December 14, 2018

LiNA Medical ApS
% Kevin MacDonald
Clinical/Regulatory Consultant
MacDonald Regulatory Consulting
4297 D Street
Sacramento, California 95819

Re: K182354
Trade/Device Name: SafeAir Telescopic Smoke Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 16, 2018
Received: November 19, 2018

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2018.12.14 14:56:52 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182354

Device Name
SafeAir Telescopic Smoke Pencil

Indications for Use *(Describe)*
SafeAir Telescopic Smoke Pencil is designed for general electrosurgical applications, including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

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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K182354
510(k) Summary
SafeAir Telescopic Smoke Pencil

1. Submission Sponsor:

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2. Submission Correspondent:

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3. Date prepared:

December 11, 2018

4. Device Identification

Type of 510(k) Submission:	Traditional
Trade or Proprietary Name:	SafeAir Telescopic Smoke Pencil
Regulation Number:	21 CFR 878.4400
Product Code:	GEI, Electrosurgical Cutting And Coagulation Device And Accessories
Class of Device: Class	II
Panel:	General and Plastic Surgery
Reason for Submission:	New device
Prior Related Submissions:	No prior submissions for the device
Multiple Devices:	n/a

5. Legally Marketed Predicate Device(s)

Stryker Neptune E-SEP Smoke Evacuation Pencil (K160693)

6. Indication for Use Statement

SafeAir Telescopic Smoke Pencil is designed for general electrosurgical applications, including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect

7. Device Description

SafeAir Telescopic Smoke Pencil is designed for general electrosurgical applications and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

SafeAir Telescopic Smoke Pencil has got telescopic function which allows to extend the length of pencil by up to 120 mm. Extension is possible after twisting the green lock-ring.

Model number	
SHK-TSP-US	SafeAir Telescopic Smoke Pencil

8. Substantial Equivalence Discussion

Both the SafeAir Telescopic Smoke Pencil and the Stryker Neptune E-SEP Smoke Evacuation Pencil (K160693) are manufactured by LiNA Medical in Poland. The subject and predicate devices are substantially equivalent in terms of technological characteristics and intended use. The primary difference is the telescopic feature present on the SafeAir Telescopic Smoke Pencil (Subject device).

Substantial Equivalence Table		
Characteristic	**Predicate Device Stryker Neptune E-SEP Smoke Evacuation Pencil K160693**	**Subject Device SafeAir Telescopic Smoke Pencil**
Product Code	GEI	Same
Regulatory Class	II	Same
Regulation Name	Electrosurgical Cutting And Coagulation Device And Accessories	Same
Regulation Number	21 CFR 878.4400	Same
Prescription	Yes	Same
Intended Use	The Neptune E-SEP is an Integrated Smoke Evacuation Pencil (pencil) designed for general	SafeAir Telescopic Smoke Pencil is designed for general electrosurgical

Substantial Equivalence Table		
Characteristic	**Predicate Device Stryker Neptune E-SEP Smoke Evacuation Pencil K160693**	**Subject Device SafeAir Telescopic Smoke Pencil**
	electrosurgical applications including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit (generator) to the operative site for the desired surgical effect	applications, including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.
Overall Design	Designed to integrate smoke evacuation into electrosurgery by combining both features into a single handpiece	Designed to integrate smoke evacuation into electrosurgery by combining both features into a single handpiece. Incorporates a telescoping feature allowing the length top extended up to 120mm
Power Supply	Monopolar Generator	Same
Voltage Rating	5.5 kV peak	Same
Electrical Connector	US-3-Pin	Same
Electrical Safety Testing	ISO 60601-1 ISO 60601-1-2 ISO 60601-2-2	Same
Sterility	Sterile Single Use, EtO, SAL 10^{-6}	Same
Packaging	Individually packaged pencil and electrode in Tyvek pouch, sold 10 per box	Same
Electrode Rod	303 SST	Same
Electrode Rod Diameter	2.36mm	Same
Electrode Connector Shape	Pentagon	Heat shrink sheath
Electrode Connector Material	ABS Polylac PA-757	PTFE Heat shrink
Electrode shaft insulation (overmold)	ABS Polylac PA-757	None
Electrode Tip Material	303 SST	Same
Electrode Tip Coating	None	Same
Electrode Tip Working length	70-165mm	70mm
Electrode Tip Insulation	None	None

Substantial Equivalence Table		
Characteristic	**Predicate Device Stryker Neptune E-SEP Smoke Evacuation Pencil K160693**	**Subject Device SafeAir Telescopic Smoke Pencil**
Adjustable Suction Sleeve Material	Acrylonitrile Butadiene Styrene with barium sulfate	Trianmx731 transparent
Evacuation Tubing Dimension	10 mm dia x 3 m length	Same
Smoke Evacuation System connector	8mm, 22m	Same
Handpiece Housing Material	Acrylonitrile Butadiene Styrene with Thermoplastic Elastomer	Same
Handpiece Dimensions	15mm dia x 190mm length	18 mm x 200 mm length
Operation Function Switches	CUT/COAG buttons available in both Rocker-switch and Pushbutton-switch configuration	CUT/COAG buttons available in Pushbutton configuration
Accessories	Holster-Clip provided	None
Tissue contacting Materials	Compliant with ISO 10993-1	Same
Range of Electrodes	Neptune ® E-SEP TM 165mm Blade Electrode, Coated and Insulated Neptune ® E-SEP TM 125mm Blade Electrode, Coated and Insulated Neptune ® E-SEP TM 70mm Blade Electrode, Coated and Insulated Neptune E-SEP 165mm blade electrode Neptune E-SEP loop t-bar electrode W20 D15 L60 Neptune E-SEP conization electrode W20 D20 L120 Neptune E-SEP 125mm blade electrode Neptune E-SEP conization electrode W13 D20 L120 Neptune E-SEP 70mm Blade electrode Neptune E-SEP 70mm needle electrode Neptune E-SEP 5mm ball electrode Neptune E-SEP loop t-bar electrode W20 D20 L120 Neptune E-SEP loop t-bar electrode W20 D20 L60	Same

Substantial Equivalence Table		
Characteristic	**Predicate Device** **Stryker Neptune E-SEP Smoke Evacuation Pencil K160693**	**Subject Device** **SafeAir Telescopic Smoke Pencil**
	Neptune E-SEP 165mm blade electrode coated Neptune E-SEP conization electrode W13 D15 L120 Neptune E-SEP loop u-bar electrode W20 D20 L120 Neptune E-SEP conization electrode W16 D18 L 120 Neptune E-SEP loop t-bar electrode W10 D10 L120 Neptune E-SEP 70mm blade electrode coated Neptune E-SEP loop t-bar electrode W20 D15 L120 Neptune E-SEP 3mm ball electrode Neptune E-SEP conization electrode W16 D8 L120 Neptune E-SEP 125mm blade electrode coated Neptune E-SEP loop t-bar electrode W15 D12 L120	

The SafeAir Telescopic Smoke Pencil shares the same intended use, device operation, overall technical and functional capabilities as the predicate device. In addition, the SafeAir Telescopic Smoke Pencil is similar in design and function to the Stryker Neptune E-SEP Smoke Evacuation Pencil (K160693) in terms of mode of operation and use. In reference to manufacturing, the SafeAir Telescopic Smoke Pencil and the Stryker Neptune E-SEP Smoke Evacuator Pencil are manufactured in the LiNA Medical's Poland manufacturing facility under the same environmental conditions.

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the SafeAir Telescopic Smoke Pencil and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, LiNA completed a number of non-clinical performance tests. The SafeAir Telescopic Smoke Pencil meets all the requirements for overall design, sterilization, biocompatibility, and electrical safety results confirming that the design output meets the design inputs and specifications for the device.

The SafeAir Telescopic Smoke Pencil was subjected to safety performance testing in accordance with the FDA's *Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery - Guidance for Industry and Food and Drug Administration Staff. Issued: August 15, 2016.*

The SafeAir Telescopic Smoke Pencil passed all applicable testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing per ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12
- Electrical safety testing per AAMI / ANSI ES60601-1, IEC 60601-1-2, IEC 60601-2-2
- Sterilization per ISO 11135, ISO 11737-2
- Packaging, Aging and Transport testing per ASTM F88-06, ASTM F1929-98, ASTM F1980-16, ASTM D4169-16
- Thermal Spread Testing
- Flammability Testing
- Smoke Evacuation Testing

10. Clinical Performance Data

Based on the similarities in design, intended use and comparability in design verification results to the predicate device, human clinical testing was not required to establish substantial equivalence. These types of devices, including the predicate devices, have been a long market history with demonstrated safety and effectiveness for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence determination.

11. Statement of Substantial Equivalence

Based on the similarities in design, intended use statement and comparative verification test results, the SafeAir Telescopic Smoke Pencil raises no new issues of safety and effectiveness when compared to the predicate device, Stryker Neptune E-SEP Smoke Evacuation Pencil.

The SafeAir Telescopic Smoke Pencil function differs only in the telescopic feature which does not impact the intended use or significantly impact the technological features and therefore is determined to be substantially equivalent to the referenced predicate device.