April 26, 2023

LiNA Medical ApS
% Scott Blood
Director of Regulatory Services
MEDIcept. Inc.
200 Homer Ave
Ashland, Massachusetts 01721

Re: K223932
Trade/Device Name: SafeAir combi (SFR-combi-US)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, FYD
Dated: December 28, 2022
Received: March 30, 2022

Dear Scott Blood:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.04.26 14:06:27 -04'00'

Mark Trumbore, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
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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.

Submission Number *(if known)*

K223992

Device Name

SafeAir combi (SFR-combi-US)

Indications for Use *(Describe)*

The SafeAir Combi is an electrosurgical generator containing an integrated surgical smoke evacuator. The unit is intended to deliver high frequency energy for cutting and/or coagulating tissues using monopolar and bipolar tools in surgical procedures. When used with an electrosurgical pencil capable of surgical smoke evacuation, the console is also intended to remove and filtrate smoke generated during electrosurgical procedures.

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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Date: April 26, 2023

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Proprietary or Trade Name: SafeAir combi

Common/Usual Name: Electrosurgical cutting and coagulation device and accessories

Classification Name: Electrosurgical, Cutting & Coagulation & Accessories

Regulation Number: 21 CFR 878.4400, Class II
Classification Product Code: GEI, FYD

Predicate Device: K143161: Covidien Force FX Generators
Reference Predicate: K182224: LiNA Medical Smoke Evacuator compact

Device Description:
SafeAir Combi (model: SFR-Combi-US) is an electrosurgical generator with the added functionality of smoke evacuation. This device is a non-sterile medical device, indicated to be used in operating theatres for use during general surgical procedures. SafeAir Combi uses 5 different output modes: 2 cut modes (Pure and Blend), 2 coagulation modes (Fulguration and Spray) and 1 mode for bipolar accessories. The device operates with a power range of 5-200 Watts for cut modes, 5-120 Watts for coagulation modes and 5-100 Watts for the bipolar mode. The device is intended to be used as a system together with monopolar or bipolar active accessories with a neutral electrode, however this submission is only intended to cover the electrosurgical generator and smoke evacuation feature and dedicated footswitch, without any active surgical accessories. Device is intended to be operated by healthcare professionals in hospitals and clinics where electrosurgical procedures are typically performed.

Indications for Use:
The SafeAir Combi generator is an electrosurgical generator containing an integrated surgical smoke evacuator. The unit is intended to deliver high frequency energy for cutting and/or coagulating tissues using monopolar and bipolar tools in surgical procedures. When used with an electrosurgical pencil capable of surgical smoke evacuation, the console is also intended to remove and filtrate smoke generated during electrosurgical procedures.

Substantial Equivalence:

	Subject Device **LiNA Medical** **SafeAir Combi** **This Submission**	**Predicate Device** **Covidien** **Force FX Generators** **K143161**	**Reference device** **LiNA Medical** **SafeAir Smoke Evacuator compact** **K182224**	**Comparison**
Indications for Use	The SafeAir Combi generator is an electrosurgical generator containing an integrated surgical smoke evacuator. The unit is intended to deliver high frequency energy for cutting and/or coagulating tissues using monopolar and bipolar tools in surgical procedures. When used with an electrosurgical pencil capable of surgical smoke evacuation, the console is also intended to remove and filtrate smoke generated during electrosurgical procedures	The Force FX™ Electrosurgical Generator 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 (resecting, dividing, or separating) and coagulating (hemostasis).	SafeAir Smoke Evacuator compact is designed to remove and filter smoke generated during electrosurgical and laser procedures.	Same with predicate device, reference device

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	Subject Device LiNA Medical SafeAir Combi This Submission	Predicate Device Covidien Force FX Generators K143161	Reference device LiNA Medical SafeAir Smoke Evacuator compact K182224	Comparison
Input power	110 - 230 V, 50-60 Hz	100 - 240 V, 50-60 Hz	100-120V/220-240V, 50Hz/60Hz	Similar
Energy output	HF energy for electrosurgery	HF energy for electrosurgery	Not applicable	Identical
Dimensions and weight	17 x 40 x 40 cm, 22 kg	11 x 35.6 x 35.6 cm, 8.2 kg	14 x 30 x 38, 13.5 kg	Different
Working conditions	Temperature: 10 to 35 °C Relative Humidity: 15-75%, non-condensing Atmospheric Pressure: 800 to 1060 hPa	Temperature: 10 to 40 °C Relative Humidity: 30-75% Atmospheric Pressure: 700 to 1060 hPa	Temperature: 10 to 35 °C Relative Humidity: 30%-75%, non-condensing Atmospheric Pressure: n/a	Similar
Transport and storage	Circumstance Temperature: -10°C to +60°C Relative Humidity: 10% to 90% Atmospheric Pressure: 500 to 1060 hPa	Circumstance Temperature: -40 to +70 °C Relative Humidity: 25-85 % Atmospheric Pressure: 500 to 1060 hPa	Circumstance Temperature: -10 to 60 oC Relative Humidity: 25-85% non-condensing Atmospheric Pressure: n/a	Similar
Display	One LCD touchscreen min. 7 inch diagonal	No touchscreen, buttons for power settings	No touchscreen, buttons for power settings	Different
Electrical protective class	Class I	Class I	Class I	Identical
Duty cycle	25% on max power (10s activation and 30s off)	25% on max power (10s activation and 30s off)	Not applicable	Identical
CQM	Acceptable resistance range (for monopolar activation): - 10 to 130 Ohms - or up to a 30% increase in the initial measured contact resistance (whichever is less)	Acceptable resistance range (for monopolar activation): - 5 to 135 Ohms - or up to a 40% increase in the initial measured contact resistance (whichever is less)	Not applicable	Different
Monopolar	ESU generator connects its electrosurgical accessories and a neutral ESU pad to form a cyclic circuit, the HF current generated from the generator and through the accessory to achieve CUT or COAG, and then return to generator by the neutral pad.	ESU generator connects its electrosurgical accessories and a neutral ESU pad to form a cyclic circuit, the HF current generated from the generator and through the accessory to achieve CUT or COAG, and then return to generator by the neutral pad.	Not applicable	Identical
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.	Not applicable	Identical

	Subject Device LiNA Medical SafeAir Combi This Submission	Predicate Device Covidien Force FX Generators K143161	Reference device LiNA Medical SafeAir Smoke Evacuator compact K182224	Comparison
Output mode MONOPOLAR	2 Different CUT modes CUT Pure: - Power: 200 W max, - Rated load (max): 400 Ω, - Crest factor: 1.5 - Frequency: 472 kHz CUT Blend: - Power: 200 W max, - Rated load (max): 400 Ω, - Crest factor: 2.1 - Frequency: 472 kHz	3 Different CUT modes including CUT Pure with following parameters: - Power: 300W max - Rated load: 300 Ohm - Crest Factor: 1.5 - Frequency: 390 kHz and CUT Blend with following parameters: - Power: 200W max - Rated load: 300 Ohm - Crest Factor: 2.5 - Frequency: 390 kHz	Not applicable	Different
	2 Different COAG modes COAG Fulg: - Power: 120 W max, - Rated load (max): 400 Ω, - Crest factor: 6.6 - Frequency: 472 kHz COAG Spray: - Power: 120 W max, - Rated load (max): 400 Ω, - Crest factor: 7.5 - Frequency: 472 kHz	4 Different COAG Modes, including COAG Fulgurate with following parameters: - Power: 120W max - Rated load: 500 Ohm - Crest Factor: 7.0 - Frequency: 470 kHz COAG Spray with following parameters: - Power: 120W max - Rated load: 500 Ohm - Crest Factor: 8.0 - Frequency: 470 kHz	Not applicable	
Output mode – Bipolar	BIPOLAR: - Power: 100 W max, - Rated load (max): 100 Ω, - Crest factor: 1.6 - Frequency: 472 kHz	3 Different BiPolar modes, including BIPOLAR Standard with following parameters: - Power: 70W max - Rated load: 100 Ohms - Crest factor: 1.5 - Frequency: 470 kHz	Not applicable	Different
Instant response technology	Automatically senses resistance and adjusts the output voltage to maintain a consistent effect across different tissue density	Automatically senses resistance and adjusts the output voltage to maintain a consistent effect across different tissue density	Not applicable	Similar
Power ON self diagnostics	After pressing ON/OFF button, device initiates self testing procedure, which verifies correct functioning of the device. If problems occur, then alarm condition is highlighted on screen, and generator cannot be activated.	When the generator senses a system alarm conditions, an alarm sounds and an alarm number is displayed on the front panel. A system alarm condition deactivates the generator	Not applicable	Similar

	Subject Device LiNA Medical SafeAir Combi This Submission	Predicate Device Covidien Force FX Generators K143161	Reference device LiNA Medical SafeAir Smoke Evacuator compact K182224	Comparison
Filtration rate	The ULPA filter is 99.999% with efficiency at 0.1 microns particle size, SFR-FIL-C filter	Not applicable	The ULPA filter is 99.999% with efficiency at 0.1 microns particle size, SFR-FIL-C filter	Identical to reference device
Filter Life	5 hours	Not applicable	5 hours	Identical to reference device
Levels of smoke evacuation	10 levels	Not applicable	10 levels	Identical to reference device
Levels of smoke evacuation stop delay	10 levels	Not applicable	10 levels	Identical to reference device
Maximum flow rate at filter (claimed in IFU)	110 l/min	Not applicable	110 l/min	Identical to reference device
Maximum flow rate measured on pencil tip	94,2 l/min	Not applicable	97,8 l/min	Similar to reference device

From the comparison above, the subject device and predicate device have similar intended use, are both prescription use, and have the same operating principle. The differences in the devices have been assessed and do not raise new questions of safety or effectiveness.

Non-clinical performance testing:

Electrical Safety:
Electrical safety and electromagnetic compatibility testing were conducted in accordance with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-2 to demonstrate the basic safety, essential performance and emissions and immunity characteristics of the device. The testing demonstrated the appropriate electrical safety and electromagnetic compatibility profile for the device.

Bench / Performance Testing:
Comparative performance testing included:

- Human factors testing
- Transportation simulation
- Smoke evacuation functionality
- Testing in accordance with FDA Guidance "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery"
    - Thermal effects on tissue
    - ESU performance
    - CQM functionality
    - Accessories compatibility

The results demonstrated that the device performance was met and was substantially equivalent to the predicate device.

Substantial Equivalence Conclusion

The subject device and predicate device are intended to deliver high frequency energy for cutting and/or coagulating tissues using monopolar and bipolar tools in surgical procedures. The smoke evacuation function is not a novel feature and there are several cleared devices already used in the US today. Smoke evacuation is recommended to be used in clinical procedures such as electrosurgery in which tissue smoke plume and aerosols can be generated due to concerns about potential carcinogenic effects.

The technological characteristics between the subject and predicate devices are in most cases identical, for those cases where they are similar or different, those differences have been properly tested and evaluated. Design Verification and Validation activities carried out on the SafeAir combi device confirms that device meets specification and performs as intended.

Based on above comparison and discussion, the SafeAir Combi is deemed as safe and effective as and substantially equivalent to the predicate device.

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