April 27, 2023

ConMed Corporation
Ali Abusaleh
Regulatory Affairs Specialist
525 French Road
Utica, New York 13502

Re: K230547
Trade/Device Name: PlumePen Elite Surgical Smoke Evacuation Pencils, PlumePen Pro Surgical Smoke Evacuation Pencil, PlumePen Ultra Surgical Smoke Evacuation Pencils, PenAdapt Electrosurgical Pencil Adapter, SnapEvac Electrosurgical Pencil Adapter
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, FYD
Dated: February 27, 2023
Received: February 28, 2023

Dear Ali Abusaleh:

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: 2023.04.27 12:40:56 -04'00'

Mark Trumbore, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230547

Device Name
SnapEvac Electrosurgical Pencil Adapter and PenAdapt Electrosurgical Pencil Adapter

Indications for Use *(Describe)*

The SnapEvac and PenAdapt is an aspiration sheath that fits over an electrosurgical pencil body and leaves the tip or blade exposed. This device is considered an accessory to an electrosurgical unit (ESU). SnapEvac and PenAdapt removes surgical smoke during surgical procedures that use ESU for cutting and cauterizing. This device is used in conjunction with a suction (vacuum) source.

Contraindications: This device should not be used for microsurgery.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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.

510(k) Number *(if known)*

K230547

Device Name
PlumePen (Elite, Pro and Ultra) Surgical Smoke Evacuation Pencil

Indications for Use *(Describe)*

The PlumePen® Elite, PlumePen® Ultra, and PlumePen® Pro 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. Indicated for use to remove smoke plume from the surgical site and to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the target tissue 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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Section 6 - 510(k) Summary of Safety and Effectiveness

CONMED Smoke Evacuation Devices: PlumePen, PenAdapt and SnapEvac

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502

B. Company Contact

Ali AbuSaleh
Regulatory Affairs Specialist
(708) 407-4324
Aliabusaleh@conmed.com
Date prepared: 4/26/2023

C. Device Name

Proprietary Name:	PlumePen Surgical Smoke Evacuation Pencils (Elite, Pro and Ultra)
Common Name:	Electrosurgical Smoke Evacuation Pencil
Model Numbers:	Refer to Tables 6-1 and 6-2 in Section G
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number:	878.4400
Product Code:	GEI
Regulatory Class:	II
Panel:	General and Plastic Surgery

Proprietary Name:	PenAdapt Electrosurgical Pencil Adapter, SnapEvac Electrosurgical Pencil Adapter
Common Name:	Electrosurgical Pencil Adapter
Model Numbers:	Refer to Tables 6-1 and 6-2 in Section G
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number:	878.5070
Product Code:	FYD
Regulatory Class:	II
Panel:	General Hospital

D. Predicate Device

Primary Predicate	
Device Name:	PLUMEPEN Integrated Smoke Evacuation Pencil
Company Name:	CONMED Corporation
510(k):	K103375

Additional Predicate	
Device Name:	PenAdapt10
Company Name:	CONMED Corporation
510(k):	K000904

E. Device Description

The smoke evacuation devices that are the subject of this 510(k) are PlumePen Surgical Smoke Evacuation Pencils (Elite, Pro and Ultra), PenAdapt Electrosurgical Pencil Adapters and Electrosurgical Pencil Adapters. By interfacing with an effective smoke evacuation unit, these devices function as part of the system to remove smoke particles from the point of surgical activity during procedures that use an electrosurgical unit (ESU) for cutting and cauterizing.

PlumePen Smoke Evacuation Pencils

The PlumePen® Elite, Pro, and Ultra family of devices are sterile, single use electrosurgical hand pieces featuring an integrated smoke evacuation channel. The devices, when connected to an electrosurgical generator and smoke evacuation system are designed to remove smoke plume generated during the use of the pencil for electrosurgical procedures.

PenAdapt and SnapEvac Electrosurgical Pencil Adapters

PenAdapt and SnapEvac are sterile, single use pencil adapters which fit over standard electrosurgical pencils while keeping the blade exposed. They enable the capture and removal of smoke generated during the use of the pencil, in procedures that require cutting and cauterization, when connected to an effective smoke evacuation system.

F. Intended Use / Indications for Use

PlumePen Electrosurgical Pencils (Elite, Ultra and Pro)

The PlumePen® Elite, PlumePen® Ultra, and PlumePen® Pro 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. Indicated for use to remove smoke plume from the surgical site and to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the target tissue for the desired surgical effect.

SnapEvac and PenAdapt Electrosurgical Pencil Adapters

The SnapEvac and PenAdapt is an aspiration sheath that fits over an electrosurgical pencil body and leaves the tip or blade exposed. This device is considered an accessory to an electrosurgical unit (ESU). SnapEvac and PenAdapt removes surgical smoke during surgical procedures that use ESU for cutting and cauterizing. This device is used in conjunction with a suction (vacuum) source.

Contraindications: This device should not be used for microsurgery.

G. Comparison of the Technological Characteristics with the Predicate Device

The PlumePen Electrosurgical pencils (Elite, Pro and Ultra) are similar to the predicate device in that they remain an integration of two technologies, electrosurgery and smoke evacuation in a single device. Both the predicate and subject devices enable the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site while removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The subject and predicate devices have similar design features integrating a smoke capture channel into the main body of what is otherwise a standard electrosurgical handpiece. All PlumePen devices, including the predicate, comprise of the same critical parts: 1. Housing and buttons 2. Transparent/ translucent plume/smoke capture channel 3. Plastic Swivel 4. Electrosurgical blade 5. Power cord and suction hose.

The main difference between subject and predicate devices are the dimensions of the pencil body and placement of the smoke capture channel. The PlumePen line (Elite, Pro and Ultra) is safe, effective, and substantially equivalent to the predicate as demonstrated by non-clinical performance testing.

Table 6-1 Feature comparison between subject and predicate electrosurgical pencils

Features	Subject Device: PlumePen Electrosurgical Pencil (Elite, Pro and Ultra)	Predicate Device: PlumePen Integrated Smoke Evacuation Pencil
Model Numbers	PLP1020-25, PLP2020-25, PLP2520-25, PLPRO4020-25, PLPRO4520-25, PLPUL2020-25, PLPUL2520-25, PLP1020, PLP2020, PLP2520, PLPRO4020, PLPRO4520, PLPUL2020 and PLPUL2520-25	PLP1000 and PLP2000
510(k)	K230547	K103375
Intended Use/ Indications for Use	The PlumePen® Elite, PlumePen® Ultra, and PlumePen® Pro 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. Indicated for use to remove smoke plume from the surgical site and to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the target tissue for the desired surgical effect.	The PLUMEPEN 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. Indications for use for PLUMEPEN® Integrated Smoke Evacuation Pencil include: a. To remove smoke plume from the surgical site. b. To remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the target tissue for the desired surgical effect c. To remove tissues and control bleeding by means of high frequency electrical. current
Polarity	Monopolar	Monopolar
Rated Voltage	5 kVpk	10kV P-P
Shelf-life	3 years	3 years
Sterilization Method	Ethylene oxide, SAL of 10^{-6}	Ethylene oxide, SAL of 10^{-6}
Single use / reusable	Single patient use device	Single patient use device
Electrical Safety	Fulfils Electrical Safety requirements per IEC 60601-1 Fulfils Electrical Safety requirements per IEC 60601-2-2	Fulfils Electrical Safety requirements per IEC 60601-1 Fulfils Electrical Safety requirements per IEC 60601-2-2

PenAdapt and SnapEvac electrosurgical pencil adapters are similar to the predicate device in that they remain a sheath that can accommodate a standard electrosurgical pencil and facilitate smoke evacuation at the site of electrosurgery. The subject devices and predicate device have similar design features integrating a smoke capture channel into an accommodating sheath allowing the pencil to be inserted electrode first through the sheath tip and be secured proximally before being connected to an effective smoke evacuation system through tubing. This main difference between subject and predicate is the use of ABS in the SnapEvac devices. PenAdapt and SnapEvac are safe, effective, and substantially equivalent to the predicate as demonstrated by non-clinical performance testing.

Table 6-2 Feature comparison between subject and predicate electrosurgical Pencil Adapters

Features	Subject Device: PenAdapt and SnapEvac	Predicate Device: PenAdapt10
Model Numbers	PA2010-25, PA2010B-25, SNAPEVAC20-25, PA2010, PA2010B and SNAPEVAC20	PENADAPT10
510(k)	TBD	K000904
Intended Use/ Indications for Use	The SnapEvac and PenAdapt is an aspiration sheath that fits over an electrosurgical pencil body and leaves the tip or blade exposed. This device is considered an accessory to an electrosurgical unit (ESU). SnapEvac and PenAdapt removes surgical smoke during surgical procedures that use ESU for cutting and cauterizing. This device is used in conjunction with a suction (vacuum) source. Contraindications: This device should not be used for microsurgery.	This device is an aspiration sheath that fits over an electrosurgical pencil body and leaves the tip or blade exposed. This device is an accessory to an electrosurgical unit (ESU). The device is used to remove smoke, particles and body and other casual fluids from the point of surgical activity during surgical procedures that use ESU for cutting and cauterizing. This device is used in conjunction with a suction (vacuum) source.
Contraindications	This device should not be used for microsurgery	This device should not be used for microsurgery.
Shelf-life	3 years	1 year
Sterilization Method	PenAdapt; Gamma SnapEvac; Ethylene oxide	Gamma
Single use / reusable	Single patient use device	Single patient use device
Biocompatibility	Materials shall meet the requirements of ISO 10993-1 (tissue/bone/dentin externally communicating device of limited duration)	Materials shall meet the requirements of ISO 10993-1 (tissue/bone/dentin externally communicating device of limited duration)

H. Non-clinical Testing

Non-clinical bench testing demonstrated that PlumePen (Elite, Pro and Ultra), SnapEvac and PenAdapt are safe and effective for their intended use and are substantially equivalent in design, intended use, principals of operation, and technical characteristics to the predicates, PlumePen integrated smoke evacuation pencil cleared under K103375 the PenAdapt 10 cleared under K000904. The following testing was performed:

- Functionality verification testing, including 90% smoke capture per ISO16571
- Electrical Safety (PlumePen) per IEC 60601-1 and IEC 60601-2-2
- Biocompatibility per ISO 10993-1
- Ethylene Oxide Sterilization Validation (PlumePen and SnapEvac) per ISO 11135
- E-beam Sterilization validation (PenAdapt) per ISO 11137-1
- Packaging Validation per ISO 11607-1

I. Conclusion

The subject PlumePen Smoke Evacuation pencils (Elite, Pro and Ultra), are substantially equivalent in design, materials, indications for use, principles of operation, performance, and technological characteristics to the predicate PlumePen integrated smoke evacuation pencil cleared under K103375. Based upon the findings of non-clinical testing, the differences present no issues of safety and efficacy and the subject PlumePen family (Elite, Pro and Ultra) is substantially equivalent to the PlumePen integrated smoke evacuation pencil (K103375).

The subject PenAdapt and SnapEvac Electrosurgical Pencil Adapters, are substantially equivalent in design, materials, indications for use, principles of operation, performance, and technological characteristics to the predicate PenAdapt 10 cleared under K000904. Based upon the findings of non-clinical testing, the differences present no issues of safety and efficacy, and the subject Electrosurgical Pencil Adapters are substantially equivalent to the PenAdapt10 (K000904).