K100836
P. 1 of 7

JUN 1 3 2010

510(k) SUMMARY
SURGIVISION, INC.'S CLEARPOINT SYSTEM

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: June 16, 2010

Name of Device and Name/Address of Sponsor

ClearPoint System™

SurgiVision, Inc.
5 Musick
Irvine, CA 92618

Common or Usual Name

Neurological Stereotaxic Instrument

Classification

21 C.F.R. §882.4560

Predicate Devices

Image-Guided Neurologics, Inc. Navigus II MR Trajectory Guide (K012719)
Philips Medical Systems software package for the Achieva, Intera and Panorama MR Systems (K063559)

Intended Use / 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. The ClearPoint System is intended as an integral part of procedures that have traditionally

K100836
P. 2 of 7

used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion. The System is intended for use only with 1.5 Tesla MRI scanners.

Technological Characteristics

The ClearPoint System is comprised of a workstation laptop with workstation software, the SMARTGrid™ MRI-Guided Planning Grid, the SMARTFrame™ MRI-Guided Trajectory Frame, the SMARTFrame Accessory Kit, the SMARTFrame Handcontroller, and the MR Neuro Procedure Drape. The MR Neuro Procedure Drape was cleared for market via a separate 510(k) notice (K091343).

The SMARTGrid and associated Marking Tool are designed to assist the physician to precisely position the burr hole as called out in the trajectory planning software. The SMARTFrame is an adjustable trajectory frame 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 allows for trajectory feedback when the physician views the MR 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) that meet the physician's desired imaging quality.

See the table below for a detailed comparison of the technological characteristics of the ClearPoint System and those of the predicate devices.

K100836
P-3 of 7

SURGIVISION, INC.'S CLEARPOINT SYSTEM - SUBSTANTIAL EQUIVALENCE COMPARISON

Characteristic	SurgiVision ClearPoint System	Navigus II MR (K012719)	Software package cleared with the Achieva, Intera and Panorama MR Systems (K063559)
Product Code		HAW	LNH
Classification Regulation	21 CFR 882.4560 Neurological Stereotaxic Instrument	21 CFR 882.4560 Neurological Stereotaxic Instrument	21 CFR 892.1000 Magnetic Resonance Diagnostic Device
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. 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. The System is intended for use only with 1.5 Tesla MRI scanners.	The NAVIGUS II MR Trajectory Guide is intended to provide stereotactic guidance for the placement and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. The Trajectory Guide is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode introduction. This device will provide accurate delivery of devices or instruments to target sites 3mm and larger.	The ACHIEVA, INTERA and PANORAMA 1.0T Release 2.5-series are magnetic resonance diagnostic devices that produce cross-sectional images, spectroscopy images and/or spectra in any orientation of the internal structure of the whole body. These images when interpreted by a trained physician, yield information that may assist in diagnosis. In addition the Achieva, Intera and Panorama 1.0T devices provide capabilities to perform interventional procedures in the head, body and extremities, which may be facilitated by MR techniques, such as real time imaging. Such procedures must be performed with MR compatible instrumentation as selected and evaluated by the clinical user.
Brief Device Description	System includes planning and navigation software (ClearPoint Workstation, MRI only) designed to work with hardware, the ClearPoint SMARTFrame and accessories. Overall System is not specific to any particular neurosurgical procedure.	The NAVIGUS II MR Trajectory Guide is a stereotactic frame that is intended to be used in conjunction with MR scanner software. Device is not specific to any particular neurosurgical procedure.	The update to the Philips System software includes the following features. • Rapid Locus is a post-processing software package intended for use to support the use of interventional coils and MR stereo-tactic localization devices to perform MR-guided interventional procedures. Using information from MR images regarding the coordinates of a user-specified region of interest, and fiducial coordinates, the software provides an automatic calculation of the location and depth of the

K100836
P-4 of 7

Characteristic	SurgiVision ClearPoint System	Navigus II MR (K012719)	Software package cleared with the Achieva, Intera and Panorama MR Systems (K063559)
			targeted region of interest, such as a lesion or suspected lesion. • The Achieva, Intera and Panorama 1.0T systems can be used for imaging during interventional procedures when performed with MR-compatible devices such as in-room display and MR-safe biopsy needles.
Principal Operator	Neurosurgeon / MRI Technician	Neurosurgeon	Neurosurgeon / MRI Technician
Use Location	MRI Suite	MRI Suite	MRI Suite
Operating Principle	Stereotaxic guiding and fixation device, planning software	Stereotaxic guiding & fixation device	Can be used for planning and implementation of neuro-interventional procedures in conjunction with stereotactic frames, such as the Navigus II MR
"Frameless" stereotaxy	Yes	Yes	N/A
MRI Compatible?	Yes	Yes	N/A
Software Facilitates Placement and Trajectory of Surgical Devices	Yes	N/A	Yes
Software Features	Software features include: • pan • zoom (also: zoom to point, zoom to region, zoom all viewports) • window width/level adjustment • greylevel invert (negative image) • measure lines • viewport resize • viewport maximize / restore (toggle between current layout and 1x1 layout of selected viewport) • viewport drag (drag from one viewport to another to switch contents) • reset • show/hide annotations	N/A	Software features include: • pan • zoom (also: zoom to point, zoom to region, zoom all viewports) • window width/level adjustment • greylevel invert (negative image) • measure lines • viewport resize • viewport maximize / restore (toggle between current layout and 1x1 layout of selected viewport) • viewport drag (drag from one viewport to another to switch contents) • reset • show/hide annotations

K100936
P. 5 of 7

Characteristic	SurgiVision ClearPoint System	Navigus II MR (K012719)	Software package cleared with the Achieva, Intera and Panorama MR Systems (K063559)
	• crosshair controls – toggle show/hide		• crosshair controls – toggle show/hide
Hardware Facilitates Trajectory and Temporary Fixation of Neurosurgical Devices	Yes	Yes	N/A
Materials (body contacting)	Polymer Base with titanium screws into skull	Polymer Base with titanium screws into skull	N/A
Range of motion	+/- 26 degrees roll, +/-33 degrees pitch	25 degrees angular, 360 degrees rotation	N/A
Burr Hole Size	14mm	14mm	N/A
Bilateral option	Yes	Yes	N/A
Fiducial markers	Yes	No	N/A
Multi-lumen spacing	2.5 degrees variable	3mm fixed	N/A
Targeting lumen integral with frame	Yes	No	N/A
Remote frame and targeting control	Yes	No	N/A
Bone screws	3	3	N/A
Optional screw sites	Yes	Yes	N/A
Single Use	Yes	Yes	N/A
Sterilized	Yes	Yes	N/A
Devices supplied by Mfr in addition to the head mount	Marking Grid, Sheath, Stylet, Multiple diameter Guide Tubes, (2) Stop, Dock, Depth Stop, Hand Controller	MultiLumen Insert, Bridge (Centered & Offset), Fluid Stem, Titanium Stylet, Depth Stop, 3 Peel Away Introducer Sheath (1.5mm I.D.), Multiple diameter Guide Tubes	N/A

K100836
p. 6 of 7

Consensus Standards

The ClearPoint System complies with the following recognized consensus standards:

- NEMA PS 3.1 - 3.18 (2008) Digital Imaging and Communications in Medicine (DICOM) Set.
- AAMI/ANSI/ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing.
- ANSI/AAMI/ISO 1135-1 Sterilization of health care - products - Ethylene oxide - Part 1: Requirements for development, validation, and routine control of sterilization process for medical devices.

Performance Data

SurgiVision has conducted software validation testing, as well as accuracy and safety testing of the ClearPoint System in multiple models and settings. In all instances, the device functioned as intended and targeting accuracy observed was as expected. This testing is described in detail below.

ClearPoint System Accuracy Testing

MRI Test Device Accuracy Testing

This study was intended to demonstrate that a known pre-determined target in a phantom can be localized by the distal tip of a Test Device representative of the devices to be used with the ClearPoint System. The system software went through all procedural steps during this testing with the exception of the Marking Grid / Burr Hole location. This study demonstrated that the SMARTFrame can deliver a simulated device to the same X, Y, and Z coordinates as the Stylet/Sheath, and can deliver a simulated device to the projected X, Y, and Z coordinates without Stylet/Sheath confirmation. Finally, testing with actual medical devices (instead of simulated devices) had the same results.

System Accuracy Comparison in a Skull Phantom - Navigus II MR vs. ClearPoint System

The goal of this comparison testing was to obtain accuracy results for the ClearPoint System using a skull phantom, and to compare those results with data previously obtained for the predicate Navigus II MR (also known as the "NeXframe MR") device using the same model system. The system software went through all steps during this testing with the exception of the Marking Grid / Burr Hole location.

It was concluded that the ClearPoint System is at least as accurate as the NeXframe MR (used in conjunction with software on a cleared MRI scanner) in terms of radial error and depth error when placing a device at a target site in a simulated head/brain phantom.

System Accuracy Comparison in a Cadaver - Navigus II MR vs. ClearPoint System

A cadaver study was performed to compare the Navigus II MR ("NeXframe MR"), used in conjunction with software on a cleared MRI scanner, and the ClearPoint System for work flow performance and accuracy. The objective of the study was to perform procedures using the NeXframe MR and the ClearPoint System to access targets in a cadaver head. This testing demonstrated that the ClearPoint System was at least comparable to the NeXframe MR (used in conjunction with software on a cleared MRI scanner) in terms of both accuracy and user ratings on a variety of procedure-related assessments.

Conclusions

These test results demonstrate that the targeting accuracy of the ClearPoint System is as good as the Navigus II MR, when used in conjunction with MRI scanner software. The results support the safe and effective use of the ClearPoint System to guide a device to a brain target with an error less than 1.5mm.

ClearPoint System Safety Testing

Relevant components of the ClearPoint System were evaluated for interactions with the electromagnetic fields in an MRI suite. Specifically, the following interactions of the device components were evaluated: (1) image distortion; (2) force and torque; and (3) RF heating. With regard to image distortion, force and RF heating, the company conducted verification testing to ensure that the subject device components did not interfere with MR images and confirm their safety when used in conjunction with a 1.5T MRI scanner.

The company concluded that the ClearPoint System is MRI Conditional as defined by ASTM F2503. The analysis and measurements performed by the company demonstrated that the presence of the ClearPoint System components do not expose a patient to added risk from the electromagnetic fields in a 1.5T MRI system.

Substantial Equivalence

The ClearPoint System is as safe and effective as the Navigus II MR Trajectory Guide used in conjunction with MRI scanner software, such as the software package cleared with the Philips Medical Systems' Achieva, Intera and Panorama MR Systems. The ClearPoint System has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the ClearPoint System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the ClearPoint System is as safe and effective as the predicate devices. Thus, the ClearPoint System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Surgivision, Inc.
c/o John J. Smith, M.D., J.D.
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

JUN 16 2010

Re: K100836
Trade/Device Name: Clearpoint System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: ORR, LNH
Dated: March 23, 2010
Received: March 24, 2010

Dear Mr. Smith:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K100836

Device Name: SurgiVision, Inc. ClearPoint System™

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. 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. The System is intended for use only with 1.5 Tesla MRI scanners.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K100836