February 7, 2019

LiNA Medical APS
% Kevin MacDonald
Regulatory Consultant
Kevin F. MacDonald
4297 D Street
Sacramento, California 95819

Re: K182224
Trade/Device Name: SafeAir Smoke Evacuator compact
Regulation Number: 21 CFR 878.5070
Regulation Name: Air-Handling Apparatus for a Surgical Operating Room
Regulatory Class: Class II
Product Code: FYD
Dated: January 8, 2019
Received: January 9, 2019

Dear Kevin MacDonald:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182224

Device Name
SafeAir Smoke Evacuator compact

Indications for Use *(Describe)*
SafeAir Smoke Evacuator compact is designed to remove and filter smoke generated during electrosurgical and laser 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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510(k) Summary: K182224

510(k) Owner: LiNA Medical ApS
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Date Summary Prepared: 04 Feb 2019

Trade Name of Device: SafeAir Smoke Evacuator compact

Common Name : Air-handling apparatus for a surgical operating room

Classification: Class II

Product Code: FYD

Panel: General and Plastic Surgery Devices

Regulation Number: 21CFR 878.5070

Predicate Device: Visiclear Smoke Evacuation System – K131402

Device Description

SafeAir Smoke Evacuator compact is a device with a vacuum pump that aspirates and filtrates the surgical smoke produced during cauterization.

The main purpose of smoke evacuation systems is to remove surgical smoke plume as close as possible to the surgical site. The component of the system ensuring that this is achieved is a diathermy pencil with integrated smoke evacuation function or a click-on tubing set connected to a surgical smoke evacuator.

SafeAir Smoke Evacuator compact is designed for use in the hospital/clinic environment. It is built around a vacuum pump with a replaceable filter at the entry point. A specially designed pump control is centrally placed in the machine. The SafeAir Smoke Evacuator compact is designed with a pump with different activation functions; manual activation on the front panel, footswitch activation and activation through diathermy pencil with smoke evacuation tubing. Synchronization is possible with most of the electrosurgical units.

Table 1: Models number – main device

Reference number	Description
SFR-compact-US	SafeAir Smoke Evacuator compact

Table 2: Accessories	
Reference Number	**Description**
SFR-FSW-US	SafeAir footswitch
SFR-FIL-C-US	SafeAir ULPA filter with active carbon
SFR-CON-US	SafeAir tubing for bottle connection
SFR-TUB-7-US	SafeAir 7m Tubing Set for external exhaust
SFR-GC-US	SafeAir Grounding cable
SFR-compact-KIT-1-US	SafeAir 1 Year Service KIT for SFR-compact-US
SFR-compact-KIT-3-US	SafeAir 3 Year Service KIT for SFR-compact-US

Indications for Use

SafeAir Smoke Evacuator compact is designed to remove and filter smoke generated during electrosurgical and laser procedures.

Technological Characteristic Comparison

Table 3 compares the SafeAir Smoke Evacuator compact to the predicate devices with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing.

Table 3 – Technological Characteristic Comparison Table			
Variable	**SafeAir Smoke Evacuator *compact* (Subject Device)**	**Visiclear Smoke Evacuation System (Predicate – K131402)**	**Comparison**
510(k) number	K182224	K131402	
Product Code	FYD	Same	Same
Regulatory Class	II	Same	Same
Regulation Number	21 CFR 878.5070	Same	Same
Intended Use	SafeAir Smoke Evacuator compact is designed to remove and filtrate smoke generated during electrosurgical and laser procedures in the vicinity of its source.	The VISICLEAR Smoke Evacuation System is designed to remove and filter smoke, aerosols produced during electrosurgical and laser procedures.	Same
Direct Body Contact Materials	Not intended to come in contact with patient	Same	Same
Energy used	Electrical current	Same	Same
Operational Settings	On/Off Switch, Suction level buttons for Motor Control	Same	Same
Intended marketed accessories	Electrosurgical pencils, tubing, hoses & adaptors – sterile and non sterile	Same	Same
Filtration	The ULPA filter is 99.999% with efficiency at 0.1 microns particle size	The ULPA-grade filter is 99.999% efficiency at 0.1 to 0.2 micron particle size.	Same
Filter Life	5 hours	35 hours	Use life of the filter is established with performance testing and is consistent with intended claims.

Table 3 – Technological Characteristic Comparison Table			
Variable	**SafeAir Smoke Evacuator *compact* (Subject Device)**	**Visiclear Smoke Evacuation System (Predicate – K131402)**	**Comparison**
Filter life indicator	Indicator light	Shut down	When the indicator light is on, the user is instructed to change the filter.
Electrical safety	Tested and compliant with IEC 60601-1 and IEC 60601-1-2	Same	Same
Mechanical safety	Tested and compliant with IEC 60601-1	Same	Same
Chemical safety	neutral pH, non-patient contact	Same	Same
Mechanical safety	Tested and compliant with IEC 60601-1	Same	Same
Chemical safety	neutral pH, non-patient contact	Same	Same
Thermal safety	Operation of the device does not result in harmful temperatures tested and compliant per IEC 60601-1	Same	Same
Radiation safety	non-radioactive	Same	Same
Maximum flow rate (claimed)	110 l/min	839 l/min	Flow rate for the subject device is demonstrated to effectively entrain surgical smoke
Maximum flow rate (suction pencil)*	97.1 l /min	93.2 l/min	Similar
Maximum flow rate (suction tube)*	66.2 l/min	62.2 l/min	Similar
Minimum flow rate (suction pencil)*	41.2 l/min	43.1 l/min	Similar
Minimum flow rate (suction tube)*	26.0 l/min	25.9 l/min	Similar

*All values obtained from simulated use testing

The SafeAir Smoke Evacuator compact shares the same indications for use, device operation, overall technical and functional capabilities as the predicate devices. In addition, the SafeAir Smoke Evacuator compact is similar in design and function to the Visiclear Smoke Evacuation System (K131402) in terms of mode of operation and use.

The technological differences between the SafeAir Smoke Evacuator Compact and predicate device are limited to maximum flow and under-pressure values defined by the manufacturers. These technological differences do not have an impact on the actual clinical use parameters. As confirmed through the design verification testing, both the predicate and subject devices performed as intended, meeting the performance specification independent of the technological differences.

In the design verification testing, accessories representative of components that would be used in a commercial setting were used to assess the clinically relevant flow rate and under-pressure parameters. The accessories included Smoke Evacuation pencils or Smoke Tubing, commonly used in electrosurgical or laser procedures. Both the predicate and subject devices were tested utilizing the same method and accessories and as reported in **Table 3**, the test results were comparable between the predicate and subject devices.

The SafeAir Smoke Evacuator compact shares the same indications for use, device operation, overall technical and functional capabilities as the predicate devices. In addition, the SafeAir Smoke Evacuator compact is similar in design and function to the Visiclear Smoke Evacuation System (K131402) in terms of mode of operation and use.

Sterilization and Biocompatibility

Based on the intended use, both the predicate and subject devices are not intended to come in direct contact with the patient and therefore, do not require sterilization or to be tested for biocompatibility.

Nonclinical Performance Data

The SafeAir Smoke Evacuator compact meets all the requirements for overall design, and electrical safety results confirming that the design output meets the design inputs and specifications for the device.

The SafeAir Smoke Evacuator compact was subjected to safety performance testing in accordance with. AAMI / ANSI ES60601-1.

The SafeAir Smoke Evacuator compact passed all applicable testing in accordance with internal requirements, national standards, and international standards shown below:

- Electrical safety testing per AAMI / ANSI ES60601-1, IEC 60601-1-2,
- Software Validation and Verification per IEC 62304

Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device.