510(k) SUMMARY

FMwand Ferromagnetic Surgical System

Date of Summary: March 6, 2013

General Provisions

510(k) Owner's Name:	Domain Surgical, Inc.
Address:	1370 South 2100 East Salt Lake City, Utah 84108
Contact Person:	Curtis Jensen, Vice President of Quality and Regulatory Affairs
Phone Number:	(801) 924-4958
Fax Number:	(801) 924-4951
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR §878.4400, Product Code GEI, HGI)
Proprietary Name:	FMwand Ferromagnetic Surgical System
Common Name:	Electrosurgical cutting and coagulation device and accessories

Name of Predicate Device(s)

- Domain Surgical System, (Product Code GEI, HGI) 510(k) #K121881

Device Description

The FMwand Ferromagnetic Surgical System is a soft tissue cutting and coagulation device that consists of the FMwand Generator that is electrically connected to the sterile, single-use FMwand Handpiece by the FMwand Power Module (a resterilizable, reusable accessory cable) and a single-use, sterile air line. Like the predicate device, the handpiece includes actuation buttons that can be used to activate the handpiece tip. Also like the predicate device, an optional footpedal can be used to activate the handpiece. The connectors at both ends of the FMwand Power Module are designed to fit only the FMwand Generator and FMwand sterile, disposable accessories. The FMwand Power Module is provided non-sterile. It is intended to be cleaned and sterilized prior to the initial use and before each subsequent reuse.

Technological Comparison

Both the FMwand Ferromagnetic Surgical System and the Domain Surgical System employ ferromagnetic induction to generate heat in the handpiece tip for the purpose of cutting and coagulation of soft tissue. Both devices offer active cooling of the handpiece by circulating air through the handpiece and air line.

The FMwand Ferromagnetic Surgical System handpiece consists of a disposable, single-patient use portion (the FMwand Handpiece) and a reusable, user-resterilizable connection cable (FMwand Power Module), whereas the Domain Surgical System Handpiece is a one piece disposable accessory.

The FMwand Ferromagnetic Surgical System differs from the predicate device in that it offers a second button on the handpiece as well as a second footpedal to allow the ability to quickly switch two user-selected power levels when desired.

Device Comparison Table

Performance Feature	FMwand Ferromagnetic Surgical System	Domain Surgical System	Discussion
Manufacturer	Domain Surgical Inc.	Domain Surgical Inc.	Identical
510(k) Number	To be assigned	K121881	N/A
Prescription/ OTC	Prescription Only	Prescription Only	Identical
Product Code	GEI, HGI	GEI, HGI	Identical
Classification Regulation	21 CFR 878.4400	21 CFR 878.4400	Identical
Basis Intended Use	Cutting and coagulation of soft tissue	Cutting and coagulation of soft tissue	Identical
Indications for Use	The FMwand Ferromagnetic Surgical System is indicated for cutting and coagulation of soft tissue during surgical procedures, including Gynecologic procedures (open transabdominal only).	The Domain Surgical System is indicated for cutting and coagulation of soft tissue during surgical procedures, including Gynecologic procedures (open transabdominal only).	Identical
Heat Generation Method	Ferromagnetic induction heating provides an elevated temperature blade which will cauterize tissue as it cuts.	Ferromagnetic induction heating provides an elevated temperature blade which will cauterize tissue as it cuts.	Identical
Power Requirements	100-240 VAC, 50-60 Hz	100-240 VAC, 50-60 Hz	Identical
Generator Size	Approximately 4" x 14" x 11"	Approximately 4" x 14" x 11"	Identical
Generator Weight	Approximately 10 lbs. (4.5 kg)	Approximately 10 lbs. (4.5 kg)	Identical
Maximum Output Energy	5 to 60 W 155 Volts maximum	5 to 60 W 155 Volts maximum	Identical
Maximum Operational Temperature	450°C	450°C	Identical
Operational Control Method	Controlled power delivered to the handpiece tip	Controlled power delivered to the handpiece tip	Identical
Mode of Operation	Intermittent Operation	Intermittent Operation	Identical
Active Cooling	Air cooled handpiece	Air cooled handpiece	Identical
Output Type	Type CF	Type BF minimum	Leakage current restrictions for a Type CF rating are more stringent than for a Type BF rating.
Operating Frequency	Pure Sinusoidal Waveform (40.68 MHz)	Pure Sinusoidal Waveform (40.68 MHz)	Identical
Delivery system configuration Length Diameter	Tips of various lengths	Tips of various lengths	Identical
Handpiece Configuration	Handpiece consists of a disposable, single-patient use handpiece section connected to a reusable cable (FMwand Power Module) section.	Handpiece consists of a disposable, single-patient use handle with a disposable, single-patient use tip.	The internal circuitry as well as the tip function is equivalent in these two configurations. The change is to the form of the handpiece and to the sterilization methods.
Handpiece Actuation Button Configuration	Two actuation buttons corresponding to dual user-selected high/low power levels.	One actuation button corresponding to a single user-selected power level.	Having two power settings available for actuation at the handpiece is for user convenience. Single button handpiece is still supported.
Tip configurations	Various handpiece tip shapes.	Various handpiece tip shapes.	Identical
Footpedal Configuration	Two actuation pedals corresponding to dual user-selected high/low power levels.	One actuation pedal corresponding to a single user-selected power level.	With two power levels available, a dual footpedal is available for those users who prefer footpedal actuation of the device. The interface still supports a single footpedal if desired.

Performance Feature	FMwand Ferromagnetic Surgical System	Domain Surgical System	Discussion
Generator User Interface	User interface has added capability to support the dual user-selected power levels.	User interface can only support a single user-selected power level.	With two power levels available, the generator needs the ability to allow the user to select a low and high power setting (FMmin/FMmax). The interface still supports single-button handpieces and single footswitches.
Treatment Modality	Cutting and/or coagulation using conducted heat from an elevated temperature handpiece tip.	Cutting and/or coagulation using conducted heat from an elevated temperature handpiece tip.	Identical
Bench Testing	The FMwand Ferromagnetic Surgical System passed all bench tests performed. Details are found in Section 15 of this submission.	The Domain Surgical System passed all bench tests performed. Details are found in the original 510(k) submission, K121881.	Identical
Meets applicable portions of IEC 60601-2-2	Yes. Details are found in Section 14 of this submission.	Yes. Details are found in the original 510(k) submission, K121881.	Identical
Biocompatibility Tests	Materials used in the patient-contacting portions of the FMwand Ferromagnetic Surgical System are either known to be biocompatible or have passed testing performed according to ISO 10993-5 (Cytotoxicity), 10993-10 (Acute Systemic Toxicity) and 10993-11(Sensitization and Irritation). Details are found in Section 12 of this submission.	Materials used in the patient-contacting portions of the Domain Surgical System are either known to be biocompatible or have passed testing performed according to ISO 10993-5 (Cytotoxicity), 10993-10 (Acute Systemic Toxicity) and 10993-11(Sensitization and Irritation). Details are found in the original 510(k) submission, K121881.	Identical
Generator Sterilization Method	Generator is not intended to be provided sterile and is not intended to be sterilized by the user.	Generator is not intended to be provided sterile and is not intended to be sterilized by the user.	Identical
Handpiece/Tip Sterilization	Handpiece/Tip are single-patient use and provided sterile. Sterilization method is Ethylene Oxide: SAL 10^{-6}. Connection cable is not provided sterile and is intended to be cleaned and sterilized by the user prior to initial use and each subsequent use up to a maximum of 100 uses.	Handpiece/Tip, including cable and connector are single-patient use and provided sterile. Sterilization method is Ethylene Oxide: SAL 10^{-6}.	The sterilization method of the predicate device has been validated to an SAL of 10^{-6}. The subject device cleaning and sterilization methods will be validated to an SAL of 10^{-6}. These are equivalent.

Figure 5-1: Device Comparison Table

Indications for Use

Indications for Use: The FMwand Ferromagnetic Surgical System is indicated for cutting and coagulation of soft tissue during surgical procedures, including Gynecologic procedures (open, transabdominal only).

The indications statement for the FMwand Ferromagnetic Surgical System is the identical to that of the predicate device.

Performance Testing Data Summary

Questions of safety and effectiveness are the same for this device as they are for the predicate devices and other similar devices on the market. All applicable bench testing was performed with the FMwand Ferromagnetic Surgical System to assure that it functions as intended. Bench tests verified that the generator output was within specification and that the thermal output of the handpiece and tip corresponded to the target values.

Safety and Biocompatibility Summary

The patient contacting materials used in the FMwand Reusable Power Module were chosen for their biocompatibility, function and suitability for the intended use of this device. All necessary biocompatibility testing of applicable parts of the system was successfully completed by accredited independent testing laboratories according to ISO 10993-1 and 510(k) Memorandum G95-1.

It was also tested by an accredited independent testing laboratory to assure that it complies with the applicable electrical safety standards for medical electrosurgical devices, including the applicable sections of IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-2-2.

Conclusion

The FMwand Ferromagnetic Surgical System is substantially equivalent to the Domain Surgical System (510(k)# K121881). The intended use of the FMwand Ferromagnetic Surgical System is the same as the predicate device. The FMwand Ferromagnetic Surgical System differs from the predicate device; however the differences do not raise different types of questions of safety and effectiveness. The information presented in this premarket submission, including the bench testing, demonstrates that the FMwand Ferromagnetic Surgical System is as safe and effective as the predicate device for its intended use and functions as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 3, 2014

DOMAIN™ Surgical
Curtis Jensen
Vice President of Quality and Regulatory Affairs
1370 South 2100 East
Salt Lake City, UT 84108

Re: K130606
Trade/Device Name: FMwand Ferromagnetic Surgical System
Regulation Number: 21 CFR§ 884.4120
Regulation Name: Gynecologic electrocautery and accessories
Regulatory Class: II
Product Code: HGI
Dated: December 3, 2013
Received: December 4, 2013

Dear Curtis Jensen,

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130606

Device Name: FMwand Ferromagnetic Surgical System

Indications for Use: The FMwand Ferromagnetic Surgical System is indicated for cutting and coagulation of soft tissue during surgical procedures, including Gynecologic procedures (open, transabdominal only).

Prescription Use ___X___ AND/OR Over-The-Counter Use: _____
(Part 21 CFR 801 Subpart D) (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)

Benjamin R. Fisher -S
2014.01.03 13:19:31 -05'00'