510(k) SUMMARY

Open FMsealer

Date of Summary: June 3, 2014

JUL 3 0 2014

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
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Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR §878.4400, Product Code GEI)
Proprietary Name:	Open FMsealer
Common Name:	Electrosurgical cutting and coagulation device and accessories

Name of Predicate Devices

- FMwand Ferromagnetic Surgical System (Product Code GEI) #K130606
- LigaSure Vessel Sealing System (Product Code GEI) 510(k) #K043273

Device Description

An electrosurgical cutting and coagulation device (and accessories) is a device intended to remove tissue and control bleeding by use of high-frequency electrical current (see 21 CFR §878.4400). It is classified as a Class II (510(k)) device.

The Open FMsealer is a device intended for sealing of vessels and for soft tissue cutting and coagulation. The device is designed to be used only with the FMwand Generator (K130606). The two-piece device consists of a sterile, single-use patient-contacting shears section (Open FMsealer) and an accessory cable (Power Module or PM) that connects the FMsealer to the generator. The dual footpedal connects to the rear of the generator and can be used to activate the FMsealer if desired by the user.

The Open FMsealer is a hand-held surgical instrument intended for use in open surgical procedures where ligation of vessels or cutting and coagulation of soft tissue is desired. The Open FMsealer consists of a scissor-like handle with two actuation buttons and jaws to grasp the tissue to be affected.

The Open FMsealer is connected to the FMwand Generator (K130606) by the Power Module. The connectors on both ends of the Power Module are designed to fit only the FMwand Generator and FMwand sterile, disposable accessories. The power module and FMwand Generator were previously cleared as part of K130606.

This system creates sealing, cutting and coagulation by the application of heat and compression to tissue bundles and vessels interposed between the jaws of the instrument. Like the predicate device, the Open FMsealer includes actuation buttons that can be used to activate the device.

The Open FMsealer has been shown (in animal studies) to cut and seal vessels up to and including 7mm in diameter, lymphatics and tissue bundles as large as will fit into the jaws of the device.

Technological Comparison

The Open FMsealer employs ferromagnetic induction to generate heat in the tip. This method of heat generation is identical technology as the FMwand Ferromagnetic Surgical System (K130606), and differs from the LigaSure System which uses the resistance of the target tissue and electrical current to produce the heat necessary for cutting and sealing (bipolar electrosurgery).

Device Comparison Table (Shaded entries are identical)

Performance Feature	Open FMsealer	LigaSure Vessel Sealing System	FMwand Ferromagnetic Surgical System
Manufacturer	Domain Surgical, Inc.	Covidian AG	Domain Surgical, Inc.
510(k) Number	To be assigned	K043273	K130606
Prescription/OTC	Prescription Only	Prescription Only	Prescription Only
Product Code	GEI	GEI	GEI
Classification Regulation	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
Basis Intended Use	Sealing, cutting and coagulation of soft tissue	Sealing, cutting and coagulation of soft tissue	Cutting and coagulation of soft tissue
Heat Generation Method	Ferromagnetic induction provides an elevated temperature surface which will cauterize soft tissue as it seals and cuts.	Application of bipolar electrosurgical energy to tissue interposed between the jaws of the instrument.	Ferromagnetic induction provides an elevated temperature blade which will cauterize tissue as it cuts.
Operational Control Method	Controlled power delivered to tip of connected accessory	Controlled power delivered to tip of connected accessory	Controlled power delivered to tip of connected accessory
Mode of Operation	Intermittent Operation	Intermittent Operation	Intermittent Operation
Output Type	Type CF	Type CF	Type CF
Treatment Modality	Vessel sealing, cutting and/or coagulation using heat combined with compression of the target tissues between the jaws of the instrument.	Vessel sealing, cutting and/or coagulation using heat combined with compression of the target tissues between the jaws of the instrument.	Cutting and/or coagulation using conducted heat from an elevated temperature handpiece tip.
Bench Testing	The Open FMsealer passed all bench tests performed including testing on animals and animal tissues to show vessel sealing strength.	Preclinical studies were performed to show vessel sealing strength.	The FMwand Ferromagnetic Surgical System passed all bench tests performed
Meets applicable sections of IEC 60601-2-2	Yes. Applicable electrical safety testing has been successfully performed.	Some testing was performed to show compliance to IEC 60601-2-2 (Alarm frequency and Audio Level). It is unknown if any other testing was performed.	Yes. Applicable electrical safety testing has been successfully performed.
Biocompatibility Testing	Materials used in the patient-contacting portions of the Open FMsealer is 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.	There is no mention in the device literature, website or 510(k) summary as to whether the Generator or shears were tested for biocompatibility.	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).
Sterilization Method	Open FMsealer is for single-patient use and provided sterile. Sterilization method is Ethylene Oxide: SAL 10^{-6}.	Shears are single-patient use and provided sterile. Sterilization method is Ethylene Oxide: SAL 10^{-6}.	FMwand handpiece is for single-patient use and is provided sterile. Sterilization method is Ethylene Oxide: SAL 10^{-6}

The differences between the Open FMsealer and the predicate devices are discussed in detail in the appropriate sections of this submission. None of the differences raise new questions of safety and effectiveness.

Indications for Use

The Open FMsealer is intended for use in general and gynecological surgery and other open surgical procedures where ligation of vessels, including lymph vessels, is desired. The system creates a vessel ligation (seal) by the application of heat (coagulation) to vessels interposed between the jaws of the device. The Open FMsealer can be used to seal and ligate vessels up to 7mm and tissue bundles as large as will fit in the jaws of the instrument.

The Open FMsealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these purposes.

Performance Testing Data Summary

Questions of safety and effectiveness are the same for this device as they are for the predicate device and other similar devices on the market. All applicable bench testing was performed with the Open FMsealer to assure that it functioned as intended. The clearance of this device was not based on human clinical testing.

Performance testing that was successfully completed includes thermal testing, seal strength testing, tissue histological analysis, and acute and chronic animal studies. These studies showed that the Open FMsealer is at least as effective as the predicate device, which supports the claim of substantial equivalence.

Safety and Biocompatibility 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. Bench testing was performed with the Open FMsealer to assure that it functioned as intended. The system 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.

The patient contacting materials used in the Open FMsealer were chosen for their biocompatibility, function and suitability for the intended use of this device. Successful biocompatibility testing of applicable parts of the system was completed by accredited independent testing laboratories according to ISO 10993-1 and 510(k) Memorandum G95-1. *In-vivo* and *in-vitro* tissue testing was performed that demonstrates that the Open FMsealer is as effective at ligation and sealing of vessels or cutting and coagulation of soft tissue as the LigaSure System.

Conclusion

The Open FMsealer is substantially equivalent to the predicate devices. The intended use of the Open FMsealer is the same as the predicate devices with minor differences that have no effect on safety or effectiveness. The Open FMsealer differs from the LigaSure Shears in technological characteristics; however the differences do not raise different types of questions of safety and effectiveness. The information presented in the 510(k), including the bench, laboratory and animal testing, demonstrates that the Open FMsealer is as safe and effective as the predicate device for its intended use.

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

July 30, 2014

Domain Surgical Incorporated
Mr. Curtis Jensen
Vice President of Quality and Regulatory Affairs
1370 South 2100 East
Salt Lake City, Utah 84108

Re: K141484
Trade/Device Name: Open FMsealer
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 3, 2014
Received: June 5, 2014

Dear Mr. 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141484

Device Name: Open FMsealer

Indications for Use:

The Open FMsealer is intended for use in general and gynecological surgery and other open surgical procedures where ligation of vessels, including lymph vessels, is desired. The system creates a vessel ligation (seal) by the application of heat (coagulation) to vessels interposed between the jaws of the device. The Open FMsealer can be used to seal and ligate vessels up to 7mm and tissue bundles as large as will fit in the jaws of the instrument.

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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)

Joshua C. Nipper -S