November 24, 2020

Fulwell LLC
℅ Jet Li
Regulation Manager
Guangzhou KEDA Biological Tech Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, Guangdong
China

Re: K200931
Trade/Device Name: RF Surgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 23, 2020
Received: September 28, 2020

Dear Jet Li:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200931

Device Name
RF Surgical Generator, Model: FW-120A

Indications for Use *(Describe)*
RF Surgical Generator FW-120A is an electrosurgical generator containing monopolar and bipolar technology. It is intended for use with accessories during surgical procedures where the surgeon requires electrosurgical cutting and coagulating.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary (K200931)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 878.4400, and there were no prior submissions for the subject device.

1 Submitter Information

Sponsor: Fulwell LLC
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Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhou City, China

2 Subject Device Information

Type of 510(k) submission: Traditional
Trade/Device Name: RF Surgical Generator
Model: FW-120A
Classification Name: Electrosurgical, Cutting & Coagulation & Accessories
Review Panel: General & Plastic Surgery
Product Code: GEI
Regulation Number: 21 CFR 878.4400
Regulation Class: 2

3 Predicate Device Information

Sponsor: ELLMAN INTL., INC.
Trade/Device Name: Surgitron 120 IEC
510K number: K013255
Classification Name: Electrosurgical, Cutting & Coagulation & Accessories
Review Panel: General & Plastic Surgery
Product Code: GEI
Regulation Number: 21 CFR 878.4400
Regulation Class: 2

4 Device Description

RF Surgical Generator FW-120A, is a compact source of high power RF energy, enhanced capability of radiosurgery generator, which can be employed for a variety of radiosurgery procedures, such as cut and coagulate living human tissue.

The device which is consisted of a generator, an IEC Neutral Plate, and a Two Pedal Footswitch, provides 5 modes and corresponding output power ranges that is user/operator selectable based on the surgical procedure undertaken. The action is achieved by front panel selection of waveforms and power level. All selection is affected through push buttons and indicators which give the operator feedback of status. Power level for each mode is indicated by front panel digital displays

The device is provided with safety features of automatically system initialize self-check after power on and continuously monitored during the device running. The device will provide error information and/ or alerts when detect following faults, such as a) Accessary fail connection, b) Overheating of Main Unit, c) Neutral plates Contact resistance exceed the limit, d) System initialize error. The error monitoring is interlocked with the controls to prevent operation when fault condition happened in the unit.

The generator is configured for Monopolar and Biopolar output and the final output power could be controlled by pedal foot switch and/or hand switches.

Recommended Monopolar Handpieces 510(k) No.: K092634.

Recommended IEC Neutral Plate 510(k) No.: K102372.

5 Intended Use/Indication for use

RF Surgical Generator FW-120A is an electrosurgical generator containing monopolar and bipolar technology. It is intended for use with accessories during surgical procedures where the surgeon requires electrosurgical cutting and coagulating.

6 Performance data

Verification testing, including electrical safety/electromagnetic compatibility, software verification/validation were performed for RF Surgical Generator.

a) RF Surgical Generator has been evaluated the safety and performance by lab bench testing according to the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, 2014
- IEC 60601-2-2, Medical Electrical Equipment - Part 2-2: Particular Requirements for The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And

High Frequency Surgical Accessories, Edition 6.0 2017-03

b) RF Surgical Generator has been evaluated the basic mechanical and functional capabilities to determine substantial equivalence to the predicate device. According to the guidance document *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery,* the device has been tested for applicable items such as thermal damage, CQM and so on.

In particular, tests have been carried out with respect to the following subject areas.

1) System Performance and waveform outputs test.

2) Thermal effects testing: the thermal damage of the tissue due to the HF current was measured in terms of size (length, width and depth) of the thermal zone in all applicable modes: porcine muscle, liver, and kidney.

c) RF Surgical Generator has performed software verifications to ensure the device worked appropriately as a moderated concern level software according to the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. .

7 Comparison to Predicate Device

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise any new questions of safety or effectiveness.

Elements of comparison	Subject Device	Predicate Device	Verdict
Manufacturer	Fulwell LLC	ELLMAN INTL., INC.	--
510K number	K200931	K013255	--
Product Name	RF Surgical Generator FW-120A	Surgitron 120 IEC Also known as Surgitron 4.0 Dual RF	--
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	SE
Regulation Class	2	2	SE
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	SE
OTC & Rx	Rx	Rx	SE
Indications for Use			
Indications for Use	RF Surgical Generator FW-120A is an electrosurgical generator containing monopolar and bipolar technology. It is intended for use with accessories during surgical procedures where the surgeon requires electrosurgical cutting and coagulating.	Cutting: snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags and blepharoplasty. Blend cutting and coagulation: snoring, submucosal palatal shrinkage,	SE, Minor Difference. We remove the specified indication for use for subject device; it do not raise safety and

		traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin tags, papilloma keloids, keratosis, verrucae, basal cell carcinoma, nevi, fistulas, epithelioma, cosmetic repairs, cysts, abscesses, development of skin flaps. Hemostasis: control of bleeding, epilation, telangiectasia. Fulguration: basal cell carcinoma, papilloma, cyst destruction, tumors, verrucae, hemostasis. Bipolar: pinpoint precise coagulation, pinpoint hemostasis in any field (wet or dry), snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage.	effectiveness issue.
Device Design			
Working Theory	■ Monopolar: RF generator connects its accessories of a handpiece and an IEC Neutral Plate (adhered to patient skin) to form a cyclic circuit, the RF current generated from the generator and through the Monopolar handpiece to achieve CUT or COAG, then return to generator by the IEC Neutral Plate. ■ Bipolar: RF current generated from the generator and the cyclic circuit formed between the two tips of the bipolar forceps, the RF power through the two tips to work on patient obtaining COAG.	■ Monopolar: RF generator connects its accessories of a handpiece and an IEC Neutral Plate (adhered to patient skin) to form a cyclic circuit, the RF current generated from the generator and through the Monopolar handpiece to achieve CUT or COAG, then return to generator by the IEC Neutral Plate. ■ Bipolar: RF current generated from the generator and the cyclic circuit formed between the two tips of the bipolar forceps, the RF power through the two tips to work on patient obtaining COAG.	SE
Appearance			SE Note 1
Interface Accessories	Two Pedal Footswith, Handpieces, IEC Neutral Plate, Power Cord	Triple Footswith, Handpieces, Neutral Pad, Power Cord	SE Note 1
Operation Mode	Cutting, Blend cutting and coagulation, Hemostasis, Fulguration, Bipolar	Cutting, Blend cutting and coagulation, Hemostasis, Fulguration, Bipolar	SE
Waveforms	Cutting:4.0MHz Sinusoid Blend cutting and coagulation: 4.0MHz with fully rectified envelope Hemostasis: 4.0MHz with partially rectified envelope Fulguration: 4.0MHz with modulated Bipolar: 1.7MHz	Cutting:4.0MHz CW Sin-Wave Blend cutting and coagulation: 4.0MHz with rectified full-wave envelope Hemostasis: 4.0MHz with square wave rectified envelope Fulguration: 4.0MHz Sin-Wave Modulated Bipolar: 1.7MHz for Fulgurating Spark-Gap	SE Note 2
Activation	Cutting: via footswitch or finger switch Blend cutting and coagulation: via footswitch or finger switch Hemostasis: via footswitch or finger switch Fulguration: via footswitch or finger switch Bipolar: via footswitch	Cutting: via footswitch or finger switch Blend cutting and coagulation: via footswitch or finger switch Hemostasis: via footswitch or finger switch Fulguration: via footswitch or finger switch Bipolar: via footswitch	SE

Rated Duty Cycle	10s on, 30s off	10s on, 30s off	SE
Energy type	RF	RF	SE
Feedback system	Indicators, audio alarm, Error codes	Indicators, audio alarm, Error codes	SE
Neutral Electrode monitor resistance	MAX 1000Ω	MAX 1000Ω	SE
Input Power	Nominal line voltage and frequency: 120Vac~ ±10%, 60 Hz. /230Vac~ ±10%, 50 Hz. Input current at max output power: 3.3/1.5A.	Voltage: 240/220/120/100V, ±10% 240/230/120/100V, ±10% Frequency: 50Hz Current: For 240~220V: 3.3A, For 120~100V: 1.5A	SE Note 1
Output Power	Cutting: 120W@500Ω Blend cutting and coagulation: 80W@500Ω Hemostasis: 60W@500Ω Fulguration: 40W@500Ω Bipolar: 120W@200Ω	Cutting: 120W@500Ω Blend cutting and coagulation: 80W@500Ω Hemostasis: 40W@500Ω Fulguration: 40W@500Ω Bipolar: 120W@200Ω	SE Note 2
Fuses	T 2.0A, 250V, Two pieces for 230Vac T 4.0A, 250V, Two pieces for 120Va	2* T 2.0AL, for 250V 2* T 4.0AL, for 110V	SE Note 1
Electric shock protection	Class I	Class IIb	SE Note 1
Defibrillation protection	Type BF	Type BF	SE
Dimensions	235mm*120mm*340mm(W*H*D)	9"*5"*13" (W*H*D) ≈228mm*127mm*330mm	SE Note 1
Weight	11Kg	18lbs, ≈8.16kg	SE Note 1
Working condition	-10℃- +40℃ 30% - 75%	-10℃- +40℃ 30% - 75%	SE
Transport and Storage	-10℃- +50℃, 10% - 95% 500hPa–1060hPA	-10℃- +50℃, 10% - 95% 500hPa–1060hPA	SE
Sterility	Non-sterile	Non-sterile	SE
FDA-Recognized Standards			
Safety Performance	ANSI AAMI ES60601-1 IEC 60601-2-2	UL2601, IEC 601-1, IEC 601-2-2 BS15724:2.2	SE Note 2
EMC Performance	IEC 60601-1-2	/	SE Note 3

Note 1

Although the subject device design and specification parameters, such as appearance / dimensions / weight / power supply / electric shock protection, have a little difference to the predicate device, these minor differences do not affect the device' mainly function, which are has been testing the electrical safety via the IEC 60601 standards tests, and these differences will not create any new safety risks to the performance and safety.

Note 2

Although the waveform and output power of subject device has a little different to predicate device, the performance test has proved that the performance of subject device is substantial equivalence

to the predicate device. So the differences do not affect the safety and effectiveness.

Note 3

Although the complied standards of electrical safety and EMC performance are different to the predicate device, it's only because the version of predicate device's complied standards are invalidated and been updated. The subject device has complied to the necessary standards as existing similar products, so the differences do not affect the safety and effectiveness.

9 Conclusion

The subject device RF Surgical Generator has all features of the predicate device for intended use. Thus, the subject device is substantially equivalent to the predicate device.

10 Summary Prepared Date

22 Nov. 2020