MAR 1 4 2000

K994436

510(k) Summary

Surgi-Vision Esophageal Stylet Coil

Common/Classification Name: Accessory to
Magnetic Resonance Diagnostic Device, 21 CFR 892.1000

Surgi-Vision, Inc.
9250 Rumsey Road, Suite 100
Columbia, MD 21045

Contact: Nancy E. Taylor, Prepared: December 30, 1999

A. LEGALLY MARKETED PREDICATE DEVICES

The **Surgi-Vision Esophageal Stylet Coil** is substantially equivalent to the Surgi-Vision Endo-Esophageal MRI Coil, which was cleared for marketing on September 3, 1999, in premarket notification K992193.

B. DEVICE DESCRIPTION

The **Surgi-Vision Esophageal Stylet Coil** is a specialty coil for use in MRI imaging of the anatomical regions surrounding the esophagus. The signals picked up by the coil are conducted through a small coaxial cable to a connection with the standard surface coil connector for GE MRI systems. The coil and cable are completely sealed inside the insulating layer.

C. INTENDED USE

The **Surgi-Vision Esophageal Stylet Coil** is recommended for high-resolution Magnet Resonance Imaging of the human esophagus. The single use, disposable Stylet Coil has been designed to be inserted in the esophagus of the patient during MRI scans in order to obtain improved image quality in the anatomical regions surrounding the esophagus. The unique coil shape facilitates orientation of the coil to the anatomy. This product is to be used with a 1.5T MRI machine.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Surgi-Vision Esophageal Stylet Coil** has identical indications for use as the legally marketed predicate device.

The **Surgi-Vision Esophageal Stylet Coil** has the same technological characteristics as the predicate device. Both proposed and predicate devices have an electronic matching circuit, a connecting coaxial cable, and an inter-cavitary probe with a radiofrequency receiving coil. However, there are differences in construction and design that make it necessary to provide performance data to assure substantial equivalence. Such performance data are available and do demonstrate substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

See Section D, above.

F. TESTING

Surgi-Vision carried out testing and/or analysis of the **Surgi-Vision Esophageal Stylet Coil** that addressed the following issues:

(1) Possibility of excess RF heating;

(2) Possibility of increased susceptibility of patients to peripheral nerve stimulation; and

(3) Imaging performance.

The results of the heating experiments demonstrate that there is no excess heating when SVESC is positioned in a phantom that is representative of clinical conditions. The change in temperature observed during use of the SVESC is not significantly different then that observed without the coil. The experiments done to determine current leakage by the MRI pulsed gradient field demonstrate that there is no possibility of increased susceptibility of patients to nerve stimulation. Finally, the imaging performance demonstrates enhanced resolution of aortic regions visualized from the esophagus. The results of the testing demonstrate that there are no safety problems for imaging of a patient using the **Surgi-Vision Esophageal Stylet Coil** if the instructions for use are followed and if the whole-body average SAR is no more than the present recommended limit of 4 W/kg.

G. CONCLUSIONS

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and

various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2000

Nancy E. Taylor
CEO/President
Surgi-Vision, Inc.
9250 Rumsey Rd., Suite 100
Columbia, MD 21045

Re: K994436
Esophageal Sylet Coil
Dated: December 30, 1999
Received: December 30, 1999
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

STATEMENT OF INDICATIONS FOR USE

510(K) Number (if known): K994436

Device name: Surgi-Vision Esophageal Stylet Coil

Indications for Use:

The Surgi-Vision Esophageal Stylet Coil is recommended for high-resolution Magnetic Resonance Imaging of the human esophagus. The single use, disposable coil has been designed to be inserted in the esophagus of the patient during MRI scans in order to obtain improved image quality in the anatomical regions surrounding the esophagus. The unique coil shape facilitates orientation of the coil to the anatomy. This product is to be used with a 1.5T MRI machine.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994436