K120454

DEC 7 2012

Section 5 - 510(k) Summary for SafeAir Smoke Pencil

1. **Submission Sponsor**

LiNA Medical ApS
Formervangen 5
2600 Glostrup
Denmark
Phone: +45 4329 6666
Fax: +45 4329 6699
Contact: Louisa Memborg, Regulatory Affairs Officer

2. **Submission Correspondent**

Emergo Group
611 West 5th Street, Third Floor
Austin, TX 78701
Cell Phone: (406) 579.8124
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Rick Gillis, Ph.D., Senior Consultant
Email: project.management@emergogroup.com

3. **Date Prepared**
10 February 2012

4. **Device Name**

Trade/Proprietary Name: SafeAir Smoke Pencil
Common/Usual Name: Electrosurgical Pencil Accessory for Surgical Smoke Evacuation
Classification Name: Electrosurgical Cutting and Coagulation Device and accessories
Classification Regulation: 21 CFR 878.4400
Classification Panel: 878.4400
Product Code: GEI
Device Class: Class II

5. **Predicate Devices**

Plumepen™ Smoke Evacuation Electrosurgical Pencil; K103375
GoldVac™ Smoke Evacuation Pencil; K961616
The PenEvac™ – Multifunctional ESU Pencil with telescopic Electrodes; K081634

6. Device Description

The SafeAir Smoke Pencil is a sterile single use integrated electrosurgical pencil and smoke evacuation handpiece. The device is designed for general electrosurgical applications and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

The integration of the electrosurgical pencil and smoke evacuation enables the operator to activate an electrosurgical current as well as capture the smoke plume simultaneously. Surgical smoke produced from electrosurgery has been shown to contain viable viruses, bacteria, blood, blood fragment, carcinogens and ultra-fine particles. The amount, content and particulate size of smoke plume can vary depending on the type of procedure and surgical technique. The mutagen and carcinogen potential of smoke has been demonstrated on animal models. The effect on patients and operating room personnel can be extrapolated from the potentially harmful nature of these components. Depending on the type of tissue ablated, the inhalation hazard of electrosurgery smoke has been found to be similar to that of unfiltered cigarette smoke. Viral transmission through laser surgery smoke has been shown to occur in rare cases, and has thus changed standard practices to omit the use of these types of devices when excising viral lesions. Although this viral transmission was documented during laser surgery, surgical smoke generated from laser surgery and electrosurgery has been shown to be of similar composition and therefore could pose similar risk.

The Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health have published evidence-based statements supporting the use of smoke evacuation practices. SafeAir Smoke Pencil is designed to evacuate surgical smoke at the source of emission to minimize exposure to the patient and surgical team. As with the predicate devices, the intent of the smoke evacuation system is to remove potentially harmful surgical smoke from the surgical site. The SafeAir Smoke Pencil removes a similar volume of air and has a similar sized smoke evacuation orifice as the referenced predicate devices. The SafeAir Smoke Pencil smoke evacuation system is effective in removing smoke generated during the electrosurgery process.

The device is constructed of similar materials and design specifications as the predicate electrosurgical devices. The SafeAir Smoke Pencil combines the functions of electrosurgery and smoke evacuation into a single handpiece. The smoke evacuation orifice is located less than 1 cm from the electrosurgical blade to provide optimal smoke removal during cauterization. Studies have shown that removal of surgical smoke is most effective within 2 cm from the generation point. The smoke evacuation suction sleeve is adjustable to optimize the distance to the tip of the electrosurgical blade. As with the predicate GoldVac, the SafeAir Smoke Pencil is available in two (2) activation switch configurations, a rocker style and a push button style, which activate monopolar cut or coagulate functions. The device is connected to tubing using a dual connector to allow the user to connect to a variety of smoke evacuation systems including filtration or central vacuum systems, thus minimizing exposure of personnel to the surgical smoke plume. The device will be packaged singly for sterile distribution.

7. Intended Use

SafeAir 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.

8. Technological Characteristics and Substantial Equivalence

Substantial equivalence is based on three (3) predicate devices. The aforementioned referenced predicates are Electrosurgical Cutting and Coagulation Devices and Accessories; and Air-handling apparatus for a surgical operating room as defined in 21 CFR 878.4400 and 21 CFR 878.5070 respectively.

The LiNA SafeAir Smoke Pencil is an integration of two technologies, electrosurgery and smoke evacuation, previously cleared for use in predicate devices into a single device. The main difference from an independent electrosurgical handpiece is the incorporation of a smoke capture channel into the main body. The transparent suction sleeve is designed to be placed in a variety of positions, extended near the tip of the electrode for maximum smoke capture or retracted for maximum accessibility and visibility.

The tubing is highly flexible and houses device wiring within the smoke capture tubing for ease of use and decreased entanglement. The LiNA SafeAir Smoke Pencil is designed to be used in hospitals, operating room theaters and requires physician's prescription for use.

The LiNA SafeAir Smoke Pencil is equivalent in operational characteristics to the predicate devices; cut, coagulate, and smoke evacuation remain contained in one device. Like the predicate devices, the SafeAir Smoke Pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the target tissue for the desired surgical effect.

Manufacturer	LiNA Medical ApS	Medtek Devices, Inc.	I.C. Medical, Inc.	ConMed Corporation
Trade Name	**SafeAir Smoke Pencil**	**Predicate, PlumePen**	**Predicate, PenEvac**	**Predicate, GoldVac**
510(k) Number	Not Assigned	K103375	K961616	K081634
Product Code	GEI	GEI	GEI	GEI
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
Regulation Name	Electrosurgical Cutting and Coagulation Device and accessories	Electrosurgical Cutting and Coagulation Device and accessories	Electrosurgical Cutting and Coagulation Device and accessories	Electrosurgical Cutting and Coagulation Device and accessories
Indications for use	The SafeAir Smoke Pencil is designed for general electrosurgical applications and for removing smoke generated by electrosurgery when used in conjunction	The Plumepen is designed for general electrosurgical applications, including cutting and coagulation, and for removing smoke generated by	The Telescoping PenEvac is a multifunctional headpiece that is meant to provide the following optional functions: monopolar electrode handpiece in	The ConMed GoldVac pencils, when used with an effective smoke evacuation system, removes smoke plume from the surgical site. The pencil enables the operator

	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.	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.	an electrosurgery generator system, suction, irrigation, and to facilitate the removal of smoke generated during the procedure.	to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect
Operation Function Switches	<CUT> button labelled yellow and proximal to electrode; <COAG> button labelled blue and distal to electrode	<CUT> button yellow and proximal to electrode; <COAG> button blue and distal to electrode	<CUT> button yellow and proximal to electrode; <COAG> button blue and distal to electrode	<CUT> button yellow and proximal to electrode; <COAG> button blue and distal to electrode
Function Switch configurations available	Push Button Rocker Switch	Push Button only	Push Button only	Push Button Rocker Switch Foot Switch
Power Supply	Monopolar generator supplied by user	Monopolar generator supplied by user	Monopolar generator supplied by user	Monopolar generator supplied by user
Monopolar Generator Setting	Max 6,0 kV	Not disclosed	Not disclosed	Max 5,5 kV
Electrical Connector	US-3-Pin	US-3-Pin	US-3-Pin	US-3-Pin
Smoke Evacuation System	Yes	Yes	Yes	Yes
Adjustable Suction Sleeve	Yes	Yes	Yes	Yes
Handpiece Dimensions (Dia x Length)	15 mm x 190 mm	25 mm x 190 mm	17 mm x 190 mm	25 mm x 190 mm
Suction Sleeve Material*	Polystyrene	Polystyrene	Polycarbonate	Polycarbonate
Handpiece Housing Material*	Polystyrene	Polystyrene	Polystyrene	Polystyrene
Electrode Length	70 mm	70 mm	3.7-16.5 cm	70 mm
Electrode Dimension	17 mm x 2.3 mm	18 mm x 2.5 mm	17mm x 2.3 mm	17 mm x 2.3 mm
Adjustable Electrode	No	No	Yes	No
Electrode Material*	Stainless steel	Stainless steel	Stainless steel	Not disclosed
Complies with ISO 10993	Yes	Yes	Yes	Yes

Complies with IEC 60601-1	Yes	Yes	Yes	Yes
Complies with IEC 60601-2-2	Yes	Yes	Yes	Yes
Single Use	Yes	Yes	No	Yes
Sterile Processing	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Radiation

***Denotes patient contact material**

9. Performance Testing

The LiNA SafeAir Smoke Pencil has been shown to perform as intended with the equivalent results as the predicate devices through simulated tissue cauterization, coagulation and cutting functions. No particular requirements specific to the smoke performance exist in the standards but tests conducted with the device have shown no effect or changes to function of the electrosurgical pencil. The suction sleeve or intake portion of the device has been designed to not impede the electrosurgical function of the pencil and provides intake of the surgical smoke for filtering.

10. Non-Clinical Testing

The LiNA SafeAir Smoke Pencil and all predicate devices use polystyrene for the handpiece housing. The SafeAir Smoke Pencil and all the predicate devices use stainless steel for the electrode material. The predicate devices use either polycarbonate or polystyrene, as with the SafeAir Smoke Pencil, for the suction sleeve.

The following testing has been performed to support substantial equivalence:

Simulated Tissue Cauterization
Smoke Evacuation
Coagulation and Cutting

The SafeAir Smoke Pencil passed all testing and results were consistent with the intended use of the device.

11. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate devices. The substantial equivalence of the device is supported by the non-clinical testing. The verification and validation testing of the device electrical safety and EMC testing of the device was found to acceptable and supports the claims of substantial equivalence.

12. Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is substantially equivalent to the predicate device, and that the new

device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

The device has been designed to comply with the applicable sections of the standard for electrosurgical devices, IEC 60601-1 and IEC 60601-2-2 and Biocompatibility standard ISO 10993. It has been shown in this 510(k) submission that the differences between the SafeAir Smoke Pencil and the predicate devices do not raise any questions regarding its safety and effectiveness. The SafeAir Smoke Pencil as designed and manufactured therefore is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

LiNA Medical ApS
% Emergo Group
Rick Gillis, Ph.D.
Senior Consultant
611 West 5th Street
Austin, Texas 78701

Letter dated: December 7, 2012

Re: K120454
Trade/Device Name: SafeAir 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 15, 2012
Received: November 16, 2012

Dear Dr. Gillis:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use statement

510(k) Number (if known): K120454

Device Name: SafeAir Smoke Pencil

Indications for Use:

SafeAir 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.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)
AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120454