September 24, 2025

ProVerum Limited
Niamh Mahony
Senior Regulatory Director
2nd Floor Astor Hall
4-8 Eden Quay
Dublin 1, D01N5W8
Ireland

Re: K251734
Trade/Device Name: ProVee Video Processing Unit (PV-003)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FET
Dated: June 6, 2025
Received: August 29, 2025

Dear Niamh Mahony:

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,

Mark R. Kreitz -S

for Mark J. Antonino, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251734

Please provide the device trade name(s).

ProVee Video Processing Unit (PV-003)

Please provide your Indications for Use below.

The ProVee Video Processing Unit is indicated to power the ProVee System for BPH, and to process and display the live imaging.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251734

510(k) Summary

Prepared on: 2025-08-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	ProVerum Limited
Applicant Address	2nd Floor Astor Hall 4-8 Eden Quay Dublin 1 D01N5W8 Ireland
Applicant Contact Telephone	+353861451899
Applicant Contact	Ms. Niamh Mahony
Applicant Contact Email	niamh@proverummedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ProVee Video Processing Unit (PV-003)
Common Name	Endoscope and accessories
Classification Name	Endoscopic Video Imaging System/Component, Gastroenterology-Urology
Regulation Number	876.1500
Product Code(s)	FET

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190648	Pusen Eview Medical Video Endoscope Image Processor	FET

Device Description Summary

21 CFR 807.92(a)(4)

The ProVee VPU is a reusable accessory which supports the ProVee System for BPH in performing according to its intended use.
The ProVee VPU receives and processes image signals from the ProVee System for BPH and outputs live imaging onto the integrated display.
The ProVee VPU is a non-sterile reusable device which is non-patient contacting. The ProVee VPU is cleaned prior to use per the validated cleaning instructions which are provided in the instruction manual.
The ProVee VPU is intended to be used in a professional healthcare facility environment (hospitals, clinics, outpatient facilities, physicians' offices etc.) by physicians and/or surgeons with urological training.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The ProVee Video Processing Unit is indicated to power the ProVee System for BPH, and to process and display the live imaging.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Both the subject and predicate devices have the same indication for use, video processors that are used for the display of live imaging during endoscopic procedures. Therefore the subject device does not constitute a new intended use.

Technological Comparison

21 CFR 807.92(a)(6)

The predicate and subject devices are both video processors that are used for the display of live imaging during endoscopic procedures. There are similarities and differences in the technological characteristics:

The similarities are:
- Both devices have the same intended use.
- Both devices are video processors displaying live video-imaging data from the connected visualization device.
- Both devices are not capable of data storage.
- Both devices are reusable.
- Both devices are non-patient contacting and non-sterile.

The differences are:
- The subject device has an integrated display whereas the predicate device outputs video to an external monitor via a cable.
- The subject device can be used on mains and battery power whereas the predicate device can only be used on mains power.

The minor technological differences between the ProVee Video Processing Unit and its predicate device raise no new concerns regarding safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following tests to verify/validate the design and evaluate the safety and performance of the ProVee Video Processing Unit were performed:

Electrical Safety
Electrical safety of the device was evaluated in accordance with IEC 60601-1 and 60601-2-18. All tests were passed and the subject device meets the requirements of IEC 60601-1 and 60601-2-18.

Electromagnetic Compatibility
Electromagnetic compatibility was evaluated in accordance with IEC 60601-1-2. All tests were passed and the subject device meets the requirements of IEC 60601-1-2.

Software and Cybersecurity
Software verification and validation including cybersecurity assessments were conducted according to IEC 62304 and FDA Guidance for Industry and Staff "Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions". All tests were passed and the subject device meets the software and cybersecurity requirements.

Transport
Transportation testing was conducted in accordance with ISTA 3A and all tests were passed.

Cleaning Validation
A cleaning validation was conducted in accordance with ISO 17664-2 & ANSI/AAMI ST 98. All tests were passed and the subject device meets the reprocessing requirements. The validated cleaning instructions are provided in the instruction manual.

Functional and Performance Testing
Bench testing of functional and performance specifications was completed and demonstrated that the device met all the prospectively identified acceptance criteria.

Conclusion
The ProVee Video Processing Unit is substantially equivalent in intended use and principle of operations to the legally marketed Pusen Eview Medical Video Endoscope Image Processor (K190648). The minor differences in technological characteristics were evaluated by non-clinical performance studies and demonstrated no new questions of safety or effectiveness compared to the predicate device. Based on the supportive data provided in this 510(k), it can be concluded that the ProVee Video Processing Unit is substantially equivalent to the Pusen Eview Medical Video Endoscope Image Processor.