DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 21, 2017

Precision Surgical, LLC
% Mr. Dave Yungvirt
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K170721
Trade/Device Name: Cut-Vac Lighted Smoke Evacuation Electrosurgical Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 7, 2017
Received: March 9, 2017

Dear Mr. Yungvirt:

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
~~Unassigned~~ K170721

Device Name
Cut-Vac® Lighted Smoke Evacuation Pencil

Indications for Use *(Describe)*
The Cut-Vac® Smoke Evacuation Electrosurgical Pencil is a monopolar device designed for general electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgical current when used in conjunction with an effective smoke evacuation system. This device conducts an electrosurgical current from an electrosurgical generator and delivers it to the target tissue to achieve 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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510(k) Summary

Cut-Vac® Lighted Smoke Evacuation Electrosurgical Pencil

K170721

1. Submission Sponsor

Precision Surgical, LLC

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USA

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Title: Chief Executive Officer

2. Submission Correspondent

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Contact: Rick Gillis, PhD

Title: Senior Consultant, RA

3. Date Prepared

15 March, 2017

4. Device Identification

Trade/Proprietary Name: Cut-Vac® Lighted Smoke Evacuation Electrosurgical Pencil

Common/Usual Name: Electrosurgical Pencil

Classification Name:	Electrosurgical Pencil
Regulation Number:	21 CFR 878.4400
Product Code:	GEI, Electrosurgical, Cutting & Coagulation & Accessories
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

K141587

Zip-Pen Smoke Evacuation Electrosurgical Pencil, Megadyne Medical Products, Inc.

The Zip Pen Smoke Evacuation Pencil is a monopolar device 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. This device conducts an electrosurgical current from an electrosurgical generator and delivers it to the target tissue to achieve the desired surgical effect.

6. Indication for Use Statement

The Cut-Vac® Smoke Evacuation Electrosurgical Pencil is a monopolar device designed for general electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgical current when used in conjunction with an effective smoke evacuation system. This device conducts an electrosurgical current from an electrosurgical generator and delivers it to the target tissue to achieve the desired surgical effect.

7. Device Description

The Precision Surgical Cut-Vac® Lighted Smoke Evacuation Electrosurgical Pencil is a standard monopolar electrosurgical pencil with incorporated LED light, and suction ability for cautery smoke. It is a sterile single use device. It performs all standard functions of an electrosurgical pencil with separate buttons for Cutting and Coagulation. Cut-Vac connects to all standard electrosurgical generator units with a standard 3-prong plug. The Cut and Coag buttons, and light switch are on the top of the device. The proximal button to the tip/blade is yellow and controls Cutting. The blue button distal to the tip controls Coagulation. The green slider switch turns the LED light on and off. The LED light does not interfere with the function of the pencil and is encased in clear thermoplastic and does not contact liquid. The light allows the operator to visualize areas during surgeries or overcome shadows despite surgical Operating Room lights. It has removable separate small batteries that are located in the distal plug that attaches to the ESP, and thus are disposable in an environmentally safe method.

The retractable blade allows the operator to better control smoke evacuation by shortening the effective blade length. Cut-Vac does not have irrigation capability.

It has an 8.5 foot suction tube to attach to any suction with an additional 5 feet of electro-surgical cable from the end of the suction tube to attach to an ESP generator. The first 8.5 feet of the suction tube incorporates the electro-surgical cable to eliminate clutter on the surgical field. The electrical-surgical cable leaves the tubing through a sealed and molded closed port and terminates in a standard 3-prong electro-surgical plug. The remaining portion of the suction tubing terminates to a flexible connector that attaches to different suction canister ports. The integrated device enables the operator to cut, coagulate, evacuate smoke and illuminate the surgical site without the need for separate tools.

The Cut-Vac® device must be used in conjunction with an electrosurgical generator and grounding pads in order to power up the device.

8. Substantial Equivalence Discussion

The following table compares the Cut-Vac® Lighted Smoke Evacuation Electrical Pencil to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	**Precision Surgical, LLC**	**Megadyne Medical Products, Inc**	**Device Comparison**
Trade Name	**Precision Surgical**	**Megadyne**	
510(k) Number	Not assigned	K141587	
Product Code	GEI	GEI	Same
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	Same
Regulation Name	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	Same
Indications for Use	The Cut-Vac® Smoke Evacuation Electrosurgical Pencil is a monopolar device designed for general electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgical current	The Zip Pen Smoke Evacuation Pencil is a monopolar device designed for general electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgery when used in conjunction with	Same; No new questions regarding safety or effectiveness.

Manufacturer	Precision Surgical, LLC	Megadyne Medical Products, Inc	Device Comparison
Trade Name	**Precision Surgical**	**Megadyne**	
	when used in conjunction with an effective smoke evacuation system. This device conducts an electrosurgical current from an electrosurgical generator and delivers it to the target tissue to achieve the desired surgical effect.	an effective smoke evacuation system. This device conducts an electrosurgical current from an electrosurgical generator and delivers it to the target tissue to achieve the desired surgical effect.	
Mechanism of Action	Electrical monopolar	Electrical monopolar	Same
Electrode	Monopolar	Monopolar	Same
Handpiece Dimensions (LxWxH)	(174mmx15mmx24mm)	(200mmx18mmx12mm)	Similar; Dimensional differences do not effect performance.
Nozzle construction	Polycarbonate	Polycarbonate	Same
Electrical Connector	US-3-pin	US-3-pin	Same
Smoke Evacuation	Yes	Yes	Same
Power Supply	Monopolar electrosurgical generator	Monopolar electrosurgical generator	Same
Sterile	Yes	Yes	Same
Single-Use	Yes	Yes	Same
Shelf Life	1 year	3 years	Similar; Real-time aging for Cut-Vac is in process
RF Voltage Vmax	4.0 kV peak	5.5 kV peak	Similar; does not affect performance
Battery Operated	LED light only	None	Similar; Battery does not affect device

Manufacturer	Precision Surgical, LLC	Megadyne Medical Products, Inc	Device Comparison
Trade Name	**Precision Surgical**	**Megadyne**	
			function
Accessories	None	Nozzle Extension, Filter, Adapter	Similar; accessories provided for marketing purposes only
Complies with ISO 10993-1	Yes	Yes	Same
Electrical Safety Testing Passed	Yes	Yes	Same
Electrical Safety Testing Passed	Yes	Yes	Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Cut-Vac® Lighted Smoke Evacuation Electrical Pencil and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Precision Surgical completed a number of non-clinical performance tests. The Cut-Vac 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 Cut-Vac® Lighted Smoke Evacuation Electrical Pencil passed all the 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
- Electrical safety testing per AAMI ANSI EC 60601-1
- Electrical safety of high frequency surgical equipment testing per AAMI ANSI EC 60601-2-2
- Smoke evacuation testing per FDA Guidance document "*Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery*"
    - Simulated smoke evacuation was performed using methane as a surrogate marker. The test sampled the amount of methane drawn through the test articles, with vacuum on, for 30 seconds with performance compared to the predicate device. Tests were performed at 3 vacuum levels. The Cut-Vac performed equivalent to the predicate.
- Thermal Zone testing per FDA Guidance document "*Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery*"

- Thermal effects of Cut and Coag functions were evaluated in muscle, kidney, and liver at minimum, default, and maximum generator settings. The Cut-Vac performed equivalent to the predicate.

- Tubing leak test
  - Quantitative analyses was performed using water. No leaks were detected.

- Shelf Life Testing – 12 month Accelerated Aging was performed on the Cut-Vac devices followed by performance testing. All units passed protocol acceptance criteria.

- Storage and Transport Testing –
  - Packaging Drop Test was performed per ASTM D5276-98 and passed per the standard.
  - Transport testing was performed and passed.

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

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 the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

The Cut-Vac® Lighted Smoke Evacuation Electrical Pencil, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device(s).