



January 24, 2025

ClearPoint Neuro, Inc.
Brennan Sullivan
Regulatory Affairs Manager
120 S. Sierra Ave., Suite 100
Solana Beach, California 92075

Re: K243657

Trade/Device Name: ClearPoint System (Software Version 3.0)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: November 26, 2024
Received: November 27, 2024

Dear Brennan Sullivan:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Adam D.
Pierce -S** Digitally signed by
Adam D. Pierce -S
Date: 2025.01.24
12:36:19 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
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Physical Medicine Devices
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Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K243657

Device Name
ClearPoint System (Software Version 3.0)

Indications for Use (Describe)

The ClearPoint System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within an operating room environment and in conjunction with MR and/or CT imaging. During planning, the system is intended to provide functionality for the automatic identification, labeling, visualization, and quantification of segmentable brain structures from a set of loaded MR images. The ClearPoint System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion including deep brain stimulation (DBS) (asleep or awake) lead placement. When used in an MRI environment, the system is intended for use only with 1.5 and 3.0 Tesla MRI scanners and MR Conditional implants and devices.

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
for the ClearPoint Neuro
ClearPoint 3.0 Software
(per 21CFR 807.87)**

1. SUBMITTER/510(K) HOLDER

ClearPoint Neuro, Inc.
6349 Paseo Del Lago
Carlsbad, CA 92011
Contact Person: Brennan Sullivan
Telephone: 617-678-1028

Date Prepared: January 24, 2025

2. DEVICE INFORMATION

Name of Device:	ClearPoint System 3.0 Software
Common or Usual Name:	ClearPoint System
Classification:	Neurological Stereotaxic Instrument, 21CFR 882.4560
Regulatory Class:	Class II
Product Code	HAW

3. PREDICATE DEVICES

- ClearPoint Software Version 2.2 K233243
- ClearPoint Software Version 2.1 K222519

4. DEVICE DESCRIPTION

The updated ClearPoint Software Version 3.0 introduces modifications to support a new clinical workflow using intraoperative CT imaging when compared to the previous ClearPoint Software Version 2.2 (K233243). The ClearPoint System described in this submission is essentially identical from a technological standpoint to the cleared predicate device described in K233243 (ClearPoint System version 2.2). As mentioned above, since the prior clearance, the company has implemented software features to enable usage of the ClearPoint System during CT-guided procedures, in addition to MR-guided procedures supported in the predicate device. The hardware components are unchanged from the device described in K233243 and minor changes were made to the indications for use.

The ClearPoint System is comprised of a workstation laptop with software, the SMARTGrid Planning Grid, the SMARTFrame Trajectory Frame, the SMARTFrame Accessory Kit and the SMARTFrame Thumbwheel Extension. The SMARTGrid and associated Marking Tool are designed to assist the physician to precisely position the entry hole as called out in the trajectory planning software. The SMARTFrame is an Adjustable Trajectory Frame (ATF) that provides the guidance and fixation for neurosurgical tools.

The image-visible fluids of the Targeting Cannula along with the fiducial markers in the base of the frame allows for trajectory feedback when the physician views the intraoperatively acquired images, makes changes and confirms with subsequent image acquisitions.

Optionally, the ClearPoint System can be used with any head fixation frame to immobilize the patient's head with respect to the scanner table. ClearPoint Neuro also supplies an optional head fixation frame that can be used with the ClearPoint System.

The ClearPoint Workstation includes the following:

1. ClearPoint Workstation Software (for trajectory planning and monitoring)
2. Laptop Computer

The hardware components of the current ClearPoint System are the SMARTFrame and Accessories. They are all single use devices that are provided sterile and include the following:

1. SMARTGrid Planning Grid (interacts with the software to determine the desired location of the burr hole)
 - a. Marking Grid
 - b. Marking Tool
2. SMARTFrame Pack (SMARTFrame or SMARTFrame XG)
 - a. SMARTFrame ("ATF") with Base
 - b. Centering Device and Wharen Centering Guide
 - c. Dock
 - d. Device Lock
 - e. Screwdriver
 - f. Roll Lock Screw and Washer
3. Rescue Screws (Extra Titanium Screws)
4. Thumbwheel Extension
5. Accessory Kit
 - a. Peel-away Sheath
 - b. Stylet
 - c. Lancet
 - d. Depth Stop
 - e. Ruler
6. Scalp Mount Base
7. Guide Tubes and Device Guide Packs (Guide Cannulas)

In addition, the ClearPoint System is used with the following separately cleared or Class I, 510(k) exempt products:

- SmartTip MRI Hand Drill and Drill Bit Kit
 - MRI Neuro Procedure Drape, with Marker Pen and Cover
-

- SmartFrame Fiducial

Each of the above packs is sold separately and is intended to be used with the ClearPoint System. Each of the components has been described in detail in previous submissions. The ClearPoint System described in this 510(k) is a modification to the company's cleared ClearPoint System (K233243).

5. INDICATIONS FOR USE

The ClearPoint System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within an operating room environment and in conjunction with MR and/or CT imaging. During planning, the system is intended to provide functionality for the automatic identification, labeling, visualization, and quantification of segmentable brain structures from a set of loaded MR images. The ClearPoint System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion including deep brain stimulation (DBS) (asleep or awake) lead placement. When used in an MRI environment, the system is intended for use only with 1.5 and 3.0 Tesla MRI scanners and MR Conditional implants and devices.

6. NON-CLINICAL TESTING

ClearPoint Neuro performed extensive Non-Clinical Verification Testing to evaluate the safety and performance of the software components of ClearPoint System (Software Version 3.0). The following software verification testing was performed:

- Automated Verification
- Integrated System Verification using Magnetic Resonance Imaging
- Regression Test Verification
- Manual Testing
- Accuracy Verification using Computed Tomography Imaging

The results of all testing met the acceptance criteria and demonstrated that the proposed ClearPoint System (Software Version 3.0) complies with all design specifications and performs as expected.

Accuracy testing was performed using an MRI scanner to confirm that modifications included in the ClearPoint System 3.0 did not cause any unexpected changes in the accuracy specifications of the software, with successful results. Additionally, accuracy testing was performed in a CT scanner to validate the CT-guided clinical workflow that is new to the ClearPoint 3.0 software and establish new ground-truth accuracy specifications. Table 1 outlines the demonstrated accuracy specifications of ClearPoint System using MRI guidance and is unchanged with respect to the predicate device. Table 2 outlines the demonstrated accuracy specifications of ClearPoint System with CT image-guidance.

Table 1: ClearPoint System Accuracy Specifications - MRI

Performance Validation	Positional Error (mm)			Angular Error (deg.)		
	Mean (X,Y,Z)	Std. Dev.	99% CI	Mean	Std. Dev.	99% CI
ClearPoint System	0.14	0.37	0.44	0.32°	0.17°	0.46°
	0.16	0.54	0.60			
	0.56	0.57	0.10			

Table 2: ClearPoint System Accuracy Specifications – CT

Positional Error (mm)			Trajectory Angle Error (Degrees)		
Mean	Standard Deviation	99% CI Upper Bound	Mean	Standard Deviation	99% CI Upper Bound
0.81	0.49	0.93	0.31	0.23	0.37

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

ClearPoint System (Version 3.0) is substantially equivalent to the previously cleared ClearPoint System (Version 2.2) (K233243) and the reference device StealthStation Cranial Software, v3.1.5 (K231976). The subject device's hardware is identical in design and technological characteristics to the predicate device. The differences between the proposed and predicate devices are modifications to the software to enable its use during CT-guided neurosurgical procedures.

Both the proposed and predicate ClearPoint Systems are intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures in conjunction with MR imaging. The primary technological differences between the subject ClearPoint 3.0 and ClearPoint 2.2 predicate device are the following:

- Introduction of a full set of software modifications to support a clinical workflow using intraoperative CT imaging
- Introduction of the ability to automatically segment ClearPoint System hardware components from CT images (i.e., marking grid, frame markers, targeting cannula, inserted device)
- Introduction of a new set of image fusion tool improvements
- Introduction a set of tools and features to improve the clinical workflow post device insertion
- Obsolescence of product features that have very limited usage clinically.
- Introduction of the ability to visualize adjustable frame tower and initial frame adjustments prior to frame mounting
- Minor user interface updates for continuous improvement and product rebranding

These modifications allow for enhanced functionality and compatibility of the ClearPoint System. These changes have been verified and validated and do not raise any different questions of safety or effectiveness and the subject device is substantially equivalent to the predicate.

A substantial equivalence chart comparing the similarities and differences between the ClearPoint System and its predicate devices is provided below.



Table 3: Side-by-side comparison of ClearPoint System (Software Version 3.0) with Predicate Devices

Characteristic	Proposed ClearPoint System (v3.0)	Primary Predicate ClearPoint System (v2.2) K233243	Secondary Predicate StealthStation Cranial Software K231976
Classification	21 CFR 882.4560	21 CFR 882.4560	21 CFR 882.4560
Product Code	HAW	HAW	HAW
Indications for Use	The ClearPoint System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within an operating room environment and in conjunction with MR and/or CT imaging. During planning, the system is intended to provide functionality for the automatic identification, labeling, visualization, and quantification of segmentable brain structures from a set of loaded MR images. The ClearPoint System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion including deep brain stimulation (DBS) (asleep or awake) lead placement. When used in an MRI environment, the system is intended for use only with 1.5 and 3.0 Tesla MRI scanners and MR Conditional implants and devices.	The ClearPoint System is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. During planning, the system is intended to provide functionality for the automatic identification, labeling, visualization and quantification of segmentable brain structures from a set of loaded MR images. The ClearPoint System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion including deep brain stimulation (DBS) lead placement. The System is intended for use only with 1.5 and 3.0 Tesla MRI scanners and MR conditional implants and devices.	The StealthStation System, with StealthStation Cranial software, is intended to aid in precisely locating anatomical structures in either open or percutaneous neurosurgical procedures. The system is indicated for any medical condition in which reference to a rigid anatomical structure can be identified relative to images of the anatomy. This can include, but is not limited to, the following cranial procedures (including stereotactic frame-based and stereotactic frame alternatives-based procedures): <ul style="list-style-type: none"> • Cranial biopsies (including stereotactic) • Deep brain stimulation (DBS) lead placement • Depth electrode placement • Tumor resections • Craniotomies/Craniectomies • Skull Base Procedures • Transsphenoidal Procedures • Thalamotomies/Pallidotomies • Pituitary Tumor Removal • CSF leak repair • Pediatric Ventricular Catheter Placement • General Ventricular Catheter Placement
Environment	MRI Suite and Operating Room environment	MRI Suite	MRI Suite and Operating Room environment
Imaging Modalities	Magnetic Resonance Imaging (MRI) Computed Tomography (CT)	Magnetic Resonance Imaging (MRI)	Computed Tomography (CT) Magnetic Resonance Imaging (MRI) Nuclear Medicine
SMARTGrid Pack		Planning Grid & Marking tool	NA

SMARTFrame Pack	SmartFrame XG, Skull Mount Base, Scalp Mount Base, Bone Screws, Stand-Off Pins, Screwdriver, Centering Tool, Wharen Centering Guide (packaged and sold separately), Dock and Lock, Roll Lock Screw with Washer, Rescue Screws (packaged separately)	SmartFrame XG, Skull Mount Base, Scalp Mount Base, Bone Screws, Stand-Off Pins, Screwdriver, Centering Tool, Wharen Centering Guide (packaged and sold separately), Dock and Lock, Roll Lock Screw with Washer, Rescue Screws (packaged separately)	NA
Hand Controller	Thumbwheel Extension (Light Hand Controller)	Thumbwheel Extension (Light Hand Controller)	NA
Accessory pack	Peel away sheath, Lancet, Stylet, Depth stop, ruler	Peel away sheath, Lancet, Stylet, Depth stop, ruler	NA
Drill Guides	4.5 mm , 5.4 mm, & 6.0 mm	4.5 mm, 5.4 mm, & 6.0 mm	NA
Targeting Cannula	ID 0.0825" Materials: Ultem and PEEK	ID 0.0825" Materials: Ultem and PEEK	NA
Guide Tube Instruments Compatible (mm)	1.24 - 1.80	1.24 - 1.80	NA
Device Guide Instrument Compatibility (mm)	2.1 - 5.4	2.1 - 5.4	NA
Targeting Accuracy	± 1.5 mm @ ≤125mm	± 1.5 mm @ ≤125mm	Under representative worst-case configuration, the StealthStation® System with StealthStation Cranial Software, has demonstrated performance in 3D positional accuracy with a mean error ≤ 2.0 mm and in trajectory angle accuracy with a mean error ≤ 2.0 degrees
Packaging	Sterile, Sealed Tray/Pouch	Sterile, Sealed Tray/Pouch	NA
Software	Version 3.0	Version 2.2	3.1.5
Operating System	Microsoft Windows Operating System	Microsoft Windows Operating System	Microsoft Windows Operating System
Programming Languages	Visual C# Visual C++	Visual C# Visual C++	C++
Visualization Features	<ul style="list-style-type: none"> Display of MR images in reformatted (MPR) and 3D views. Cross-reference line display with current plane intersection correlation point indication. 	<ul style="list-style-type: none"> Display of MR images in reformatted (MPR) and 3D views. Cross-reference line display with current plane intersection correlation point indication. 	Ultrasound Video In, Ultrasound Overlay, 3D, 2D Anatomic Orthogonal, Trajectory 1 and 2, Target Guidance, Trajectory Guidance, Probes Eye, Look Ahead, Microscope Injection, Video Input

	<ul style="list-style-type: none"> • Display of 2D annotations and overlays on rendered images. • General interactive tools (e.g., pan, zoom, width/level, etc.). • 3D display of hardware models of the SMARTGrid and SMARTFrame along with volumetric image sets. • Ability to display CT images in reformatted (MPR) and 3D views. 	<ul style="list-style-type: none"> • Display of 2D annotations and overlays on rendered images. • General interactive tools (e.g., pan, zoom, width/level, etc.). • 3D display of hardware models of the SMARTGrid and SMARTFrame along with volumetric image sets. • Ability to display CT images in reformatted (MPR) and 3D views. 	
DICOM Features	<ul style="list-style-type: none"> • Retrieval of images from MR/CT scanner through network (TCP/IP) • Browse/load images from media/local storage • Configuration and testing of image transfer from scanner to workstation • Load enhanced/compressed DICOM images • Load color DICOM images that are stored with RGB Photometric Interpretation • Single image DICOM Export (local) 	<ul style="list-style-type: none"> • Retrieval of images from MR scanner through network (TCP/IP) • Browse/load images from media/local storage • Configuration and testing of image transfer from scanner to workstation • Load enhanced/compressed DICOM images • Load color DICOM images that are stored with RGB Photometric Interpretation 	Network Connectivity CD, DVD, USB DICOM Import DICOM Export
Image Fusion/Registration	<ul style="list-style-type: none"> • Ability to automatically register/fuse MR-to-MR and MR-to-CT images acquired in different frames of reference • Ability to seed automatic registration/fusion based on an initial input transform • Slider control used to set the relative weight of the two blended image volumes • Tools for reviewing the accuracy of registration and manual override capabilities 	<ul style="list-style-type: none"> • Ability to automatically register/fuse MR-to-MR and MR-to-CT images acquired in different frames of reference • Ability to seed automatic registration/fusion based on an initial input transform • Slider control used to set the relative weight of the two blended image volumes • Tools for reviewing the accuracy of registration and manual override capabilities 	Exam-to-Exam Registration: Identity Merge Registration, Manual Merge Registration and Automatic Merge Registration. Patient Registration: PointMerge registration, Tracer registration, Touch-N-Go registration, StealthAiR registration, O-arm registration, Stereotactic Localizer Registration and StarFix Bone Anchor Registration

	<ul style="list-style-type: none"> Spherical region-of-interest tools to define regions to consider for automatic registration/fusion 		
Localization Technology	<ul style="list-style-type: none"> Magnetic Resonance Imaging (MRI) Computed Tomography (CT) 	<ul style="list-style-type: none"> Magnetic Resonance Imaging (MRI) 	<ul style="list-style-type: none"> Optical (infra-red) Electromagnetic Mechanical based stereotactic
Planning Features	<ul style="list-style-type: none"> Ability to create one or more trajectory paths (entry and target selection) Advanced visualization using multiple viewing layouts and viewing planes Viewport crosshair correlation capabilities Display graphic annotations representing trajectory paths Display trajectory point distances and trajectory depth measurements Compare two selected image series side-by-side Display segmented brain regions overlaid on loaded image sets. Visualize 3D frame mount positions and frame tower angulation 	<ul style="list-style-type: none"> Ability to create one or more trajectory paths (entry and target selection) Advanced visualization using multiple viewing layouts and viewing planes Viewport crosshair correlation capabilities Display graphic annotations representing trajectory paths Display trajectory point distances and trajectory depth measurements. Compare two selected image series side-by-side Display segmented brain regions overlaid on loaded image sets. Visualize 3D frame mount positions 	Plan Entry and Target Selection 3D Model Building Advanced Visualization Create Patient Based Anatomical Coordinate Space Stereotactic Frame Settings Brain Atlas: Schaltenbrand-Wahren Atlas with Talairach Grid StarFix Designer Annotations
Help/Troubleshooting Tools	<ul style="list-style-type: none"> User Manual available on workstation. Status message indications/warnings with ability to show specific troubleshooting instructions. User visible software log so that previously displayed status messages (and troubleshooting instructions) can be re-visited throughout the course of a procedure. 	<ul style="list-style-type: none"> User Manual available on workstation. Status message indications/warnings with ability to show specific troubleshooting instructions. User visible software log so that previously displayed status messages (and troubleshooting instructions) can be re-visited throughout the course of a procedure. 	N/A

Image Segmentation Algorithms	<ul style="list-style-type: none"> • Algorithm to automatically identify anterior commissure (AC) and posterior commissure (PC) locations within the brain. • Algorithms to automatically locate and identify marking grid, targeting frame components, cannula, and device tip from both MR and CT image sets. • Automated measurement of brain tissue volumes and structures from MR images. • Automatic segmentation and quantification of brain structures using proprietary shape-constrained segmentation algorithms from MR images. 	<ul style="list-style-type: none"> • Algorithm to automatically identify anterior commissure (AC) and posterior commissure (PC) locations within the brain. • Algorithms to automatically locate and identify marking grid, targeting frame components, cannula, and device tip from MR image sets. • Automated measurement of brain tissue volumes and structures from MR images. • Automatic segmentation and quantification of brain structures using proprietary shape-constrained segmentation algorithms from MR images. 	N/A
MRI Scan Plane Parameters	Geometric computations to display position and orientation of prescribed scan plane parameters for Siemens, Philips, and GE MR scanner manufacturers.	Geometric computations to display position and orientation of prescribed scan plane parameters for Siemens, Philips, and GE MR scanner manufacturers.	N/A
Hardware Adjustment Computations	Computations used to indicate required frame adjustments needed to adjust targeting cannula to desired trajectory.	Computations used to indicate required frame adjustments needed to adjust targeting cannula to desired trajectory.	N/A
Low-Level Math Library	Low-level math utilities used for geometric computations.	Low-level math utilities used for geometric computations.	N/A
Workflow	Support for pre-surgical and intraoperative surgical workflows using MR and CT image guidance	Support for pre-surgical and intraoperative surgical workflow using MR image guidance	Support for Pre-surgical and intraoperative surgical workflows using optical / electromagnetic localization technology.