November 27, 2023

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

Re: K233243
Trade/Device Name: ClearPoint System (Software Version 2.2)
Regulation Number: 21 CFR 882.4560
Regulation Name: Neurological Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW, QIH
Dated: September 28, 2023
Received: September 28, 2023

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.

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: 2023.11.27 13:25:33 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233243

Device Name

ClearPoint System (Software Version 2.2)

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 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.

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

A. Device Information

Category	**Comments**
Sponsor:	ClearPoint Neuro, Inc. 6349 Paseo Del Lago Carlsbad, CA 92011
Correspondent Contact Information:	Brennan Sullivan 120 S. Sierra Ave. Solana Beach, CA 92075 617-678-1028 bsullivan@clearpointneuro.com
Device Common Name:	Neurological Stereotactic Instrument
Device Regulation & Name:	Neurological Stereotaxic Instrument, 21CFR 882.4560
Classification & Product Code: 510(k) Number:	Class II HAW K233243
Device Proprietary Name:	ClearPoint System Software Version 2.2

Primary Predicate Device Information:

Predicate Device:	ClearPoint System (v2.1)
Predicate Device Manufacturer:	ClearPoint Neuro, Inc.
Predicate Device Common Name:	Neurological Stereotactic Instrument
Predicate Device Premarket Notification #	K222519
Predicate Device Classification & Name	Neurological Stereotaxic Instrument, 21CFR 882.4560
Predicate Device Classification & Product Code:	Class II HAW

Additional Predicate Device Information:

Predicate Device:	ClearPoint Maestro Brain Model
Predicate Device Manufacturer:	ClearPoint Neuro, Inc.
Predicate Device Common Name:	System, Image Processing, Radiological
Predicate Device Premarket Notification #	K213645
Predicate Device Classification & Name	Medical Imaging Management and Processing System, 21CFR 892.2050
Predicate Device Classification & Product Code:	Class II QIH

B. Date Summary Prepared

November 27, 2023

C. Description of Device

The updated ClearPoint Software Version 2.2 integrates the ClearPoint Neuro Maestro Brain Model software (K213645) into the previous ClearPoint Software Version 2.1 (K222519). The ClearPoint Maestro™ Brain Model product is a stand-alone software application for automatic labeling, visualization, and quantification of segmentable brain structures from a set of MRI images and has been incorporated into the ClearPoint System software. The ClearPoint System described in this submission is essentially identical from a technological standpoint to the cleared predicate device described in K222519 (ClearPoint System). As mentioned above, since the prior clearance, the company has integrated the Maestro Brain Model into the software of the predicate device. Specifically, the company has released an updated version of software 2.1, which was part of the last clearance, and has now been upgraded to software 2.2.

The ClearPoint System is comprised of a workstation laptop with software, the SMARTGrid™ MRI-Guided Planning Grid, the SMARTFrame™ MRI-Guided 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 MRI visible fluids of the Targeting Cannula along with the fiducial markers in the base of the frame allow for trajectory feedback when the physician views the MRI images, makes changes and confirms with subsequent MR images.

The ClearPoint System can be used with any MRI-compatible head fixation frame to immobilize the patient's head with respect to the scanner table, as well as with any imaging coil(s) (supplied by scanner manufacturers) that meet the physician's desired imaging quality. 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 MRI 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 (2 different diameters)
   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 MR Fiducial

Each of the above packs is sold separately and is intended to be used with the ClearPoint Workstation. 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 (K222519).

D. 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 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.

E. Comparison of Technological Characteristics

ClearPoint System (Software Version 2.2) is substantially equivalent to the previously cleared ClearPoint System (Software Version 2.1) (K222519). The subject device's hardware is identical in design and technological characteristics. The differences between the proposed and predicate devices are modifications to the software to include additional functionality that has been previously cleared in the ClearPoint Neuro Maestro 510(k) (K213645).

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 within the MRI environment and in conjunction with MR imaging. Specifically, the following modifications have been made in ClearPoint Software Version 2.2:

- Integration of Maestro Brain Model functionalities:
  - Optional automatic segmentation of anatomical cortical and subcortical structures at user request.
  - Visualization of brain structure segmentations overlaid semi-transparently onto 2D views of any registered scan.
  - Visualization of brain structure segmentations as polygon models embedded in the scene in 3D views of any registered scan.
  - Computation of volume measurements corresponding to each segmented brain structure.
  - Workflow for verifying the brain structure segmentation results.
  - Summarizing brain structure volume measurements in a clinical procedure report.
- Full compatibility with Windows 11 Operating System
- Ability to load color DICOM images stored with RGB Photometric Interpretation.
- Capabilities to display images in either Neurological or Radiological viewing orientation within the application viewports according to user preference.
- Ability to express anatomical coordinate values and associated landmarks relative to an origin point at either the mid-commissure (MCP) point or posterior commissure (PC) point.
- A new set of measurement graphic tool improvements
- Some workflow-specific optimizations which provide more efficient and generalized software workflow.
- Translating the software user interface to support nine additional languages.

These modifications were made as part of continuous product improvement efforts. Specifically, the modifications allow for enhanced functionality and compatibility of the ClearPoint System. The inclusion of the Maestro Brain Model functionalities incorporates the functions of a standalone software product that has previously been subject of a cleared 510(k), (K213645). These changes have been verified and validated and do not raise any different questions of safety or effectiveness.

- Optional automatic segmentation of anatomical cortical and subcortical structures at user request.
- Visualization of brain structure segmentations overlaid semi-transparently onto 2D views of any registered scan.
- Visualization of brain structure segmentations as polygon models embedded in the scene in 3D views of any registered scan.
- Computation of volume measurements corresponding to each segmented brain structure.
- Workflow for verifying the brain structure segmentation results.
- Summarizing brain structure volume measurements in a clinical procedure report.

These changes to the ClearPoint System 2.1 Software have been validated and do not impact the safety or efficacy of the device. A substantial equivalence chart comparing the similarities and differences between the ClearPoint System and its predicate device is provided below. The primary differences between the proposed ClearPoint System 2.2 and the predicate are the incorporation of the functionality of an additional 510(k)-cleared device and additional minor differences in the technological characteristics between the Proposed device and the predicate do not raise different questions of safety or efficacy.

Table 1: Side-by-side comparison of ClearPoint System (Software Version 2.2) with Predicate Device

Characteristic	Proposed ClearPoint System (v2.2)	Primary Predicate ClearPoint System (v2.1) K222519	Reference Predicate ClearPoint Maestro K213645
Classification	21 CFR 882.4560	21 CFR 882.4560	21 CFR 892.2050
Product Code	HAW	HAW	QIH
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 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	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. 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.	ClearPoint Maestro™ Brain Model is intended for automatic labeling, visualization, volumetric and shape quantification of segmentable brain structures from a set of MR images. This software is intended to automate the process of identifying, labelling, and quantifying the volume and shape of brain structures visible in MRI images.

	3.0 Tesla MRI scanners and MR conditional implants and devices.		
Environment	MRI Suite	MRI Suite	MRI Suite
SMARTGrid Pack	MRI Planning Grid & Marking tool	MRI Planning Grid & Marking tool	NA
SMARTFrame Pack	SmartFrame XG, 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, 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 & 6.0 mm	4.5 mm & 6.0 mm	NA
Targeting Cannula ID	0.0825”	0.0825”	NA
Targeting Cannula Material	Ultem and PEEK	Ultem and PEEK	NA
Guide Tube/Device Guide/Drill Guide ID	Drill Guide ID: 4.5 mm (included in SmartFrame Pack) Drill Guide Tube ID: 3.4 mm (included in SmartFrame Pack) Guide Tube ID: 3.2 mm Guide Tube ID: 2.5 mm Guide Tube ID: 2.1 mm Guide Tube ID: 1.7 mm	Drill Guide ID: 4.5 mm (included in SmartFrame Pack) Drill Guide Tube ID: 3.4 mm (included in SmartFrame Pack) Guide Tube ID: 3.2 mm Guide Tube ID: 2.5 mm Guide Tube ID: 2.1 mm Guide Tube ID: 1.7 mm	NA
Targeting Accuracy	± 1.5 mm @ ≤125mm	± 1.5 mm @ ≤125mm	NA
Packaging	Sterile, Sealed Tray, Inside Sterile Tyvek Pouch (Wharen Centering Guide and Drill and Device Guides are Sterile in a double Tyvek Pouch Without a Tray; Wharen Centering Guide Packaging includes PVC)	Sterile, Sealed Tray, Inside Sterile Tyvek Pouch (Wharen Centering Guide and Drill and Device Guides are Sterile in a double Tyvek Pouch Without a Tray; Wharen Centering Guide Packaging includes PVC)	NA
Software	Version 2.2	Version 2.1	Version 1.0
Operating System	Windows 10, Windows 11	Windows 10	Windows 10
Programming Languages	Visual C# Visual C++	Visual C# Visual C++	C++ Qt
Visualization Software Toolkit	Fovia HDVR®	Fovia HDVR®	Visualization Toolkit (VTK)
Visualization Features	• Display of MR and CT images in reformatted (MPR) and 3D views. • Cross-reference line display with current plane intersection correlation point indication	• Display of MR and CT images in reformatted (MPR) and 3D views. • Cross-reference line display with current plane intersection correlation point indication	• Display of MR images in reformatted (MPR) and 3D views. • Cross-reference line display with current plane intersection

	• 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	• 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	correlation point indication • Display of 2D annotations and overlays on rendered images • General interactive tools (e.g., pan, zoom, width/level, etc.)
DICOM Toolkit	MergeCOM-3 Dicom Toolkit®	MergeCOM-3 Dicom Toolkit®	Insight Toolkit (ITK)
DICOM Features	• Transfer 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	• Transfer 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	• Browse/load images from media/local storage • Load enhanced / compressed DICOM images • Export bitmask of segmented brain structures in DICOM format
Image Registration Framework	Insight Toolkit (ITK)	Insight Toolkit (ITK)	NA
Image Fusion/Registration	• 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	• 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	NA
Volume of Interest Definition	• Ability to define and visualize 3D structures within a loaded image set • Tools for defining 3D volumes of interest manually • Display and computation of volume interest measurements (e.g., total volume, volume overlap)	• Ability to define and visualize 3D structures within a loaded image set • Tools for defining 3D volumes of interest manually • Display and computation of volume interest measurements (e.g., total volume, volume overlap)	NA

Image Segmentation Algorithm	• Algorithm to automatically identify anterior commissure (AC) and posterior commissure (PC) locations within the brain. This algorithm has the same implementation as in the predicate device. • Algorithms to automatically locate and identify marking grid, targeting frame components, cannula, and device tip. These algorithms have the same implementation as in the predicate device. • Automated measurement of brain tissue volumes and structures. This algorithm has the same implementation as the predicate device. • Automatic segmentation and quantification of brain structures using proprietary shape-constrained segmentation algorithms. These algorithms have the same implementation as the predicate device.	• 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.	• Automated measurement of brain tissue volumes and structures. • Automatic segmentation and quantification of brain structures using proprietary shape-constrained segmentation algorithms.
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.	NA
Hardware Adjustment Computations	Computations used to indicate required frame adjustments needed to adjust cannula to desired trajectory. These computations are the same as in the predicate device	Computations used to indicate required frame adjustments needed to adjust cannula to desired trajectory	NA
Low-Level Math Library	Low-level math utilities used for geometric computations. These utilities are the same as in the predicate device	Low-level math utilities used for geometric computations.	Identical
Workflow	Optional workflow for initiating an automatic segmentation of brain structures from a loaded MR scan and visualizing / verifying the results.	No ability to perform automatic segmentation of brain structures from a loaded MR scan.	Optional workflow for initiating an automatic segmentation of brain structures from a loaded MR scan and

			visualizing/verifying the results.
	Visualize segmented brain structures as overlays on any scan loaded into the application	No ability to visualize segmented brain structures	Visualize segmented brain structures as overlays on a reference scan loaded into the application
	Output volumetric measurements corresponding to each segmented brain structure	No ability to present volume measurements for segmented brain structures	Output volumetric measurements corresponding to each segmented brain structure

F. Summary of Supporting Data

ClearPoint Neuro performed extensive Non-Clinical Verification Testing to evaluate the safety and performance of the software components of ClearPoint System (Software Version 2.2). The following software verification testing was performed:

- Automated Verification
- Integrated System Verification
- Localization Verification
- Regression Test Verification
- Manual Testing

The results of all testing met the acceptance criteria and demonstrated that the proposed ClearPoint System (Software Version 2.2) complies with all design specifications and performs as expected.

G. Discussion of Performance Data

Accuracy testing was performed to confirm that modifications included in ClearPoint System 2.2 did not cause any unexpected changes in the accuracy specifications of the software, with successful results. Table 2 outlines the demonstrated accuracy specifications of ClearPoint System.

Table 2: ClearPoint System Accuracy Specifications

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

H. Conclusion

The subject ClearPoint System (Version 2.2) and the predicate ClearPoint System (Version 2.1) have similar indications for use, technological characteristics, and principles of operation. In addition, the minor differences in the ClearPoint Version 2.2 Software do not alter the fundamental clinical purpose or present different questions of safety or effectiveness as compared to the ClearPoint System 2.1 predicate. Thus, the ClearPoint System Version 2.2 Software is substantially equivalent to the ClearPoint System 2.1 (K222519).