DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 6, 2017

Elliquence, LLC.
Mr. Paul Buhrke IV
QA/RA Manager
2455 Grand Avenue
Baldwin, New York 11510

Re: K162490
Trade/Device Name: Disc-FX System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, HRX
Dated: November 22, 2016
Received: November 25, 2016

Dear Mr. Buhrke:

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" (21 CFR 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,

Jennifer R. Stevenson -A

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162490

Device Name
Disc-FX System

Indications for Use *(Describe)*
The Disc-FX System is intended for use in ablation and coagulation of intervertebral disc material during discectomy procedures in the cervical, thoracic, and lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510 (k) Summary

(As required by 21 CFR 807.92(a))

Date Prepared

September 2, 2016

Submitter's Information (807.92(a)(1))

Company Name and Address:

Elliquence, LLC.
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Establishment Registration for Elliquence, LLC is 3007024186.

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Paul D. Buhrke IV– QA/RA Manager
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Device Information (807.92(a)(2))

Trade Name
Disc-FX® System

Common/Usual Name
Bipolar electrosurgical device and arthroscopic accessories

Classification Name and Regulation
Arthroscope & Accessories; 21 CFR 888.1100
Electrosurgical Cutting and Coagulation Device and Accessories; 21 CFR 878.4400

Class
FDA Classification: Class II
FDA Product Code: GEI, HRX

Predicate Devices (807.92(a)(3))

- Disc-FX® System (K052241)
- Arthrocare® Coblator IQ™ Perc-D® Spinewand® (K100353)

Device Description (807.92(a)(4))

The Disc-FX® System is a single-use, disposable kit which is intended for use in ablation and coagulation of intervertebral disc material during discectomy procedures in the cervical, thoracic, and lumbar spine. This device originally received regulatory clearance under 510(k) number K052241 with indications for use limited to the lumbar spine. The design of the Disc-FX® System remains unchanged; the purpose of this 510(k) submission is solely to expand the existing indications of use to include both cervical and thoracic applications.

The Disc-FX® System consists of the following components:

1. Trigger Flex® Bipolar System
2. Trigger Flex® Depth Stop
3. Surgical guidewires
4. Straight cannula
5. Beveled cannula
6. Tapered dilator
7. Trephine

Intended Use (807.92(a)(5))

The Disc-FX® System is intended for use in ablation and coagulation of intervertebral disc material during discectomy procedures in the cervical, thoracic, and lumbar spine.

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Substantial Equivalence Comparison (807.92(a)(6))

The Disc-FX® System is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the two chosen predicate devices:

(1) Disc-FX® System (K052241)
(2) Arthrocare® Coblator IQ™ Perc-D® Spinewand® (K100353)

The following chart provides a side-by-side comparison of the Subject Device and the two predicate devices:

	Disc-FX® System (Subject Device)	**Disc-FX® System (K052241)**	**ArthroCare® Coblator IQ™ Perc-D® SpineWand® (K100353)**
510(k) submitter/holder	elliquence, LLC	Original submitter: Ellman International Inc. Current holder: elliquence, LLC	ArthroCare Corp.
Intended use	The Disc-FX® System is intended for use in ablation and coagulation of intervertebral disc material during discectomy procedures in the cervical, thoracic, and lumbar spine.	The Disc-FX® System is intended for use in ablation and coagulation of intervertebral disc material during discectomy procedures in the lumbar spine.	The ArthroCare® Coblator IQ™ Perc-D® SpineWand® is indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs.
Target anatomy	Cervical, thoracic, and lumbar spine	Lumbar spine	Cervical, thoracic, and lumbar spine
Device classification and code(s)	Arthroscope: Class II, HRX Electrosurgical accessory: Class II, GEI	Arthroscope: Class II, HRX Electrosurgical accessory: Class II, GEI	Electrosurgical accessory: Class II, GEI
Regulation(s)	21 CFR 888.1100: Arthroscope & Accessories 21 CFR 878.4000: Electrosurgical Cutting & Coagulation Device and Accessories	21 CFR 888.1100: Arthroscope & Accessories 21 CFR 878.4000: Electrosurgical Cutting & Coagulation Device and Accessories	21 CFR 878.4000: Electrosurgical Cutting & Coagulation Device and Accessories
Principle of operation	Bipolar electrosurgery	Bipolar electrosurgery	Bipolar electrosurgery
Mechanics of action	Ablation & coagulation of intervertebral disc material	Ablation & coagulation of intervertebral disc material	Ablation & coagulation of intervertebral disc material
Components	1. Trigger-Flex® 2. Depth-stop 3. Guidewires 4. Cannula, straight 5. Cannula, beveled 6. Tapered dilator 7. Trephine	1. Trigger-Flex® 2. Depth-stop 3. Guidewires 4. Cannula, straight 5. Cannula, beveled 6. Tapered dilator 7. Trephine	1. ArthroCare® Coblator IQ™ Perc-D® SpineWand® (various models) 2. (Used with separately-marketed/cleared needles/cannulas)

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	Disc-FX® System (Subject Device)	Disc-FX® System (K052241)	ArthroCare® Coblator IQ™ Perc-D® SpineWand® (K100353)
Access cannula / instrumentation diameter	3.3mm outer diameter (cannula)	3.3mm outer diameter (cannula)	Used with 17G cannula (~1.5mm outer diameter) or 19G cannula (~1.1mm outer diameter) (*Separate from 510(k) submission)
Electrode diameter	2.5mm	2.5mm	0.8mm or 1.0mm (varies by model)
Electrode shaft length	240mm	240mm	76mm, 157mm, 208mm, 219mm or 274mm (varies by model)
Manual controls	Yes; compression of Trigger-Flex® handle controls distal tip protrusion	Yes; compression of Trigger-Flex® handle controls distal tip protrusion	No
RF energy source	elliquence Surgi-Max® generators	elliquence Surgi-Max® generators	ArthroCare® Coblator IQ™ Controller
Maximum power output (Wattage)	120W	120W	400W
RF output frequency	1.7 MHz	1.7 MHz	100 kHz
Patient leakage current	Type BF	Type BF	Type BF
Activation method	Footswitch	Footswitch	Footswitch
Internal memory/circuitry for generator recognition	None	None	None
Single-use only	Yes	Yes	Yes
Supplied sterile / sterilization method	Yes / Ethylene oxide	Yes / Ethylene oxide	Yes / Irradiation
Expiration dating	Yes	Yes	Yes
Packaging	Sterile blister tray, cardboard box	Sterile blister tray, cardboard box	Sterile blister tray, cardboard box
Material composition	Bipolar Probe (Trigger-Flex®): ABS, nylon 12, Loctite, PVC, SUS 304 stainless steel, nickel-plated stainless steel, polypropylene, silicon, and copper Access components: ABS and SUS 304 stainless steel	Bipolar Probe (Trigger-Flex®): ABS, nylon 12, Loctite, PVC, SUS 304 stainless steel, nickel-plated stainless steel, polypropylene, silicon, and copper Access components: ABS and SUS 304 stainless steel	Bipolar probe (Perc-D® SpineWand®): Stainless steel, polycarbonate Access components: Stainless steel, plastic
Patient-contacting materials	Stainless steel , nylon 12, Loctite	Stainless steel , nylon 12, Loctite	Stainless steel, polycarbonate
Temperature Probe	No	No	No
Cooling function	Saline attachment capability	Saline attachment capability	Saline attachment capability

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Non-Clinical Testing (807.92(b)(1))

Testing included to support substantial equivalence:

- Various performance tests including mechanical testing and simulated use tests
- Comparison of the thermal effect of the subject device on intervertebral tissue as compared to predicate
- Electrical safety and electromagnetic compatibility testing in accordance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2
- Testing to support the shelf life determination and sterility of the product
- Biocompatibility analysis

Clinical Testing (807.92(b)(2))

Clinical testing was not included in this submission.

Conclusion (807.92(b)(3))

Based upon a comparison of the intended uses, technological characteristics, and performance testing, we have concluded that the subject device is substantially equivalent to the predicate devices.