K111073

510(k) Summary

JUN 2 2 2011

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the SurgiVision ClearPoint System 3T.

1. **Company Making the Submission:**

Name of Owner:	**SurgiVision, Inc.**
Address:	**5 Musick** **Irvine, CA 92618**
Telephone:	**949-900-6833**
Fax:	**949-900-6834**
Contact:	**Edward Waddell**
E-mail:	**ewaddell@surgivision.com**

2. **Device Name:**

Common Name:	Neurological Stereotaxic Instrument
Proprietary Name:	ClearPoint System 3T
Classification:	II
Regulation Number:	21 CFR 882.4560
Product Code:	LNH, ORR

3. **Predicate Device:**
ClearPoint System, ruled substantially equivalent K100836 on June 16, 2010.

4. **Intended Use Statement:**
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 and 3.0 Tesla MRI scanners.

5. **Description of Device:**
The hardware and software components of the SurgiVision ClearPoint System

3T are identical to the predicate device. The sole purpose of this 510(k) application is to expand the indications for the ClearPoint System to 3.0 Tesla MRI scanners. The ClearPoint System 3T is intended to provide trajectory planning, guidance and fixation of neurosurgical tools during minimally invasive stereotactic surgical procedures in the brain conducted in the MR suite. The System itself provides no therapeutic or diagnostic functionality.

The ClearPoint Stereotactic System is comprised of two separate device groups, a hardware and a software group. The software group is known as the ClearPoint Workstation. It includes the following:

- ClearPoint Workstation Software (for trajectory planning and monitoring)
- Laptop Computer

The hardware device group under the ClearPoint Stereotactic System umbrella is known as the SmartFrame and Accessories.

6. Summary of the Technological Characteristics of the Device Compared to the Predicate Device

	SurgiVision ClearPoint System 3T	**Predicate Device: ClearPoint System K100836**
Classification	21 CFR 882.4560	21 CFR 882.4560
Product Code	LNH, ORR	LNH, ORR
Intended 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 and 3.0 Tesla MRI scanners.	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 in 1.5 Tesla MRI scanners.

	SurgiVision ClearPoint System 3T	**Predicate Device: ClearPoint System K100836**
Software Version	ClearPoint 1.1	ClearPoint 1.1
Compatibility with environment and other devices	1.5/3T MRI environment	1.5T MRI environment
System Accuracy	Equivalent to ClearPoint System	±1.5mm

7. Testing:

Testing to applicable standards has been completed with acceptable outcomes. The following bench testing has been performed:

Testing addressed force, torque, heating, image artifacts, B_0 and accuracy testing within the 3T environment, using ClearPoint 1.1 software and accessories, ruled substantially equivalent within K100836. These tests demonstrated that the ClearPoint System 3T functions as intended and is substantially equivalent to the legally marketed predicate ClearPoint System.

Non-clinical testing demonstrated the ClearPoint SmartFrame and Accessories as MRI Conditional.

8. Rx or OTC:

The SurgiVision ClearPoint System 3T is an Rx prescription device per 21 CFR Part 801, Subpart D.

9. Substantial Equivalence:

The SurgiVision ClearPoint System 3T is as safe and effective as the predicate ClearPoint System. The ClearPoint System 3T has the same intended uses and essentially identical indications, technological characteristics, and principles of operation as its predicate device. Performance data demonstrate that the ClearPoint system 3T is as safe and effective as the predicate ClearPoint System.

SurgiVision, Inc.

Edward Waddell

Edward Waddell
Director of Regulatory Affairs

Date: Jan 17, 2011

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 Mr. Edward Waddell
Director, Regulatory
5 Musick
Irvine, CA 92618

JUN 2 2 2011

Re: K111073
Trade/Device Name: ClearPoint System 3T
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: ORR, LNH
Dated: April 15, 2011
Received: April 18, 2011

Dear Mr. Waddell:

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.

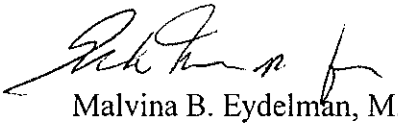
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

Indications for Use Statement

510(k) Number (if known): K111073

Device Name: SurgiVision, Inc. ClearPoint System™ 3T

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 and 3.0 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 IF NEEDED)

Con 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 K111073