February 27, 2025

Veol Medical Technologies Pvt Ltd.
% Tatiana Jabor Botura
Regulatory Affairs Consultant
Passarini
Edifício Pórtico Sul - R. José Jaime Delibo, 160 - Nova Alia
Ribeirão Preto, SP 14026-563
BRAZIL

Re: K241595
Trade/Device Name: EzVu Visual Vasopressor Injector (EV-19)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: January 24, 2025
Received: January 28, 2025

Dear Tatiana Jabor Botura:

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,

Reginald K. Avery -S

for Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241595

Device Name
EzVu Visual Vasopressor Injector (EV-19)

Indications for Use *(Describe)*
EzVu Visual Vasopressor Injector (EV-19) is intended to inject vasopressor solution into the uterine musculature during laparoscopic surgery.

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.

EzVu Visual Vasopressor Injector (EV-19)

510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor

Veol Medical Technologies PVT. LTD.
Plot - A 747, Near Pavan Bus Stop,
Pawane MIDC, TTC Industrial Estate,
Koparkhairane,
Navi Mumbai
Mumbai
Maharashtra 400705

Contact Person and Preparer

Tatiana Jabor Botura

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Data Prepared

February 26, 2025

DEVICE NAME AND CLASSIFICATION

Trade Name	EzVu Visual Vasopressor Injector (EV-19)
Common Name	Endoscope and accessories
Regulation Number	21 CFR 876.1500
Regulatory Class	II
Product Code	FBK (endoscopic injection needle, gastroenterology-urology)
Classification Panel	Gastroenterology/Urology

PREDICATE DEVICE INFORMATION

K220292, Disposable Endoscope Injection Needle by Yangzhou Fartley Medical Instrument Technology Co., Ltd has been identified as the predicate device for the 510(k) submission for the EzVu Visual Vasopressor Injector (EV-19) by Veol Medical Technologies Pvt Ltd to support the substantial equivalence comparison.

The predicate device has not been subject to any design-related recall.

SUBJECT DEVICE INFORMATION

Indications For Use

EzVu Visual Vasopressor Injector (EV-19) is intended to inject vasopressor solution into the uterine musculature during laparoscopic surgery.

Subject Device Description

EzVu Visual Vasopressor Injector (EV-19) is a 330 mm long and 5 mm diameter hollow bore laparoscopic instrument, used to enable laparoscopic flashback visualization before injecting Vasopressor drug into the uterine musculature during laparoscopic surgery. It consists of a stainless steel needle at the distal end, securely connected to a hub, an elongated shaft with transparent window at the distal end and stopcock with luer connection at the proximal end onto which a syringe can be attached. The shaft is made of transparent plastic tube, surrounded by a stainless steel tube along the proximal portion of the injector to provide stability. The stainless steel tube around the transparent plastic tube is wrapped in a heat shrink. The injector is available in one needle size (19 gauge).

Technological characteristics

Comparison parameters	Subject Device	Predicate Device
Device Name	EzVu Visual Vasopressor Injector (EV-19)	Disposable Endoscope Injection Needle
510(k) number	K241595	K220292
Product Code	FBK	FBK
Regulation No.	21 CFR 876.1500	21 CFR 876.1500
Regulation Name	Endoscope and Accessories	Endoscope and Accessories
Class	Class II	Class II
Indication for Use	EzVu Visual Vasopressor Injector (EV-19) is intended to inject vasopressor solution into the uterine musculature during laparoscopic surgery.	The Disposable Endoscope Injection Needle is used for endoscopic injection into gastrointestinal mucosa and submucosa to: * introduce a sclerosing agent, vasoconstrictor, or other solutions into selected sites to control actual or potential bleeding lesions in the digestive system; * aid in Endoscopic Mucosal Resection (EMR), Endoscopic Submucosal Dissection (ESD), or polypectomy procedures; * control non-variceal hemorrhage
Configuration	EzVu is a 330 mm long and 5 mm diameter hollow bore laparoscopic instrument with a metallic needle at its distal end.	The disposable endoscope Injection Needle consists of Sheath, Handle buckle, handle, Booster tube, handle end cap, Outer tube, Inner tube, Metal end cap and injection needle tip
Single Use	Single Use	Single Use
Needle Gauge	19G	19G, 22G,23G, 25G
Outer Diameter (mm)	5	1.8, 2.4
Working length (mm)	330	600,1200,1600,1800,2300, 2500

Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1
Method	EO Sterilization	EO Sterilization
SAL	10^{-6}	10^{-6}

Differences between Subject Device & Predicate Device

● Indications for Use: The indications for use for the subject device slightly differs from that of the predicate due to variations in the targeted application area. While the subject device is designed for laparoscopic use, the predicate device is intended for use in conjunction with an endoscope. However, the intended use is the same – delivery of liquid agents into the tissue or mucosa.

● Device Name: Each device bears a distinct name.

● Configuration: Although the fundamental configuration of all devices remains similar—comprising a tube with an attached needle for drug delivery—the subject and predicate device have different working lengths, diameters, and needle gauges to address the anatomical environment. However, the different dimensions do not introduce different questions of safety and effectiveness.

Overall, the differences do not result in a new intended use or raise different questions of safety and effectiveness.

Non-Clinical Performance Data:

Biocompatibility

The subject device meets the requirements of ISO 10993-1:2020 – "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" and the 2023 FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* to address device biocompatibility for an external communicating device with tissue, bone, or dentin contact for less than 24 hours. The following endpoints were assessed:

- Cytotoxicity: ISO 10993-5:2009
- Irritation: ISO 10993-10:2021
- Sensitization: ISO 10993-10:2021
- Acute Systemic Toxicity: ISO 10993-11:2017

- Material-Mediated Pyrogenicity: ISO 10993-11:2017

Sterility

The subject device meets the requirements of ISO 11135:2014 – Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation, and routine control of a sterilization process for medical devices and the 2024 FDA guidance document *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* to support device sterility. The ethylene oxide and ethylene chlorohydrin residuals were measured after sterilization to meet the residual limits identified in ISO 10993-7:2008(R)2012.

Shelf Life and Package Integrity

The subject device meets the requirements of ISO 11607-1:2019 – Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems; The following test methods and standards were used to confirm shelf life and package integrity:

- Blister Packaging – Visual Inspection
- Label Adhesion – Visual Inspection
- Dye Penetration – ASTM F1929-23 – Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- Ink Fastness – Internal Methods
- Positive Air Pressure Leakage – Internal Methods
- Negative Air Pressure Leakage – Internal Methods
- Seal Strength – ASTM F88-23 – Standard Test Method for Seal Strength of Flexible Barrier Materials
- Tensile Strength – Internal Methods
- Accelerated Aging – ASTM F1980-21 – Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Bench Performance Testing

The following bench tests were conducted on the EzVu Visual Vasopressor Injector (EV-19):

- Connection Strength
- Flow Rate
- Positive Air Pressure Leakage

- Positive Liquid Pressure Leakage
- Negative Air Pressure Leakage
- Patency of Lumen
- Compression
- Device Bending
- Needle Penetration Force - ISO 7864:2016 – Sterile hypodermic needles for single use – Requirements and test methods.
- Corrosion Resistance - ISO 9626:2016 – Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods.
- Needle Stiffness - ISO 9626:2016 – Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods.
- Resistance to Breakage - ISO 9626:2016 – Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods.
- Needle Bonding Strength -ISO 7864:2016 – Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods.

The subject device passed all performed bench testing.

Clinical performance Data:

An observational clinical study for the EzVu Visual Vasopressor Injector (EV-19) was conducted as a multi-center, prospective observational study to evaluate the performance, usability, and safety of the device during laparoscopic myomectomy procedures. The study did not involve any interventions by the sponsor and focused on validating the intended use, transparency of the distal window, and compatibility with laparoscopic instruments. The study included 13 women, aged 30-40 years, with BMI of 18-40. A total of 24 injections across 13 patients were used, and 5 trained laparoscopic gynecological surgeons performed these procedures. The primary and secondary endpoints were as follows:

Primary Endpoint:

- Blood Stain should be clearly visible in the transparent window when aspirated.
- No leakage or breakage should be observed in any samples of the EzVu device.

Secondary Endpoint:

- The performance of EzVu and other laparoscopic instruments should not be affected when used together in the procedure.

Data Collected

- Device identifier tracking (UDI recorded for each use)
- Visual inspection of the device before and after use
- Insertion and positioning through trocar port
- Blood aspiration visualization through the transparent window
- Injection of vasopressor drug and any potential leakage observations
- Feedback from surgeons via Likert scale (1-5) for 19 usability questions
- Photographic documentation for each procedure

There were no reported adverse events in the study. Blood aspirate was detected in 4 out of 25 cases. All surgeons provided usability ratings of 4.6 or greater, indicating favorable device usability. The device maintained structural integrity throughout the study. Compatibility with laparoscopic instruments was confirmed. The study results support the safety and usability of the EzVu Visual Vasopressor Injector (EV-19) in clinical settings.

Conclusion:

In conclusion, the results of non-clinical and clinical performance testing demonstrate that the EzVu Visual Vasopressor Injector (EV-19) by Veol Medical technologies is as safe and effective as the predicate device Disposable Endoscope Injection Needle by Yangzhou Fartley Medical Instrument Technology Co., Ltd., to support a substantial equivalence determination.