K093218
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Section V–510(k) Summary

MAY 18 2010

5.1. Device Information

Category	*Comments*
Sponsor:	Company: FemSuite, LLC Address: The Presidio 16A Funston Avenue San Francisco, Ca, 94129, USA
Correspondence Contact Information:	Dr. Pavan Sethi, Ph.D. Vice President, Regulatory, Quality & Scientific Affairs Tel: (408) 513-7529 Pavan@femsuite.com
Device Common Name:	Hysteroscope
Device Classification and Code:	Class II, HIH
Device Classification Name:	Hysteroscope and accessories
Device Proprietary Name:	FemEye Two™

5.2. Predicate Device Information

Predicate Device	**Manufacturer**	**Predicate Device Common Name**	**Predicate Device Classification and Code**	**Predicate Device Classification**
MicroSpan Hysteroscope	Imagyn Medical, Inc	Hysteroscope	Class II, HIH	21CFR884.1690
Gyrus ACMI ® Invisio ® Digital Hysteroscope System	Gyrus ACMI, Inc	Hysteroscope	Class II, HIH	21CFR884.1690

5.3. Date Summary Prepared

Date Submitted: October 09, 2009

5.4. Description of Device:

The FemEye Two™ Hysteroscope is designed as a handheld, low-voltage camera device suitable for use during both in-office as well as in-hospital diagnostic procedures. The FemEye Two is a continuous flow hysteroscope intended to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures.

The device consists of a hysteroscopic endoscope and is provided sterile for single patient use. It consists of a small diameter, rigid shaft and a handle. The shaft contains a camera

and integrated light source as well as an irrigation/working channel port. The non-disposable portion of the FemEye Two is the battery cartridge which powers the device.

5.5. Intended Use

The FemSuite, LLC, FemEye Two™ Hysteroscope is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures. Generally recognized indications for diagnostic hysteroscopy include:

- Abnormal Uterine Bleeding
- Infertility and Pregnancy Wastage
- Evaluation of Abnormal Hysterosalpingogram,
- Intrauterine Foreign Body
- Amenorrhea
- Pelvic Pain

5.6. Comparison to Predicate Device:

FemSuite's FemEye Two™ is substantially equivalent in intended use and operation to following predicate devices:

K961688	Imagyn Medical Microspan Hysteroscope
K092278	Gyrus ACMI Invisio Digital HysteroscopeSystem

The FemEye Two is identical to Imagyn Medical Microspan Hysteroscope in method of operation and intended use. The FemEye Two provides video images similar in resolution to the predicate device. Both systems provide light adequate to allow physicians to visualize the cervical and uterine cavity. Both devices have one inflow and one outflow channel for saline instillation for irrigation and distention.

The FemEye Two is different in design from Imagyn Medical Microspan Hysteroscope . The FemEye Two provides illumination of the cervical and uterine cavity using an integrated white-light LED and a fiber optic light guide, while the predicate Microspan Hysteroscope provides illumination by means of fiber optic bundles that deliver light from an external OES Xenon light source. The FemEye Two uses embedded CMOS (complimentary medical oxide semiconductor) technology to generate an image, whereas the predicate device uses fiber optic technology to generate an image. The FemEye Two™ is a sterile, single patient use, disposable device except for the battery which is provided non sterile and is reusable. The Microspan Hysteroscope is supplied non sterile and must be sterilized prior to each use. The device is reusable but is intended to be used with a single use sterile sheath. The FemEye Two is designed to be used for diagnostic hysteroscopy, where as Microspan Hysteroscope is designed to be used for operative hysteroscopy in addition to diagnostic hysteroscopy.

In addition to method of operation and intended use for diagnostic hysteroscopy, the FemEye Two is identical to Gyrus ACMI Invisio Digital Hysteroscope System in video imaging technology. Both devices are endoscopic, and transmit images through a video camera to a video monitor and use a light source for illumination. Both

devices have an embedded video camera, an embedded light source, and an integrated cable.

However, the devices have different design for video imaging technology. FemEye Two has integrated LEDs in the shaft where as Gyrus ACMI Invisio Digital Hysteroscope has integrated LEDs in the handle. FemEye Two has an integrated cable to connect to external video monitor, where as in Gyrus ACMI Invisio Digital Hysteroscope System, an integrated cable connects the endoscope to the camera control unit (CCU).

These differences do not impact the intended use or optical performance of the FemEye Two. The testing described below demonstrates that the differences in the devices do not raise any unresolved issues of safety or efficacy.

FemSuite concludes that the devices are substantially equivalent.

5.7. Summary of Supporting Data:

Biocompatibility data demonstrates that the device is in compliance with *ISO 10993*.

Electrical Safety and Electromagnetic Compatibility data demonstrates that the device is in compliance with *IEC 60601-2-18 IEC, 60601-1* and *IEC 60601-1-2*.

Bench testing has demonstrated that the device is in compliance with *ISO 8600-3* and *ISO 8600-5*. In addition the bench testing included the Tensile Strength test, Torque test, Fatigue test and Flow test. The Tensile Strength Test demonstrated that joints can withstand a 5.0 lb tensile load, the Torque Test demonstrated that the device can withstand a 1 lb- inch torque, Fatigue test demonstrated that the rotation knob can withstand multiple actuations without affecting the image functionality of the device and the Flow test verified the flow of 120 ml per minute without any leaks.

A clinical usability study was performed with FemEye Two. The results of this usability study indicate that the FemEye Two is safe and effective when operated by the intended user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Pavan Sethi, M.D., Ph.D.
Vice President, Regulatory, Quality & Scientific Affairs
FemSuite, LLC
19991 7th Street East
SONOMA CA 95476

MAY 18 2010

Re: K093218
Trade/Device Name: FemEye Two™
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: May 10, 2010
Received: May 12, 2010

Dear Dr. Sethi:

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.

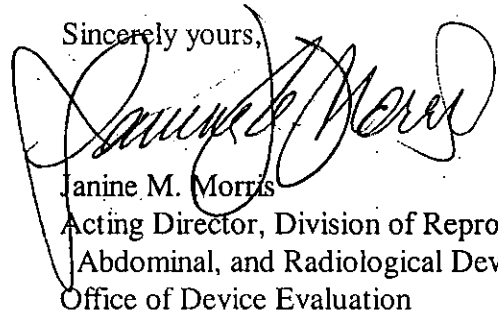
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section IV–Indications for Use Statement

510(k) Number: K093218

Device Name: FemSuite, LLC, FemEye Two™

Indications for Use:

The FemEye Two™ Hysteroscope is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures. Generally recognized indications for diagnostic hysteroscopy include:

- Abnormal Uterine Bleeding
- Infertility and Pregnancy Wastage
- Evaluation of Abnormal Hysterosalpingogram,
- Intrauterine Foreign Body
- Amenorrhea
- Pelvic Pain

Prescription Use ___X___ (Per 21 CFR §801 subpart D) OR Over-The-Counter Use_____ (Per 21 CFR §801 subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K093218