May 20, 2025

Flexicare Medical Limited
Rebecca Funston
Director of Regulatory Affairs and Quality Assurance
Cynon Valley Business Park Mountain Ash.
Rhondda Cynon Taf, Wales CF45 4ER
United Kingdom

Re: K250243
Trade/Device Name: ProVu Single Use Video Stylet with Reinforced ET Tube (Size 6.5) (038-995-065U); ProVu Single Use Video Stylet with Reinforced ET Tube (Size 7.0) (038-995-070U); ProVu Single Use Video Stylet with Reinforced ET Tube (Size 7.5) (038-995-075U); ProVu Single Use Video Stylet with Reinforced ET Tube (Size 8.0) (038-995-080U)
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR, BSR
Dated: April 23, 2025
Received: April 23, 2025

Dear Rebecca Funston:

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.

Submission Number *(if known)*

K250243

Device Name

ProVu Single Use Video Stylet with Reinforced ET Tube (Size 6.5) (038-995-065U);
ProVu Single Use Video Stylet with Reinforced ET Tube (Size 7.0) (038-995-070U);
ProVu Single Use Video Stylet with Reinforced ET Tube (Size 7.5) (038-995-075U);
ProVu Single Use Video Stylet with Reinforced ET Tube (Size 8.0) (038-995-080U)

Indications for Use *(Describe)*

The ProVu Endotracheal Tube with Video Stylet is intended for intubation procedures. The ProVu Endotracheal Tube with Video Stylet is indicated for use as a temporary artificial airway in adults requiring mechanical ventilation. It is intended for oral and nasal intubations.

The ProVu Endotracheal Tube with Video Stylet is indicated for viewing during non-difficult and difficult intubation procedures and for verifying endotracheal tube placement.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2025/03/20

1. Submission sponsor

Name: Flexicare Medical Limited
Address: Cynon Valley Business Park Mountain Ash. CF45 4ER. United Kingdom
Contact person: Rebecca Funston
Title: Director of Regulatory Affairs and Quality Assurance
Tel: +44 (0)1443 474647

2. Subject Device Information

Trade/Device Name	ProVu Video Stylet and Reinforced Endotracheal Tube
Common Name	Endotracheal Tube
Regulatory Class	Class II
Classification	21CFR 868.5730 / tube, tracheal (w/wo connector)/ BTR
Product code	BTR, BSR
Submission type	Traditional 510(K)

3. Predicate Device

VIVASIGHT-SL (TVTTM) device manufactured by "ETView Ltd" at date of clearance (Now owned by Ambu) and cleared under "K152438".

4. Device Description

The ProVu Video Stylet with Reinforced ET Tube is a sterile, single-use, video-enabled stylet and ETT intubation system with malleable and directional control intended to assist with oral and nasal intubations and designed for use in adults in a hospital environment.

The device comprises of two main components:

- The ProVu Reinforced Endotracheal tube
- The ProVu Video Stylet (with a removable malleable rod)

5. Intended use & Indication for use

The ProVu Endotracheal Tube with Video Stylet is intended for intubation procedures. The ProVu Endotracheal Tube with Video Stylet is indicated for use as a temporary artificial airway in adults requiring mechanical ventilation. It is intended for oral and nasal intubations.

The ProVu Endotracheal Tube with Video Stylet is indicated for viewing during non-difficult and difficult intubation procedures and for verifying endotracheal tube placement.

6. Comparison to the Predicate Device

	ProVu Video Stylet with Reinforced ET Tube	**ETView Ltd.'s VIVASIGHT-SL (TVT™)**	**Comparison**
510(k)	K250243	K152438	/
Indications for use	The ProVu Video Stylet with Reinforced ET Tube is intended for intubation procedures. The ProVu Video Stylet with Reinforced ET Tube is indicated for use as a temporary artificial airway in adults requiring mechanical ventilation. It is intended for oral and nasal intubations. The ProVu Video Stylet with Reinforced ET Tube is indicated for viewing during non-difficult and difficult intubation procedures and for verifying endotracheal tube placement.	The ETView VivaSight-SL (TVTTM) is intended for intubation procedures. The ETView VivaSight-SL (TVTTM) is indicated for use as a temporary artificial airway in adults requiring mechanical ventilation. It is intended for oral and nasal intubations. The VivaSight-SL (TVTTM) System is indicated for viewing during non-difficult and difficult intubation procedures, for verifying endotracheal tube and endobronchial blocker placement and repositioning, for viewing during suctioning and for general inspection of the airway.	Equivalent
Product Code	BTR, BSR	BTR	Same
Regulation No.	21 CFR 868.5730	21 CFR 868.5730	Same
Classification	Class II	Class II	Same
Supplied/Use	Single use	Single use	Same
Method of sterilization	EtO	EtO	Same
Basic structure	Standard ETT	Standard ETT	Same
Endotracheal Tube Material	- Polyvinyl Chloride (PVC) - Polypropylene (PP)	- Polyvinyl Chloride (PVC) - Polypropylene (PP)	Same

Imaging Sensor	Video camera	Video camera	Same
Video transfer	Colored real time image acquisition from the aperture of the tracheal lumen	Colored real time image acquisition from the aperture of the tracheal lumen	Same
Video Format	Motion Joint Photographic Experts Group	Composite Video Baseband Signal	Similar
Bevel	Opening to the bottom. The camera situates centrally within lumen.	Opening to the bottom with the camera on the top	Similar
Display system	Cable connection to ProVu 8” display	Cable connection to VivaSight-Max Monitor-7” monitor	Equivalent
Tube Dimensions: Internal Diameter	Four models: • ID 6.5 mm • ID 7.0 mm • ID 7.5 mm • ID 8.0 mm	Three models: • ID 7.0 mm • ID 7.5 mm • ID 8.0 mm	Similar
Tube Dimensions: Outer Diameter	Four models: • 9.0mm • 9.4mm • 10.1mm • 10.8mm	Three models: • OD 10.0 mm • OD 10.5 mm • OD 11.0 mm	Similar
Cuff	Medical grade PVC, High volume, low pressure	Medical grade PVC, High volume, low pressure	Same
Number of Murphy Eyes	2	2	Same
Shelf life	0.5 year	3 Years	Similar
Packaging	Rigid Blister tray, EO Permeable paper top	EO Permeable peel pouch	Same
Target population	Adult	Adult	Same
Emergency use	Emergency and elective	Emergency and elective	Same
Environment of use	Hospital	Hospital	Same
Duration of use	<30d	<30d	Same
Standards met	ISO 5356-1 ISO 5361 ISO 14971 ISO 11135 IEC 60601-1	ISO 5356-1 ISO 14971 ISO 11135 IEC 60601-1 IEC 60601-1-2	Same

	IEC 60601-1-2 IEC 60601-2-18	IEC 60601-2-18	
Biocompatibility	ISO 10993-1 ISO 18562	ISO 10993-1	Same

7. Non-clinical Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the subject device was evaluated in accordance with the FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," and ISO 18562-1" Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process" as recognized by FDA.
The subject device is an externally communicating device with tissue contact for a prolonged duration (up to 30 days) with indirect gas pathway contact. The following tests are provided.

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Material Mediated Pyrogenicity
- Subcutaneous Implantation
- Chemical Characterisation
- Toxicological Risk Assessment

Per ISO 18562-1 "Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process", Gas Pathway Testing using the methods in ISO 18562-2 "Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter" and ISO 18562-3 "Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)" was completed as part of the biocompatibility testing.

Sterilization and shelf-life testing

The subject device is provided sterile, and its shelf-life is 0.5 year.
Sterilization Process has been validated according to ISO 11135:2014.
EO/ECH residual test was performed according to ISO 10993-7:2008.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the subject device. The system complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2 for EMC.

Bench performance testing
The following bench tests were performed:
• ISO 5361 Third edition 2016-09-01 Anaesthetic and respiratory equipment - Tracheal tubes and connectors
• ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets

Usability validation
Usability validation was conducted according to FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices”.

8. Clinical study
Not applicable.

9. Conclusion
Performance testing and compliance with voluntary standards demonstrate that the subject device is substantially equivalent to the predicate device.