K102101

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the SurgiVision MR Compatible Ventricular Cannula.

1. Company Making the Submission:

JAN 2 6 2011

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

2. Device Name:

Common Name:	Ventricular Cannula
Proprietary Name:	MR Compatible Ventricular Cannula
Classification:	Class I
Regulation Number:	882.4060
Product Code:	HCD

3. Predicate Device:

Adson Cannula (9Fr x 14 cm; stainless steel) (class I, 510(k)-exempt)

4. Description of Device:

The Cannula has a stepped distal tip with a 30 cm rigid ceramic stylet protecting the fluid lumen while providing rigidity to the distal portion of the device. Soft tubing protects the lumen in the center portion and at the distal end where it terminates at a female luer fitting. The fluid containing central lumen is manufactured from non-reactive silica.

The cannula will be marketed in the following sizes:
16 ga Ventricular Cannula, .008" ID x 4ft
16 ga Ventricular Cannula, .008" ID x 10ft
14 ga Ventricular Cannula, .021" ID x 4ft
14 ga Ventricular Cannula, .021" ID x 10ft

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5. Intended Use Statement:

The MR Compatible Ventricular Cannula is intended for injection of Cytarabine or removal of CSF from the ventricles during intracranial procedures. The device is not intended for implant. The device is intended for "single patient use only."

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

	SurgiVision Ventricular Cannula (VC)	Predicate Device: Adson Ventricular Cannula	Discussion
Classification	21 CFR 882.4060	21 CFR 882.4060	Equivalent
Product Code	HCD	HCD	Equivalent
Intended Use	Injection of Cytarabine to the ventricles of the brain or aspiration of CSF from the ventricles of the brain	Injection or aspiration of fluid in the ventricles of the brain	Equivalent
Indications for Use	Gains access to the brain ventricles	Gains access to the brain ventricles	Equivalent
	Allows Injection of Cytarabine into the brain ventricles	Allows injection of fluids into the brain ventricles	VC validated using Cytarabine
	Allows aspiration of CSF from the brain ventricles	Allows aspiration of fluids from the brain ventricles	VC validated using primate CSF
	Not implantable	Not implantable	Equivalent
	Single Patient Use	Reusable	VC is validated for single patient use. Component materials do not lend to multiple use and re-sterilization
Target Population	Pt.s needing injection of Cytarabine to the brain ventricles or aspiration of CSF from the brain ventricles	Pt.s needing aspiration or injection of fluids from the brain ventricles	VC validated using Cytarabine and primate CSF
Anatomical Sites	Brain ventricle	Brain ventricle	Equivalent
Where Used	Operating Room	Operating Room	Equivalent
	MRI Diagnostic / Surgical Room	N/A	VC device is MR Compatible/ MR Safe, whereas the predicate device is not indicated for MR environments
Energy used	N/A	N/A	Equivalent
Human Factors	Labeling indicates size and length	Labeling indicates size and length	Equivalent
	Labeling contains flow vs. pressure tables	No information provided	VC provides additional information to the

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	SurgiVision Ventricular Cannula (VC)	Predicate Device: Adson Ventricular Cannula	Discussion
			physician regarding flow and pressures for the various sizes
	Can be manipulated with gloved hand	Can be manipulated with gloved hand	Equivalent
Design	Designed to be placed through a prepared opening through the skull and dura into the brain ventricle	Designed to be placed through a prepared opening through the skull and dura into the brain ventricle	Equivalent
	Rigid section to enter the brain	Rigid section to enter the brain	Equivalent
	Straight section to enter the brain	Straight section to enter the brain	Equivalent
	Hole at distal end for fluid movement	Hole at distal end for fluid movement	Equivalent
	No side holes	Three .055" (1.4 mm) side holes located 11 mm to 21 mm from the distal end	The VC can only transfer fluids from the distal end
	No marking on body of device	CM markings on body	VC Device length is provided with the instructions
	Length of rigid section: 10.5" (30 cm)	Length of rigid section: 5.5" (14 cm)	The VC has a longer length to facilitate handling of the device when the patient is within the bore of an MR scanner
	Inside diameter: .008" (0.2 mm) to .021" (0.53 mm)	Inside diameter: .079" (2.0 mm)	Both devices are moving fluids and their different inside / outside diameters result in different flow rates.
	Outside diameter: .065" (1.6 mm) and .080" (2.0 mm)	Outside diameter: .120" (3.0 mm)	
	No Stylet	Stylet	VC has stepped features for dimensional transitions at the tip and the predicate device uses a stylet to create the transitions

	SurgiVision Ventricular Cannula (VC)	Predicate Device: Adson Ventricular Cannula	Discussion
			VC does not have a stylet that would have to be removed prior to assisted injection or aspiration
			VC allows immediate un-assisted aspiration of CSF from ventricle (with visualization by physician) during placement
	Lumen extension (3 foot) allows remote (end of scanner bore) injection/aspiration	No Proximal Extension present	VC has an incorporated proximal lumen extension, this provides a single lumen extending from the rigid cannula to the proximal connector
	Lumen extension (9 foot) allows remote (outside of scanner 5 gauss line) Injection/aspiration using a non-MRI safe pump	No Proximal Extension Present	VC has an incorporated proximal lumen extension; this provides a single lumen extending from the rigid cannula to the proximal connector. This extension provides a continuous lumen that is MR compatible and can connect to a remote, not MR safe pump for injection/aspiration.
Performance	Sufficiently rigid to pass through brain tissue without additional support	Sufficiently rigid to pass through brain tissue without additional support	Equivalent
	Contains a channel through which fluids can be removed (aspiration) or placed (injection) into the ventricle	Contains a channel through which fluids can be removed (aspiration) or placed (injection) into the ventricle	Equivalent
	Flow rate of: 0.3 ml/hr (.008" I.D.) to 25.0 ml/hr (.021" I.D.) at 0.7 PSI	Flow rate of 16,000 ml/hr at 0.7 PSI	Both devices are moving fluids and the different flow rates result only from their different diameters
Materials	Rigid body: Ceramic	Rigid body: Stainless Steel or Sterling Silver	Both devices use rigid material for the body, VC provides a

	SurgiVision Ventricular Cannula (VC)	Predicate Device: Adson Ventricular Cannula	Discussion
			rigid body that is MR Compatible due to ceramic material
	Stylet: N/A	Stylet: Stainless Steel or Sterling Silver	VC has features that provide rigidity and tip transition which are accomplished by the stylet
	Through lumen: Polymer covered silica	Through lumen: Stainless Steel or Sterling Silver	Both devices have a continuous through lumen but the VC is MR compatible
	Lumen extension (outer support tubing): PVC extrusion	No lumen extension.	VC is provided with lumen extension
	Proximal Connector: Female Luer connector	Proximal Connector: Female Luer connector	Equivalent
Biocompatibility	Tissue contact tested per ISO 10993: Biological Evaluation of Medical Devices	Presumed	Equivalent
Compatibility with environment and other devices	Safe in a 1.5T MRI environment	Not safe in a 1.5T MRI environment	VC device is designed for MR environment
	Female Luer connector on proximal end fits all male luer connectors (e.g. syringe tips)	Female Luer connector on proximal end fits all male luer slip connectors (e.g. syringe tips)	Equivalent
Sterility	Yes per ANSI/AAMI/ISO 11137-2: Sterilization of health care products -- Radiation	Provided non-sterile and sterilized on-site	Equivalent
Electrical Safety	N/A	N/A	Equivalent
Mechanical safety	N/A	N/A	Equivalent
Chemical Safety	Silica lumen non-reactive	Stainless steel	Equivalent
Thermal Safety	MRI Safe. All brain contacting components tested safe in a 1.5T environment	Not MRI safe	VC use is not restricted to non-MRI environment
Radiation safety	N/A	N/A	Equivalent

Summarizing the differences noted above:

- The SurgiVision MR Compatible Ventricular Cannula (VC) is single patient use and is not re-sterilizable.
- The VC is provided sterilized and pyrogen free in Tyvek packaging.
- The VC is MR safe and can be used within an MR environment.
- The VC labeling provides additional information to the physician regarding flow rates as a function of pressure. The predicate provides no such information.
- The VC has no side holes in the lumen.
- The VC has no depth marking on the barrel as the physician will be adjusting location with direct visualization under MR using a stereotactic frame
- The length of the rigid section of the VC is longer than the predicate for ease of handling within the MR bore.

- The VC does not require a stylet for entry to the ventricles that requires removal prior to injection or aspiration.
- The VC has an integral extension for injection or aspiration external to the bore.
- The VC and predicate flow rates differ because of the different lumen sizes and extension.

These recognized differences between the VC and the predicate are intended to meet the needs of the MR work environment and do not represent changes that effect the safety or effectiveness of the device.

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

   - Sterilization and Shelf Life, including sterilization validation using the VDmax25 procedure of ISO 11137-2.
   - Biocompatibility Testing including cytotoxicity, material mediated pyrogen, ISO maximization study, intracutaneous toxicity and systemic toxicity with acceptable results.
   - Performance Testing – Bench, including design verification testing, comparison testing with the predicate Adson Cannula, pressure withstand testing and injection/aspiration testing, lateral tip deflection testing, transit testing in conformance to D4169 and accelerated aging testing.
   - Cytarabine injection testing and aspiration of primate CSF was completed with acceptable results..

   These tests demonstrated that the MR Compatible Ventricular Cannula functions as intended and is substantially equivalent to legally marketed predicate device.

8. **Rx or OTC:**

   The MR Compatible Ventricular Cannula is an Rx prescription device per 21 CFR Part 801, Subpart D.

9. **Substantial Equivalence:**
   The MR Compatible Ventricular Cannula has the same indications for use as the predicate device, Adson Cannula. While there are technological differences between the MR Compatible Ventricular Cannula and the Adson Cannula, such as the device material, construction and dimensions, these differences do not raise new types of safety and effectiveness questions when all listed warnings and cautions are followed. The MR Compatible Ventricular Cannula is substantially equivalent to the marketed Adson Cannula.

SurgiVision, Inc.
_____ Date: 1/21/11
Edward Waddell, Director of Regulatory Affairs

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
Surgi Vision, Inc.
5 Musick
Irvine, CA 92618

JAN 26 2011

Re: K102101
Trade/Device Name: SurgiVision MR Compatible Ventricular Cannula
Regulation Number: 21 CFR 882.4060
Regulation Name: Ventricular cannula
Regulatory Class: Class I
Product Code: HCD
Dated: January 17, 2011
Received: January 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

Enclosure

Indications for Use Statement

510(k) Number (if known): K102101

Device Name: SurgiVision, Inc. MR Compatible Ventricular Cannula
Indications for Use:

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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)

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

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