

K961844

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## Appendix 1

### Summary of Safety and Effectiveness

#### General Information

Classification: Class II

Common Name: Surgical Planning and Guidance System

Device Trade Name: Operating Arm System (OAS) with CT and MR Imaging

Intended Uses: OAS is a surgical planning system which enables the surgeon to plan a surgical procedure so as to optimize his approach. The OAS provides the surgeon with visual information to make assessments during a surgical procedure. OAS is indicated for the operative planning of surgical procedures, for example: tumor resection, ventricular shunt placement, craniotomy, and ENT-intranasal ethmoidectomy.

Predicate Devices: Radionics Operating Arm System (with CT images), K951262;  
 ISG Technologies Allegro Viewing Wand System, K911783;  
 FLEXcon Company, Inc. Beekley XSpot stick-on fiducial markers included in RSA Operating Arm PMN, K951262.

Establishment Name and Address: Radionics Software Applications, Inc.  
 22 Terry Avenue  
 Burlington, MA 01803

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Establishment registration number: 1222895

Performance Standard: None established under Section 514.

#### Substantial Equivalence Determination

A summary of the information contained in this premarket notification that addresses safety and effectiveness follows.

## ***Description of the Device and Basis for Substantial Equivalence***

The Operating Arm System, addressed in this premarket notification, has the same intended use and similar technological characteristics as the commercially available Radionics Operating Arm System (with CT images) and the ISG Viewing Wand System. New features described in this submission include the additional support of MR images and Radionics adhesive fiducial markers. The OAS provides an interactive, image-guided means of localizing targets in surgical procedures. It consists of an articulated Operating Arm, a computer workstation, application software, probes, and a Mayfield Attachment. The Operating Arm consists of a series of articulating joints and connecting links combined with an instrument holder. It is a five-jointed, five degree of freedom pointing device used for position (x, y, z) and angle measurement. Upon calibration of the instrument in the surgical environment, the surgeon manipulates the Arm to select points in surgical space which are interpreted by the computer and related to corresponding points in image space. Similarly, the ISG Viewing Wand System consists of an articulated Arm, a computer workstation, application software, probes, and a Mayfield Attachment. It is a six-jointed six degree of freedom electrogoniometer used for position (x, y, z) and angle measurement.

## ***Safety Summary***

RSA Operating Arm System (OAS) system testing verifies that the stereotactic CT and MR localizer transformation equations are correctly encoded into the OAS software. Further, it verifies that all target coordinate input and displays in OAS are accurate. The results from the OAS are compared to a phantom with targets of known position. As was previously reported for the OAS with CT images, the articulated mechanical Arm is accurate to a mean value of  $0.36 \pm 0.28$  mm (mean  $\pm$  std dev) when used to sample points over a clinically significant surgical volume. This accuracy is maintained over a period of extended operation.

## ***General Safety and Effectiveness Concerns***

The device labeling contains instructions for use. It includes indications for use, cautions, warnings and user quality assurance procedures. The training and installation sessions ensure that the user understands all aspects of the Operating Arm System: mechanical, computer, and software and its intended functionality. This information promotes safe and effective use of the device.