AUG 31 2001

K01781

510(k) Summary

Intercept-Urethral Microcoil

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

Surgi-Vision, Inc.
20 Firstfield Road, Suite 200
Gaithersburg, MD 20878

Contact: Nancy E. Taylor, Prepared: June 7, 2001

A. LEGALLY MARKETED DEVICE

The **Intercept-Urethral Microcoil** was cleared for marketing as the Surgi-Vision Prostate Coil on November 28, 2000 in premarket notification K0022916. Surgi-Vision, Inc. submits the present premarket notification of additional indications for use for the Surgi-Vision Prostate Coil under the name of the **Intercept-Urethral Microcoil.**

B. DEVICE DESCRIPTION

The **Intercept-Urethral Microcoil** (IUMC) is an intracavitary specialty coil for use in MR imaging of the anatomical regions surrounding the urethra. The signals picked up by the coil are conducted through a small coaxial cable and interfacing network to a connection with the standard surface coil connector for MRI systems.

The imaging coil and the coaxial cable are completely sealed inside the insulating sleeve. This isolates the coil from direct contact with any physiological membrane or fluids. During a typical procedure the coil is advanced into the subject's urethra and positioned in the region of interest. The balun, tuning/matching and decoupling circuit is located at the distal end of the device, and is always outside the body.

C. INTENDED USE

The **Intercept-Urethral Microcoil** is recommended for high-resolution Magnetic Resonance Imaging of the male and female urethra and

surrounding tissue. The single use, disposable coil was designed to be inserted in the urethra of the patient during MRI scans in order to obtain improved image quality in the anatomical regions surrounding the urethra including the prostate in males. The flexible coil facilitates placement of the coil in the anatomy. This product is to be used with a 1.5T GE Signa MRI machine. The signals picked up by the coil are conducted through a small coaxial cable to a connection with the standard surface coil connector for MRI systems. The coil and cable are completely sealed inside the insulating layer.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

This premarket notification concerns only additional intended uses for the IUMC. Concurrently, the name will be changed from the Surgi-Vision Prostate Coil to the Intercept Urethral Microcoil.

In all other aspects, the IUMC is the device that was cleared for marketing by FDA on November 28, 2000, in premarket notification K002916.

E. TECHNOLOGICAL CHARACTERISTICS

See Section D, above.

F. TESTING

Surgi-Vision carried out testing and/or analysis of the **Intercept-Urethral Microcoil** that addressed the following issues:

(1) Possibility of excess RF heating;

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

(3) Imaging performance; and

(4) Mechanical testing.

The results of the heating experiments demonstrate that there is no

excess heating when IUMC is positioned in a phantom that is representative of worst case clinical conditions. The change in temperature observed during use of the IUMC is not significantly different then that observed without the coil.

The calculations 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.

The imaging performance was evaluated in the male and female urethra. These images are shown in **Exhibit 7**.

Mechanical test results demonstrated that there are no safety issues and that all of the performance specifications were met. Stiffness, tensile, tracking, torque, and electrical testing were all completed to the satisfaction of the specifications. Mechanical flexing resulted in insignificant changes in the electrical properties of the coils. These results are described in **Exhibit 8**.

G. CONCLUSIONS

This pre-market submission has demonstrated the IUMC is safe and effective for the additional indications as required 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

AUG 31 2001

Ms. Nancy E. Taylor
CEO/President
Surgi-Vision Inc.
20 Firstfield Road, Suite 200
GAITHERSBURG MD 20878

Re: K011781
Intercept Urethral Microcoil
(MRI specialty coil)
Dated: June 7, 2001
Received: June 7, 2001
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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4,xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(K) Number (if known): K011781

Device name: Intercept-Urethral Microcoil

Indications for Use:

The **Intercept-Urethral Microcoil** is recommended for high-resolution Magnetic Resonance Imaging of the male and female urethra and surrounding tissue. The single use, disposable coil was designed to be inserted in the urethra of the patient during MRI scans in order to obtain improved image quality in the anatomical regions surrounding the urethra including the prostate in males. The flexible coil facilitates placement of the coil in the anatomy. This product is to be used with a 1.5T GE Signa MRI machine. The signals picked up by the coil are conducted through a small coaxial cable to a connection with the standard surface coil connector for MRI systems. The coil and cable are completely sealed inside the insulating layer.

(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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011781