June 13, 2019

FULWELL LLC
℅ Jet Li
Regulation Manager
Guangzhou LETA Testing Tech Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
GuangZhou, China 510060

Re: K183564
Trade/Device Name: Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 14, 2019
Received: May 16, 2019

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 and Part 809); 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

Jennifer R. Stevenson
Acting Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183564

Device Name
Electrosurgical Generator, Model FW-350A

Indications for Use *(Describe)*
The Electrosurgical Generator – Model FW-350A is a non-sterile, reusable multi-purpose electrosurgical generator that is designed to perform monopolar and bipolar functions in the surgical operation area.

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

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.There is no prior submission for this device.

1 510 (k) submitter

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2 Subject Device Information:

Type of 510(k) submission: Traditional
Trade Name: Electrosurgical Generator – Model FW-350A
Common Name: Electrosurgical cutting and coagulation device and accessories.
Classification Name: electrosurgical, cutting & coagulation & accessories
Review Panel: General& Plastic Surgery
Product Code: GEI
Regulation Number: 21 CFR 878.4400
Regulation Class: II

3 Predicate Device Information:

Sponsor	Valleylab. Inc.
Device Name	Valleylab Force Fx
510(k) Number	K944602
Product Code	GEI
Regulation Number	878.4400

Regulation Class	2

1. Device Description

Electrosurgical Generator-Model FW-350A has Monopolar and Bipolar modes that can satisfy the general requirements of electrosurgical field. The CQMS function can monitor the area of patient body applied with ESU pad during the operation every 40μs. Once the pad loses or that area shrinks, the computer will cut off all outputs within 40μs to prevent patient from getting burnt. The PPS system ensure the safety of a constant output that send out compulsory stimulation at the initial instant of every CUT or COAG to make the operation process go smoothly. Moreover, the memory function can decrease the medical staff workload and human errors. At last, the Power ON self diagnostics function can diagnosis whether all working modes and functions are working normally and feedback information by code displaying and alarm voice prompt that the operational safety is improved greatly.

The electrosurgical generator can be compatible with electrosurgical accessories based on their output rating with FDA clearance. For example:
FDA 510k cleared Electrosurgical pencil：510(k) No.: K092634 or other FDA cleared pencil
FDA 510k cleared Electrosurgical pad: 510(k) No.: K102372 or other FDA cleared pad

5. Intended Use / Indications for Use

The Electrosurgical Generator – Model FW-350A is a non-sterile, reusable multi-purpose electrosurgical generator that is designed to perform monopolar and bipolar functions in the surgical operation area.

6. Design

Operating principles:
There're two working modes of electrosurgical generator: **monopolar and bipolar**
A. monopolar mode:
With this mode, cutting and coagulation of the tissues are accomplished by an integral circuit that consists of electrosurgical generator and its applicable accessories (ESU pencil, split ESU pad, which are not included in this submission, as long as the Up≥4500V of these accessories that will be compatible, details refer to user manual). In most applications the current goes through the patient body by electrosurgical pencils and then returns to the generator by the circuit made of electrosurgical pad.
B. Bipolar forceps mode:
Bipolar forceps provide high frequency electric power to human body by the two points of the forceps that coagulate the blood to make hemostatic effect through dehydrating the vessels between the bipolar forceps. However, this function is limited within the area between the two forceps points and its damage on the tissue and influence area is far less than the electrosurgical pencils does, therefore, it is suitable to the ligation of small vessels (diameter <4mm) and salpinx and more widely used in the operations requiring high precision such as brain surgery, microsurgery, Ophthalmology and Otorhinolaryngology and gynecological surgery. The safety advantage of bipolar forceps is gaining more and more recognitions and its applications are being enriched.
Please refer to "VOL_006_Attachment 4. Proposed Labeling" to get detailed information

7. Physical characteristics

Please refer to "VOL_007_Attachment 5. Performance Test Report" to get more information.

Basic Unit Characteristics

Model	**FW-350A**
Category of the Device:	Class I Equipment (IEC 60601-1)
Type:	Type CF Equipment Defibrillator Proof
Duty Cycle:	Intermittent loading continuous operation(10s/30s)
Max. power:	350W
Working frequency:	(330~460) kHz
Software version of the equipment:	Version: 350AV1.1
Input power:	
Input Voltage:	120/230V~VAC
Mains line frequency:	60Hz/50Hz
Power consumption:	880VA
Fuse(two):	F6AΦ5X20
Dimensions and Weight:	
Width:	380mm
Depth:	430mm
Height:	165mm
Weight:	7kg
Operating Parameters:	
Ambient temperature range:	5~40 C°
Relative humidity:	≤80%
Atmospheric pressure:	86.0~106.0 Kpa.
Warm-up time:	If transported or stored at temperatures outside the operating temperature range, allow one hour for the generator to reach room temperature before use.
Transport and Storage:	
Ambient temperature range:	-40C° to +55C°
Relative humidity:	RH≤80 %
Atmospheric pressure:	50kPa to 106kPa

8. Test Summary

Electrosurgical Generator – Model FW-350A had been evaluated the safety and performance by lab bench testing as following:

8.1 Safety and EMC Compliance with following standard:

1) IEC 60601-1: 2012: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

2) IEC60601-1-2: 2014: Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic Compatibility

3) IEC60601-2-2: 2009: Medical Electrical Equipment - Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

8.2 Performance testing

To demonstrate that the Electrosurgical Generator meets all design specifications and performance requirements, nonclinical bench testing has been performed in accordance with the internal R&D process in compliance with the proposals and recommendations of FDA guidance: "Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery" – Guidance for Industry and Food and Drug Administration Staff, August 15, 2016.

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.

3) Preclinical Test/Histology study

Thermal Zone Damage on tissue. Side by side testing was performed on ex vivo animal tissues (liver, kidney, and muscle) and thermal damage was assessed by measuring the depth/ length/width of damage at minimum, default, and maximum power settings using histology.

8.3 Software validation

The software was designed and developed according to a software development process and was verified and validated. The software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on May 11, 2005.

8.4 Clinical testing

Clinical and animal studies were not necessary.

9. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of Electrosurgical Generator – Model FW-350A is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices is below listed items, but they do not raise new issues of safety or effectiveness:

• Minor difference on Maximum power, and some output waveform parameters

• Out shape and dimension

Substantial equivalence is demonstrated by acknowledged verification/validation methodologies.

Element of Comparison	**Subject Device**	**Predicate Device**	**SE Comparison**
Manufacturer	FULWELL LLC	Valleylab. Inc.	N/A
Model name	FW-350A	Valleylab Force Fx	N/A
510(k) number	pending	K944602	N/A
Type	CF(with protection for discharge effect of defibrillator)	CF	Same

Element of Comparison		Subject Device	Predicate Device	SE Comparison
Indication for use		The ESU generator FW-350A is a non-sterile, reusable multi-purpose ESU generator that is designed to perform monopolar and bipolar functions in the surgical operation area.	The Valleylab Force Fx is an isolated, microprocessor based ESU generator intended for use in the operating room for general procedures where ESU cutting and coagulation is required. The generator is equipped with monopolar and bipolar outputs.	Same
Working theories	**Monopolar**	ESU generator connects its accessories of a ESU pencil and a split ESU pad (adhered to patient skin) to form a cyclic circuit, the HF current generated from the generator and through the ESU pencil to achieve CUT or COAG, then return to generator by the ESU pad.	ESU generator connects its accessories of a ESU pencil and a split ESU pad (adhered to patient skin) to form a cyclic circuit, the HF current generated from the generator and through the ESU pencil to achieve CUT or COAG, then return to generator by the ESU pad.	Same
	Bipolar	HF current generated from the generator and the cyclic circuit formed between the two tips of the bipolar forceps, the HF power through the two tips to work on patient obtaining COAG, no need extra ESU pad.	HF current generated from the generator and the cyclic circuit formed between the two tips of the bipolar forceps, the HF power through the two tips to work on patient obtaining COAG, no need extra ESU pad.	
Labeling		See Chapter 13	See Chapter 13	SE
Physical Specification	**Appearance**			N/A

Element of Comparison		Subject Device	Predicate Device	SE Comparison
	Essential components	Chassis and Cover, Front panel controls, Power supply board, Microprocessor board, Footswitch board, Interface circuits, Front panel receptacles.	Chassis and Cover, Front panel controls, Power supply board, Microprocessor board, Footswitch board, Interface circuits, Front panel receptacles.	Same
	Energy	HF energy	HF energy	Same
	Dimensions and weight	43cm(L)×38cm(W)×16.5(H), Weight:7kg	35.6cm(L)×43.9cm(W)×11.1(H), Weight<10.9kg	NA
	Working condition	Circumstance Temperature : 5~40 ℃ Relative Humidity : ≤80% Atmospheric Pressure: 86.0~106.0 Kpa.	Circumstance Temperature : 10~40 ℃ Relative Humidity : 30≤RH≤ 95% Atmospheric Pressure: 70.0~106.0 kPa.	1.Minor Different
	Transport and Storage	Ambient temperature : -40℃ to +55℃ RH≤80 % Atmospheric pressure: 50kPa to 106kPa	Ambient temperature : -40℃ to +70℃ RH:10% to 100%, non condensing Atmospheric pressure: 50kPa to 106kPa	2.Minor Different
	Fuses	Two, 6A	Two, 8A	3.Minor Different
	Safety performance	Conforming with ES60601-1 ;IEC 60601-2-2 ;	Conforming with IEC 60601-1 ;IEC 60601-2-2 ;	Same
	EMC performance	IEC60601-1-2	IEC60601-1-2	Same
	Sterility	Not applicable	Not applicable	Same
	Display	Huge High-definition digital display	Power and Err display with huge high-definition digital on the display screen	Same
	Input power	120V/230V, 60Hz/50Hz	100-120V/220-240V, 60Hz/50Hz	4.Minor Different
Performance Specificatio	**Output mode**	**CUT:** **Pure cut:** 350Wmax, Load:500Ω, Crest factor:1.6 **Blend 1(macro):** 250Wmax, Load:500Ω, Crest factor:1.8	**CUT:** **Low cut:** 300Wmax, Load:300Ω, Crest factor:1.5 **Pure cut:** 300Wmax, Load:300Ω, Crest factor:1.5 **Blend:** 200Wmax, Load:300Ω,	5.Minor Different

Element of Comparison			Subject Device	Predicate Device	SE Comparison
			Blend 2(micro): 150Wmax, Load:500Ω, Crest factor:2.4	Crest factor:2.5	
			COAG: **COAG1(Spray):** 120Wmax, Load:500Ω, Crest factor:7.2 **COAG2(Forced):** 100Wmax, Load:500Ω, Crest factor:6.7 **COAG3(Soft):** 50Wmax, Load:500Ω, Crest factor:4.7	**COAG:** **Low (Desiccate):** 120Wmax, Load:500Ω, Crest factor:5.0 **Med (Fulgurate):** 120Wmax, Load:500Ω, Crest factor:7.0 **High (Spray):** 120Wmax, Load:500Ω, Crest factor:8.0	
			BIPOLAR: **Bipolar1(macro):** 100Wmax, Load:100Ω, Crest factor:1.6 **Bipolar2(micro):** 100Wmax, Load:100Ω, Crest factor:1.6	**BIPOLAR:** **Low (Precise):** 70Wmax, Load:100Ω, Crest factor:1.5 **Med (Standard):** 70Wmax, Load:100Ω, Crest factor:1.5 **Macro:** 70Wmax, Load:100Ω, Crest factor:1.5	
	Waveforms	**CUT**	**Pure cut:** 431Khz sinusoid, 100%duty cycle; **Blend1**:431kHz sinusoid at 50% duty cycle with a 32kHz repetition rate; **Blend2:**431kHz sinusoid at 70% duty cycle with a 32kHz repetition rate.	**Low:** 390kHz sinusoid, 100%duty cycle, similar to Pure cut mode except the maximum voltage is limited to a lower value; **Pure:** 390kHz sinusoid with effect mode, 100%duty cycle; **Blend:** 390kHz bursts of sinusoid recurring at 27kHz intervals.50%duty cycle.	6.Minor Different
		COAG	**COAG1(Spray):** 431kHz sinusoidal bursts with a repetition frequency of 32kHz; **COAG2(Forced):** 431kHz sinusoidal bursts with a repetition frequency of 32kHz; **COAG3(Soft):** 431kHz sinusoidal bursts with a repetition frequency of 32kHz;	**Low (Desiccate):** 240kHz sinusoid repeated at 39kHz, 8% duty cycle; **Med (Fulgurate):** 470kHz damped sinusoid bursts with a repetition frequency of 30kHz into 500ohms; **High (Spray):** 470kHz damped sinusoidal bursts with a randomized repetition centered at 28kHz, frequencies include 21kHz < f < 35kHz. Output is further modulated by a random 250Hz envelop with a variable duty cycle.	
		BIPOLAR	**Bipolar1(macro):** 431Khz sinusoid, 100% duty cycle; **Bipolar2(micro):** 431Khz sinusoid, 100% duty cycle;	**Low(precise):** 470kHz sinusoid, 100%duty cycle; Med(standard): 470kHz sinusoid, 100%duty cycle; **Macro:** 470kHz sinusoid, 100%duty cycle	
	Power		880VA	850VA	7.Minor

Element of Comparison		Subject Device	Predicate Device	SE Comparison
	consumption			Different
	Output frequency	330~460KHz Sinusoid	390~470KHz Sinusoid	8.Minor Different
	Current (120V)	Idle:0.1Amax Cut: 5.0A max Coag:2.5Amax Bipolar: 2.0A max	Idle:0.4A max Cut: 7.0A max Coag: 4.0A max Bipolar: 2.0A max	9.Minor Different
	Compatibility	Vpeak=4500V	Vpeak=9000V	10.Minor Different
	Open circuit Vp-p(max)	Monopolar CUT Pure: 2120V Blend1: 2720V Blend2: 2200V	Monopolar CUT Low : 1350V Pure: 2300V Blend: 3300V	11.Minor Different
		Monopolar COAG COAG1(Spray):4500V COAG2(Forced): 4150V COAG3(soft): 2500V	Monopolar COAG Desiccate:3500V Fulgurate: 8500V Spray: 9000V	
		Bipolar: Bipolar1(macro): 500V Bipolar2(micro):350V	Bipolar: Precise: 450V Standard: 320V Macro: 750V	
	Operation mode	Under maximum power settings and rated load conditions (pure cut350W, 500ohm load) the generator is suitable for activation times of 10seconds on, 30seconds off for 1 hour.	Under maximum power settings and rated load conditions (pure cut300W, 300ohm load) the generator is suitable for activation times of 10seconds on, 30seconds off for 1 hour.	Same
Special Functions	**CQMS**	The ESU pad contact quality monitor system (CQMS) will measure the resistance between the ESU pad and patient, if the resistance was beyond the defined upper limit, the alarm system will be activated.	Force FX (REM): The Return Electrode Contact Quality Monitor will measure the resistance, if the resistance was beyond the range of defined by an upper and lower limit, the alarm system will be activated.	12.Minor Different
	PPS/Instant response technology	Automatically senses resistance and adjusts the output voltage to maintain a consistent effect across different tissue density (bipolar or cut modes only)	Automatically senses resistance and adjusts the output voltage to maintain a consistent effect across different tissue density (bipolar or cut modes only)	13.Similar
	Memory	10 memory settings, the previous power setting digits presented when restart	Recall the last activated previous setting when Power On next time by pressing RECALL	14.Minor Different
	Power ON self diagnostics	In the self diagnosis process after Power ON, all working modes and functions operating are simulated and monitored by software control to determine whether they are performed normally, followed by transmitting of corresponding	Force Fx: When the generator senses a system alarm conditions, an alarm sounds and an alarm number is displayed on the front panel. A system alarm	15.Minor Different

Element of Comparison		Subject Device	Predicate Device	SE Comparison
		test data to the display module through the control module. If failure occurs, the respective code will be displayed accordingly as prompt and alarm voice delivered simultaneously, which disables all subsequent operations automatically.	condition deactivates the generator.	
	Operating	Only one output device to be activated at any given time	Only one output device to be activated at any given time	Same

Difference further discussion

Items	Further discussion
Working, storage and transportation parameters (1,2 different)	These data is to specify the conditions of working, transportation and storage, for different device, the internal circuit design and components choosing are different, so they also have similar difference on working or storage conditions. But the temperature, RH and atmospheric pressure are approximate and complied with the normal conditions, so it can be deemed as the substantially equivalence.
Fuses (3. different)	The model selection of fuse is according to the maximum current that maybe present, and the function is to protect the unit. The different device has the different maximum input current, accordingly with the different fuse parameter, but these factors do not affect the actual application.
Input power (4. different)	The design of input voltage is according to the supply voltage of the local country or state. Our parameter 120/230V, 60Hz/50Hz is applied to America and Europe, and moreover, there is a permission of ±10% fluctuation, thus the subject device is actually the same as predicated ones.
Output mode (5. different)	Both the subject device and predicated ones have monopolar CUT, monopolar COAG and BIPOLAR. Both of them are sinusoid as well as a similar output power under the same output mode, accordingly with the similar crest factor; For maximum power difference, Thermal effect testing was evaluated between subject device and predicate device with comparable power and model setting, the comparison shown that such minor difference will not affect the safety. So the delicate differences have no influence on safety and performance.
Waveforms (6. different)	The frequency is above 200 kHz, belong to High frequency range based on IEC60601-2-2 Requirement; The related waveform of FW-350A and Force Fx are mainly with the same shape, the slight differences are because of respective design parameter, which have no influence in the actual application process. And through the thermal damage zone testing, Thermal effect was evaluated and compared between predicate device and subject device.

Items	Further discussion
	So such minor difference on waveform would not affect the safety and effectiveness
Power consumption (7. different)	It means the power absorbed by the unit itself, for different unit has different consumption. The lower consumption, the more power saving, however, more or less of this parameter, doesn't impact the output effect on patients.
Output frequency (8. different)	The output frequency of subject device and predicated devices are more than 200kHz, so both of them are met the requirements of high frequency electrosurgical equipment.
Current (9. different)	The results were obtained from actual testing, and are very similar with the predicate device, furthermore, these data has no influence on application.
Compatibility (10. different)	It specifies the choosing of applied accessories, which as a safety information supplied to inform user that the rated voltage of accessories must greater than unit Vpeak. Therefore, this data has no influence on normal output. (Please refer to IEC60601-1 and IEC60601-2-2 test reports).
Open circuit Vp-p(max) (11. different)	The effect of each operational modes is determined by their frequency, waveforms, output power and Vp-p, even there is difference for Vp-p of the subject and predicate device, but it can still obtain the same effect by adjusting other parameters. CUT and BIPOLAR modes are small difference on Vp-p of the subject and predicate device, so we can adjust the output power to obtain the same effect. However, the COAG modes Vp-p of predicate device is much more than subject device, especially for the spray mode is very high of the Vp-p, it really can obtain a rapidly hemostasis for a large area bleeding by its powerful spark, but a patient burnt is often caused by this fierce spark due to user mistakes or inexpert operation, considering this factor, we improved on FW-350A to reduce the Vp-p under the condition of ensuring the same effect so as to increase the application safety.
CQMS (12. different)	FW-350A (CQMS): Alarm range: > 113ohms (a split ESU pad used); Force Fx (REM): Alarm range < 5ohms or ⩾ 135ohms (a split ESU pad used); CQMS can monitor the contact quality of ESU pad to patient; REM can not only monitor the contact quality but also detect whether a solid ESU pad was being used. We have already informed there is a split ESU pad recommended to be used, that marked clearly in the Instruction for use. So this difference cannot influence the safety and effectiveness of our FW-350A.
PPS/IRT (13. similar)	The PPS and IRT were proved as the similar functions.
Memory (14. different)	They are Substantially equivalence.
Power ON self diagnostics (15. different)	Force Fx: power On self diagnostics activated to perform a self test by turn of Bipolar mode, CUT mode, COAG mode, if there was any trouble, the related Error code would be displayed; FW-350A: power On self diagnostics activated to perform a selfish test by turn of CUT mode, COAG mode, Bipolar mode, if there was any trouble, the related Error code would be displayed; So, the difference is test sequence and Error code, both the subject device and predicate device have the same purpose to ensure the unit is came into a normal idle

Items	Further discussion
	mode. Therefore, they are Substantially equivalence

Substantially equivalence Conclusion:

Electrosurgical Generator- Model FW-350A has been carefully compared to legally marketed devices with respect to intended use, essential components, dimension and weight, safety and EMC performance, special functions and performance specifications. They are same in intended use, essential components, function and working theories, and they are identical in physical specification and special functions as well as performance specifications. The safety and performance tests have been done to validate the safety and performance of the device.

Although the FW-350A is slightly differ from the predicate devices as above described, after further discussing we can conclude that it won't affect the effectiveness and safety of the proposed device. Accordingly, we can come to conclusion that the proposed device and predicate devices are **substantial equivalence**