220V transformer. Its main components are:

- electronic and PC circuit boards powered by switching power supplies;
- an electromechanical 5-axis multijointed arm displaced by 24V DC motors;
- a RS-232 computer interface enabling communications with external computers or workstations which operate the external imaging software driving the NeuroMate Stereotactic System.

The NeuroMate Stereotactic System's controller has been specifically developed for surgical applications. It includes several functions at the mechanical and software levels, which, in case of dysfunction, guarantee the patient safety and the medical staff safety.

NeuroMate Stereotactic System's controller is a "distributed controller" comprising the following elements:

- an *axis controller* for each joint;
- a *main controller module* coordinating NeuroMate's motion; it performs the necessary transformations between the Cartesian space and joint space;
- a *field bus* linking the main controller to the axis controllers;
- a *supervisor module* performing all functions related to user interface, and generating the motion orders for the NeuroMate Stereotactic System to navigate in Cartesian space.

#### E. Performance Data

Overall performances of the NeuroMate Stereotactic System were assessed as a result of different testing sequences designed to:

- verify the device's technical and functional characteristics ,
- verify the operation of the device's safety systems, and
- measure the accuracy and repeatability performances in spatial positioning and orientation of the multi-jointed arm carrying a specific payload.

The results of these measurements are well within the performance specifications of the device and provide a clear indication of the relatively high spatial accuracy of the NeuroMate Stereotactic System.

- Accuracy may be defined as the success of the device in reaching a known location in space: the measured positioning accuracy was 0.73 mm, and the measured angular accuracy was 0.14°.
- Repeatability is the ability of the device to return to the same position in space repeatedly: the measured repeatability was 0.136 mm.

#### F. Clinical Testing

Between Sept. 1995 and Apr. 1996, the NeuroMate Stereotactic System was tested at the Neurosurgery Department of Grenoble University Hospital in France. The objectives of the clinical testing were to establish that the NeuroMate Stereotactic System could

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position an instrument in any required stereotactic spatial position corresponding to pre-determined entry and a target points, as determined by the neurosurgeon.

A cohort of 45 patients (16 females; 29 males) with a mean age of 42 years (range 6-75) underwent various stereotactic procedures with the assistance of NeuroMate. The procedures were as follows: biopsy (11 cases), cysternostomy (4 cases), tumoral cyst (1 case), Parkinson (17 cases), electro-encephalogram stimulation for the treatment of acute epilepsy (12 cases).

The stereotactic approaches used included single oblique, double oblique, frontal, lateral, and parietal trajectories corresponding to standard accesses around the patient's head. In all cases, NeuroMate performed as intended and successfully positioned the instrument holder at the required stereotactic spatial and angular position.

As a result of these clinical tests, the benefits of using the NeuroMate Stereotactic System for the positioning of an instrument holder can be summarized as follows:

- NeuroMate can access any part of the patient's head for single or multiple trajectories without the mechanical limitations encountered in the use of frames;
- the choice of optimal trajectories adapted to anatomical, functional, and surgical considerations is facilitated by the accessibility provided by NeuroMate;
- NeuroMate was successful in directly positioning its instrument holder at the appropriate stereotactic location in 75% of the cases; following readjustment judged clinically necessary by X-ray control *in-situ*, the requested positioning was achieved in every case (100%);
- NeuroMate's simulation capabilities, particularly when bi-planar X-rays are available in the Operating Room, can significantly enhance the clinical effectiveness of the instrument holder positioning: deviations between requested positioning and clinically optimal positioning were < 2mm in 65% of the cases without simulation, and increased to 97% with treatment simulation;
- NeuroMate positioning readjustment immediately prior to surgical treatment could be easily performed and was judged clinically satisfactory in 94% of cases at the first request, and in all cases at the second request.

#### **G. Substantial Equivalence**

The IMMI's NEUROMATE Stereotactic System is substantially equivalent to the BRW Stereotactic System (Radionics; K811452) and the Compass Stereotactic System (Stereotactic Medical Systems; K871046) in terms of its performance data and intended uses. A direct comparison of significant performance data for these predicate devices and for the NeuroMate Stereotactic System is summarized in Table A. A direct comparison of the intended uses is summarized in Table B.

The technical characteristics of the NeuroMate Stereotactic System are equivalent to those of the BRW and Compass Stereotactic Systems. Differences that exist between these devices, relating to technical specifications, materials, physical appearance, and control systems, do not affect the relative safety and effectiveness of NeuroMate.

The NeuroMate Stereotactic System, the BRW Stereotactic System and the Compass Stereotactic System are intended for the stereotactic spatial positioning and orientation of an instrument or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments.

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|-----------------------------------------|------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| <b>Manufacturer</b>                     | <b>RADIONICS</b>                                                                               | <b>Stereotactic Medical Systems, Inc.</b>                                                    | <b>IMMI, Inc.</b>                                                           |
| <b>Model</b>                            | <b>BRW CT Stereotactic System</b>                                                              | <b>COMPASS Stereotactic Positioning System</b>                                               | <b>NEUROMATE Stereotactic System</b>                                        |
| <b>K-Number</b>                         | <b>K811452</b>                                                                                 | <b>K871046</b>                                                                               |                                                                             |
| <b>Class</b>                            | <b>II</b>                                                                                      | <b>II</b>                                                                                    |                                                                             |
| <b>Head Ring Assembly</b>               | <b>Yes (BRW-HR)</b>                                                                            | <b>Yes</b>                                                                                   | <b>Yes: from other existing manufacturers</b>                               |
| <b>Localizer Ring</b>                   | <b>Yes (BRW-LR)</b>                                                                            | <b>Yes</b>                                                                                   | <b>No: use other existing manufacturer localizers for images</b>            |
| <b>Rigid connection to table</b>        | <b>Yes (Mayfield Assembly)</b>                                                                 | <b>Yes (Stereotactic Headframe)</b>                                                          | <b>Yes: with mechanical frame</b>                                           |
| <b>Arc System</b>                       | <b>Yes (BRW-AS: based on AP, LAT, and VERT coordinates converted into angular coordinates)</b> | <b>Yes (3-D slide &amp; arc quadrant)</b>                                                    | <b>Multi-jointed electro-mechanical arm; rigid spatial position locking</b> |
| <b>Instrument Holder</b>                | <b>Yes (set on Arc System: BRW-AS)</b>                                                         | <b>Yes (set on Arc Carrier)</b>                                                              | <b>Yes: mounted on 5<sup>th</sup> joint; rigid instrument holding</b>       |
| <b>Calibration</b>                      | <b>Yes</b>                                                                                     | <b>Yes</b>                                                                                   | <b>Yes: register on head ring</b>                                           |
| <b>Phantom assembly for calibration</b> | <b>Yes (BRW-PB)</b>                                                                            | <b>Yes</b>                                                                                   | <b>No</b>                                                                   |
| <b>Isocentric target position</b>       | <b>Yes</b>                                                                                     | <b>Yes</b>                                                                                   | <b>Yes: isocentric stereotactic targeting</b>                               |
| <b>Trajectory through 2 points</b>      | <b>Yes (set up from computer solution providing BRW-AS stereotactic settings)</b>              | <b>Yes (set up from computer solution providing precise stereotactic headframe settings)</b> | <b>Yes: different types of possible motions</b>                             |

Table A. Performance Data: Stereotactic Systems

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|                                                                                         |                                                                                                                                   |                                                                                                               |                                                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| <b>Manufacturer</b>                                                                     | <b>RADIONICS</b>                                                                                                                  | <b>Stereotactic Medical Systems, Inc.</b>                                                                     | <b>IMMI, Inc.</b>                                                                                           |
| <b>Model</b>                                                                            | <b>BRW CT Stereotactic System</b>                                                                                                 | <b>COMPASS Stereotactic Positioning System</b>                                                                | <b>NEUROMATE Stereotactic System</b>                                                                        |
| <b>K-Number</b>                                                                         | <b>K811452</b>                                                                                                                    | <b>K871046</b>                                                                                                |                                                                                                             |
| <b>Class</b>                                                                            | <b>II</b>                                                                                                                         | <b>II</b>                                                                                                     |                                                                                                             |
| <b>Location accuracy:</b><br><b>Position:</b><br><b>Angle:</b><br><b>Repeatability:</b> | <b>Position: 1.5 mm</b><br><b>Angle: 0.5°</b>                                                                                     | <b>Position: 0.7 mm</b>                                                                                       | <b>Position: &lt; 0.75 mm</b><br><b>Angular: &lt; 0.14°</b><br><b>Repeatability: &lt; 0.15 mm</b>           |
| <b>Computer and Software</b>                                                            | <b>Yes: Calculate target coordinates relative to Head Ring from image data; calculate arc angles for desired probe trajectory</b> | <b>Yes: Computer Assisted Stereotaxy; calculate headframe settings from image data for desired trajectory</b> | <b>Yes: Computer Assisted Stereotaxy; calculate trajectory and instrument orientation from image data</b>   |
| <b>Motorized Motion</b>                                                                 | <b>No</b>                                                                                                                         | <b>Yes: Motorized motion of the headframe along X,Y,Z through 3 stepper motor slides</b>                      | <b>Yes: Motorized motion of the instrument holder through electro mechanical, 5 axis, multi-jointed arm</b> |

Table A (Continued). Performance Data: Stereotactic Systems

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|---------------------------------------|------------------------------------------------------------------------|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| <b>Manufacturer</b>                   | <b>RADIONICS</b>                                                       | <b>Stereotactic Medical Systems, Inc.</b>      | <b>IMMI, Inc.</b>                                                                                                              |
| <b>Model</b>                          | <b>BRW CT Stereotactic System</b>                                      | <b>COMPASS Stereotactic Positioning System</b> | <b>NEUROMATE Stereotactic System</b>                                                                                           |
| <b>K-Number</b>                       | <b>K811452</b>                                                         | <b>K871046</b>                                 |                                                                                                                                |
| <b>Class</b>                          | <b>II</b>                                                              | <b>II</b>                                      |                                                                                                                                |
| <b>Accessibility</b>                  | <b>From any suitable direction (rotatable head posts on Head Ring)</b> | <b>From any suitable direction</b>             | <b>From any suitable direction: displace multi-jointed arm around patient's head avoiding pre-programmed forbidden volumes</b> |
| <b>Multiple targets</b>               | <b>Yes: through one burr hole</b>                                      | <b>Unknown</b>                                 | <b>Yes: through one burr hole</b>                                                                                              |
| <b>Range of target access</b>         |                                                                        |                                                |                                                                                                                                |
| <b>Conventional stereotaxy access</b> | <b>Yes</b>                                                             | <b>Yes</b>                                     | <b>Yes: universal approach any trajectory</b>                                                                                  |
| <b>Transnasal pituitary access</b>    | <b>Yes</b>                                                             | <b>Unknown</b>                                 | <b>Yes</b>                                                                                                                     |
| <b>Posterior fossa access</b>         | <b>Yes (cervical approaches by lowered/tilted Head Ring)</b>           | <b>Unknown</b>                                 | <b>Yes</b>                                                                                                                     |
| <b>Full lateral access</b>            | <b>Yes</b>                                                             | <b>Yes: lateral access</b>                     | <b>Yes: universal approach</b>                                                                                                 |
| <b>Sterile draping</b>                | <b>Yes</b>                                                             | <b>Yes</b>                                     | <b>Yes</b>                                                                                                                     |

Table B . Intended Uses: Stereotactic Systems

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