May 9, 2025

Vigeon Technology Co., Ltd.
℅ Anita Chen
Consultant
ZhengCheng Consulting Limited Company
No.19, 335 Lane, Fu-Xi Road, Shulin District
New Taipei City, 238
Taiwan

Re: K250400
Trade/Device Name: "Vigeon" Laparoscopic Universal Smoke Evacuator (VG003)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 12, 2025
Received: February 12, 2025

Dear Anita Chen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.05.09 22:26:26 -04'00'

James Jang, Ph.D.
Acting 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)*
K250400

Device Name
"Vigeon" Laparoscopic Universal Smoke Evacuator (VG003)

Indications for Use *(Describe)*
This product is indicated for use in minimally invasive procedures for removing smoke generated by electrocautery and small amount of fluids when used in conjunction with an effective suction equipment.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92

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1. Submitter

Mailing Address	Vigeon Technology Co., Ltd. 10F., No. 80, Sec. 2, Chang'an E. Rd., Zhongshan Dist., Taipei City 104, Taiwan (R.O.C.)
Contact Person	Liang Tong Kuo
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Date Prepared	2025.02.10

2 Subject Device

Proprietary Name:	"Vigeon" Laparoscopic Universal Smoke Evacuator
Model Name	VG003
Device	electrosurgical, cutting & coagulation & accessories
CFR classification	21 CFR 878.4400
Product Code	GEI
Device Class	II

3 Predicate Device

510(k) number:	K160128
Proprietary name:	Endopath® Electrosurgery Probe Plus II□
Product Code	GEI
510(k) number:	K213317
Proprietary name:	ShinEvac® Smoke Evacuation Pencil
Product Code	GEI

4 Device Description: The smoke evacuator has two parts - the exhaust tube and the control valve. The product can be installed on 5mm surgical electrode/high-energy instrument in minimally invasive surgery. The product is connected with the vacuum suction system, using negative pressure to

extract smoke, small amount of blood and water from the tip of the surgical instrument. The product design may improve the visibility of visual field and patient safety during surgery.

5. Intended Use: This product is indicated for use in minimally invasive procedures for removing smoke generated by electrocautery and small amount of fluids when used in conjunction with an effective suction equipment.

6. Technological Characteristics and Substantial Equivalence Comparison with Predicate: A comparison of the device features, intended use, and other information demonstrates that the "Vigeon" Laparoscopic Universal Smoke Evacuator is substantially equivalent to the predicate device as summarized in below table.

Device	Subjective device	Primary Predicate device	Predicate device
	"Vigeon" Laparoscopic Universal Smoke Evacuator	ENDOPATH Electrosurgery Probe Plus II	ShinEvac® Smoke Evacuation Pencil
510k Number	K250400	K160128	K213317
Product Code	GEI	GEI	GEI
Intended Use/ indication for use	This product is indicated for use in minimally invasive procedures for removing smoke generated by electrocautery and small amount of fluids when used in conjunction with an effective suction equipment.	The ENDOPATH Electrosurgery Probe Plus II system has application in minimally invasive procedures to facilitate tissue dissection, coagulation, irrigation, and fluid evacuation through a common trocar sleeve.	The ShinEvac® Smoke Evacuation 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 and electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

Device	Subjective device	Primary Predicate device	Predicate device
	"Vigeon" Laparoscopic Universal Smoke Evacuator	ENDOPATH Electrosurgery Probe Plus II	ShinEvac® Smoke Evacuation Pencil
Target Patient Population	General population	General population	General population
Target User Population	Surgeon	Surgeon	Surgeon
Anatomical sites	1. Abdominal cavity 2. Pelvic region 3. Thoracic cavity 4. Soft tissue areas	1. Abdominal cavity 2. Pelvic region 3. Thoracic cavity 4. Soft tissue areas 5. Vascular structures 6. Musculoskeletal system	1. Head and neck 2. Breast 3. Abdominal cavity 4. Pelvic region 5. Extremities 6. Thoracic cavity 7. Vascular structures 8. Skin and superficial layers
Design	- Control valve and exhaust tube	Handle and shaft	Pencil body with removable evacuation tube
Method of Introduction	It has applications for minimally invasive procedures to facilitate smoke and fluid evacuation through a common trocar sleeve.	It has applications for minimally invasive procedures to facilitate fluid evacuation through a common trocar sleeve.	It can remove surgical smoke when connected to an evacuator.
Mechanics of Action	It is used in conjunction with an effective evacuation system.	It is used in conjunction with an effective evacuation system.	It is used in conjunction with an effective evacuation system.
Compatibility with Environment and Other Devices	Compatible with an electrosurgical unit, a larger trocar with a 5 mm reducer and an effective smoke evacuation system.	Compatible with a standard monopolar unit, a larger trocar with a 5 mm reducer and an effective evacuation system.	Compatible with an electrosurgical unit and an effective smoke evacuation system.
OTC/Prescription Use	Prescription	Prescription	Prescription
Single/Multiple Use	Single use	Single use	Single use
Sterility	Sterile by Ethylene Oxide (EO)	Sterile by Gamma radiation	Sterile by Ethylene Oxide (EO)

The subject device has the same intended use of fluid/smoke evacuation as the predicate devices. The device design is different with the predicate devices. Although there's a minor technological characteristic between the subject device and predicate devices, all are compatible with electrosurgical or monopolar units and effective smoke evacuation systems, both of which are standard surgical tools used for the same. Device performance, biocompatibility and sterilization studies were evaluated and verified, the testing data demonstrates the proposed device performs as safely and effectively as the predicate device. The subject device is substantial equivalence with the predicate devices.

7. Performance Testing

Phantom experiment, performance testing of suction function, safety testing of the safety distance and operational safety testing have been carried out to demonstrate that this device meets the performance specifications and safety requirement.

8.Biocompatibility testing

In vitro cytotoxicity, Skin Sensitization, Intracutaneous Irritation, Acute Systemic Toxicity, Pyrogen and hemolysis test were evaluated.

9.Sterilization Validation

Sterilization validation was conducted in accordance with ISO 11135:2014.

10. Conclusion

Based on the intended use, technological characteristics, performance testing and comparison to the predicate device, the "Vigeon" Laparoscopic Universal Smoke Evacuator is substantially equivalent to the predicate device and raises no new questions of safety or effectiveness.