

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Device, Hemostasis, Vascular

Device Trade Name: PerQseal® Elite Vascular Closure Device

Device Procode: MGB

Applicant's Name and Address: Vivasure Medical Ltd.,
Parkmore Business Park West,
Galway, Co. Galway,
Ireland H91 V3KP

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P250015

Date of FDA Notice of Approval: October 16, 2026

II. INDICATIONS FOR USE

The PerQseal Elite Vascular Closure Device (VCD) is indicated for the percutaneous closure of common femoral arteriotomies in patients following interventional endovascular catheterization procedures utilizing 14 – 22 F sheaths (arteriotomies up to 26 F).

III. CONTRAINDICATIONS

There are no known contraindications to the use of this device. Attention is drawn to the warnings, precautions, and special patient populations. Furthermore, when used in accordance with these instructions there are no known interactions between the implant material and/or its products of metabolism and other medical devices, medicinal products and/or other substances expected to be used in conjunction with the PerQseal Elite VCD.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the PerQseal Elite Vascular Closure Device labeling.

V. DEVICE DESCRIPTION

The PerQseal® Elite Vascular Closure Device (VCD) consists of a Delivery System and a bioabsorbable implant as shown in **Figure 1**.

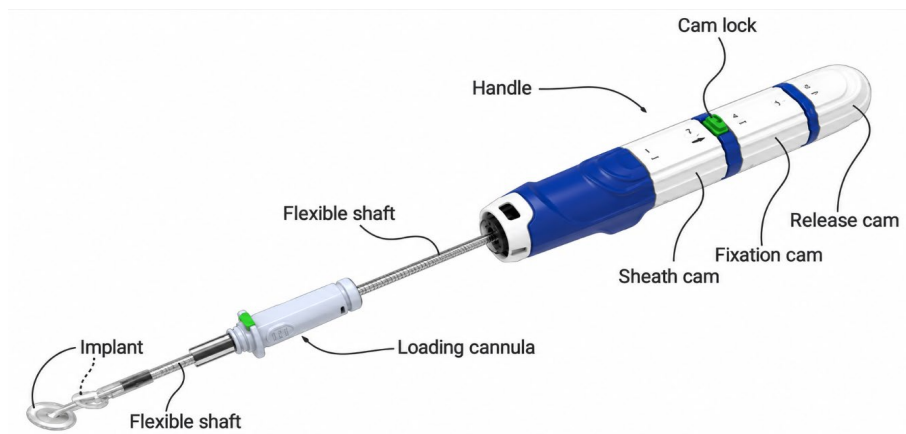


Figure 1: PerQseal Elite VCD

The PerQseal Elite VCD implant (**Figure 2**) is comprised of four components: scaffold, patch, pin and external fixation. All implant components are made from the same polydioxanone (PDO) polymer that is biodegradable and bioabsorbable. The PerQseal Elite implant is designed to be degraded and absorbed within 180 days of implantation. The PerQseal Elite VCD implant can accommodate a 0.035" guidewire and includes an external fixation component to aid in preventing dislodgement of the patch.

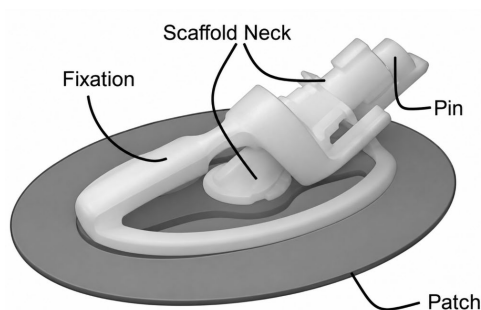


Figure 2: PerQseal Elite VCD Implant (Deployed configuration)

The PerQseal Elite VCD delivery system has a handle at the proximal end connected to a flexible shaft and a loading cannula, which attaches to the implant at the distal end. The PerQseal Elite VCD device is supplied in a procedure pack configuration consisting of the delivery system, implant, and introducer (sheath and dilator).

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for closure of femoral arteriotomies resulting from large-bore endovascular catheterization procedures. For large-bore arteriotomies, the alternatives are commercially available vascular closure devices or surgical closure. Each alternative has its own advantages and disadvantages.

VII. MARKETING HISTORY

The PerQseal Elite VCD has received the CE Mark for distribution and sale in the European Union in compliance with Regulation (EU) 2017/745. Following introduction of the PerQseal Elite device, Haemonetics (Vivasure Medical's parent company) elected not to commercialize earlier device iterations and voluntarily withdrew the associated CE certificates. This decision was not made for any reason related to the safety or effectiveness of the devices.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of potential adverse effects (e.g., complications) associated with use of the PerQseal Elite VCD:

- Allergic or foreign body reaction
- Anemia
- Arterial intimal dissection
- Arterial stenosis at the access site
- Arterial thrombus
- Arteriovenous fistula
- Bleeding from the access site
- Bruising at the access site
- Compartment syndrome
- Cutaneous or subcutaneous inflammation at the access site
- Death
- Device malfunction or failure
- Edema related to the access site
- Embolization of the intraarterial implant components
- Embolization of thrombus, calcific debris, tissue, or air
- Hematoma
- Infection
- Inflammatory reaction to the implant material
- Lower extremity ischemia
- Nerve injury
- Numbness related to the access site
- Oozing from the access site
- Pain at the access site
- Partial or complete arterial occlusion
- Pseudoaneurysm
- Pulse deficit(s) at or distal to the access site
- Retroperitoneal bleeding
- Vascular injury, including tear, perforation, or rupture
- Vascular spasm
- Vasovagal response
- Venous thrombus

For the specific adverse events that occurred in the clinical study, please see Section X below.

IX. **SUMMARY OF NON-CLINICAL STUDIES**

Comprehensive preclinical testing of the subject PerQseal Elite Vascular Closure Device has been performed and contribute, together with the clinical study data described in Section X below towards demonstrating a reasonable assurance of safety and effectiveness of the PerQseal Elite Vascular Closure Device. Where relevant, all tests were performed using finished components, devices, or representative test specimens manufactured in accordance with current specifications. A summary of the non-clinical testing performed is outlined below.

A. **Laboratory Studies**

A summary of the laboratory testing conducted on the PerQseal Elite VCD is provided in **Table 1** below.

Table 1: Summary of Laboratory Studies on PerQseal Elite VCD

Test	Purpose	Acceptance Criteria	Result
Scaffold (Foot Core) Securement	Measure the tensile strength of the attachment between the foot-core and the delivery system	The Scaffold (foot-core) shall withstand a ≥ 15 N Pull force from the delivery system (pre-deployment)	Passed
Fixation Tip Tensile Strength	Measure the chemical bonding / tensile strength between the distal end of the fixation tube and the fixation tip	The fixation tip shall withstand a ≥ 30 N pull force from fixation tube	Passed
Fixation Hub Tensile Strength	Measure the tensile strength of a bond in the delivery system	The Fixation Hub shall withstand a ≥ 30 N pull force from the Fixation Tube	Passed
Alignment Hub Tensile Strength	Measure the tensile strength of a bond in the delivery system	The Alignment Hub shall withstand a ≥ 15 N pull force from the Alignment Tube	Passed
Bayonet Hub Tensile Strength	Measure the tensile strength between the Bayonet hub and the Bayonet tube	The Bayonet Hub shall withstand a ≥ 15 N pull force from the Bayonet Tube	Passed
Push Hub Tensile Strength	Measure the tensile strength of a bond in the delivery system	The Push Hub shall withstand a ≥ 15 N pull force from the Push Tube	Passed
Compatibility with Accessories	Complete simulated use testing to evaluate if the device is compatible with	The combined leakage rate from the device and accessories during use shall be ≤ 900 ml	Passed

Test	Purpose	Acceptance Criteria	Result
	accessories used during the procedure		
Implant – Ability to Seal	Evaluate whether the device can seal when tracked through a worst-case sheath, delivered at a worst-case angle, with a worst-case residence time in the loading annual tube and implanting into a worst-case vessel size using a simulated use test fixture	The Implant should be capable of creating an effective seal. An effective seal is considered successful deployment of the Implant (including Fixation and Pin) as well as an average of ≤ 20 ml / min of fluid loss post deployment	Passed
Compression Resistance	Complete simulated use testing to evaluate if the device maintains its ability to seal arteriotomies after compression	The arterial diameter in the region surrounding the implant should be capable of withstanding a reduction of 50% of the original arterial diameter whilst ensuring an adequate seal after the compressive force has been removed i.e. an average of ≤ 20 ml / min of fluid loss post removal of the force. The deployed Implant Fixation shall be intact and deployed above the outside wall of the vessel	Passed
Delivery System Corrosion Resistance	Evaluate corrosion resistance of all metallic components of the delivery mechanism of the device as per ISO 10555-1 Annex A	When tested in accordance with the method given in ISO 10555 - 1 Annex A, metallic components of the Delivery System shall show no signs of corrosion	Passed
Device Surface	Visually inspect the device to determine if it is free of defects that would render the device unsuitable for its intended use	Under visual inspection, device surface shall be free of defects that would render the device unsuitable for its intended use	Passed
Guidewire Compatibility	Complete simulated use testing to evaluate if the device is compatible with a 0.035” guidewire	The delivery system and Scaffold shall have a guidewire channel that accommodates up to a 0.035” guidewire and permits proximal and distal movement during delivery	Passed

Test	Purpose	Acceptance Criteria	Result
Introducer Sheath and Delivery System Compatibility	Complete simulated use test to evaluate compatibility of the delivery system with the introducer	The delivery system cannula shall be capable of being inserted into and mating with the introducer sheath	Passed
Kink Resistance	Complete simulated use testing to evaluate if the device is compatible with accessories used and visually inspect for kinks	The delivery system shall not kink under conditions of normal use	Passed
Ability and Mechanism to Deploy	Complete simulated use testing to determine ability to deploy the implant	The implant deployment should be capable of being achieved by rotation of the fixation Cam followed by the release cam. Once rotated, the fixation cam shall hit a stop and cannot be rotated further (either clockwise or anti - clockwise)	Passed
Delivery Mechanism Effective length	Measure the effective length of the delivery system	The effective length of the delivery system shall be 204 mm +/- 5 mm	Passed
Material Properties – Implant Patch	Measure the Inherent Viscosity (IV) to assess the material properties	The Implant Patch shall have an Inherent Viscosity between 100 – 220 cm ³ /g	Passed
Material Properties – Implant Scaffold	Measure the Inherent Viscosity (IV) to assess the material properties	The Implant Scaffold shall have an Inherent Viscosity between 100 – 220 cm ³ /g	Passed
Material Properties – Implant Fixation	Measure the Inherent Viscosity (IV) to assess the material properties	The Implant Fixation shall have an Inherent Viscosity between 100 – 220 cm ³ /g	Passed
Material Properties – Implant Pin	Measure the Inherent Viscosity (IV) to assess the material properties	The Implant Pin shall have an Inherent Viscosity between 100 – 220 cm ³ /g	Passed
Patch Thickness	Dimensional measurement of the implant patch thickness	The Patch shall have an average thickness of 230 µm +70 µm / - 20 µm	Passed
Patch Profile	Dimensional measurement of implant patch outer diameter	The patch outer profile shall have a major diameter of 20 mm +/- 0.25 mm and a minor diameter of 15 mm +/- 0.25 mm	Passed
Visualization	Verify if the distal tip of the delivery system is visible under imaging	The distal tip of the Delivery System shall be visible and distinguishable using angiographic or radiographic	Passed

Test	Purpose	Acceptance Criteria	Result
		Imaging	

B. Animal Studies

The preclinical evaluation of the PerQseal Elite device included one chronic Good Laboratory Practice (GLP) porcine study and one acute delivery system study. In the acute studies, the device was deployed over an *in-situ* sheath, and hemostasis was achieved within the protocol's specified timeframes. The chronic study evaluated 18 pigs at 30-, 100-, and 180-days post-implant, 6 pigs for each timepoint. The device was used in the abdominal aorta and inferior vena cava (due to animal model limitations in the femoral sites to approximate human femoral tissue and sizing characteristics) to assess vessel sealing, material durability, and local tissue response. Histological assessments at 180 days indicated that device degradation was nearly complete, accompanied by a local tissue response that included residual microscopic material and macrophage infiltrates.

During the chronic study, imaging and histology recorded a neointimal tissue response and some cases of luminal narrowing (stenosis) associated with the device patch, which was most prominent at the 30-day timepoint. Additionally, instances of delivery malfunctions were observed during the study, which informed subsequent manufacturing and procedural updates applied in the clinical study. To address the luminal narrowing observed in the animal model, clinical mitigations and labeling requirements have been established, specifically restricting device use to vessels larger than 7 mm in diameter. With these clinical parameters and labeling restrictions applied, the preclinical data aligns with the overall Elite clinical data, and considering this totality of the data, supports a determination that the device is safe and effective.

C. Biocompatibility

Testing was designed to evaluate the device's cytotoxicity, irritation, sensitization, acute systemic toxicity, sub-chronic toxicity, chronic toxicity, material mediated pyrogenicity, genotoxicity, implantation, and carcinogenicity. Alternative assessments or testing methods (per ISO 10993) were utilized where appropriate.

Table 2: Summary of Biocompatibility Evaluations of the PerQseal Elite VCD

Biocompatibility Endpoint	Standard	Method	Result
Cytotoxicity	ISO 10993-5	Extract-based testing	Not cytotoxic
Irritation	ISO 10993-23	Intracutaneous injection in rabbits	Non-irritant
Sensitization	ISO 10993-10	Guinea Pig Maximization Test	Not sensitizing
Acute Systemic Toxicity	ISO 10993-11	Injection in mice	No systemic toxicity

Sub-Chronic Toxicity	ISO 10993-17, ISO 10993-18	Chemical characterization and toxicological risk assessment	No concerns identified
Chronic Toxicity	ISO 10993-17, ISO 10993-18	Chemical characterization and toxicological risk assessment	No concerns identified
Carcinogenicity	ISO 10993-17, ISO 10993-18	Chemical characterization and toxicological risk assessment	No concerns identified
Material Mediated Pyrogenicity	USP General Chapter <151>	Intravenous injection in rabbits	Non-pyrogenic
Genotoxicity	ISO 10993-3	Bacterial Mutagenicity Test (Ames Assay)	Non-mutagenic
Implantation	ISO 10993-6	In vivo animal studies	No adverse histopathological responses

D. Degradation, in vitro in vivo correlation (IVIVC) and polymer characterization

The PerQseal Elite implant is designed to be fully degraded and absorbed after 180 days of implantation. All components of the implant are constructed using the synthetic polymer polydioxanone (PDO). Degradation studies, *in vivo-in vitro* correlation (IVIVC), and polymer characterization were performed on the bioabsorbable implant.

The PerQseal Elite polymer degradation and absorption process was studied through in vivo animal studies. These studies confirmed that the Elite implant promotes encapsulation and adherence to the luminal surface, maintains adequate performance through the encapsulation period, and is completely degraded within 180 days post-implantation.

E. Sterilization Validation

Sterilization validation has been conducted for the PerQseal Elite VCD per ISO 11135:2014, for ethylene oxide (EO) sterilization. All devices are sterilized using a 100% EO sterilization cycle achieving a sterility assurance level (SAL) of 10^{-6} . As part of the process validation, EO residuals and endotoxins were confirmed to be within established limits.

The PerQseal Elite VCD was adopted into the current sterilization process via a product adoption assessment conducted per applicable sections of ISO 11135:2014 and TIR28:2016. The adoption assessment confirmed there are no changes to the sterilization cycle parameters between the original validation performed on a previous iteration of the PerQseal device and the product adoption validation, and that the Elite product load density falls within the validated range.

To support the product adoption, studies were conducted to address bioburden method validation, natural product bioburden, bacterial endotoxin testing, sub-lethal, and sterilant residuals. All studies confirmed the sterilization process is adequate to support safe release of the PerQseal Elite VCD.

F. Packaging and Shelf-life Validations

Shelf-life and transit validation studies, including assessments of packaging seal integrity and aging testing, were conducted to demonstrate that the PerQseal Elite VCD packaging can maintain a sterile barrier over the proposed shelf life.

The PerQseal Elite Vascular Closure Device is packaged in a dual-barrier system consisting of a sterile Tyvek® pouch enclosed within a moisture-barrier foil pouch, which is sealed in an inert nitrogen atmosphere to protect the bioabsorbable PDO implant. Packaging design verification was conducted under nominal, thermal and distribution (T&D), and accelerated aging conditions, evaluating seal integrity, seal strength, packaging inspection, and device placement. All testing met the required acceptance criteria.

To support an 18-month shelf life for the PerQseal Elite VCD, 18-month real-time aging testing was completed on the Elite implant, covering key performance assessments including material properties, dimensional measurements, simulated use, seal integrity, and packaging inspection. All results met the pre-defined acceptance criteria. This 18-month real-time aging data for the implant was combined with 24-month accelerated aging data for the delivery system handle to form the complete shelf-life data package. FDA confirmed that this data package is appropriate to support an initial 18-month shelf life for the final PerQseal Elite VCD.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed clinical studies to establish a reasonable assurance of safety and effectiveness of the PerQseal Elite VCD to achieve percutaneous closure of common femoral arteriotomies in patients undergoing percutaneous catheter-based interventional procedures using 14 - 22 F sheaths (arteriotomies up to 26 F).

The ELITE Study, a clinical trial conducted solely in the European Union, is the primary study that directly evaluates the PerQseal Elite VCD device. Data from this clinical study were the basis for the PMA approval decision. The PATCH Study, a separate pivotal study conducted in the US under G210227/S001 and in the EU that evaluates earlier developmental versions of the device (PerQseal and PerQseal+ VCD devices), provides supplemental clinical evidence and experience for the underlying PerQseal technology platform.

The ELITE Study is summarized in this section. A summary of PATCH Study is provided in Section XII as supplemental clinical information.

ELITE Study

A. Study Design

Patients were treated between September 18, 2023 and September 8, 2025. The database for this PMA reflected data collected through April 20, 2026 and included 121 patients. There were eight (8) investigational sites. The study was a prospective, multicenter, single-arm study. The study was not blinded prior to, during or post the procedure. Patients undergoing a percutaneous catheter-based interventional procedure (e.g., TAVR, EVAR, TEVAR, circulatory assist or ECMO via large bore femoral catheter) requiring an arteriotomy created by 14 to 22 F sheaths (arteriotomies up to 26 F), via the common femoral artery were screened for inclusion into the study. The study primary safety and effectiveness endpoints were compared to performance goals (PGs). A clinical acceptance criterion (CAC) was established for the secondary safety endpoint.

An independent Clinical Events Committee (CEC) was responsible for adjudicating all vascular access site complications. The CEC was combined with the Data Safety Monitoring Committee (DSMC), with both committees comprising the same independent physician members. An independent core laboratory performed blinded review of duplex ultrasound images for subjects with reported or suspected access site complications.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the ELITE study was limited to patients who met the following inclusion criteria:

- 1) Age $\geq$ 19 years
- 2) Clinically indicated for a percutaneous arterial interventional catheter-based procedure, e.g., transcatheter aortic valve replacement/implantation (TAVR/TAVI) or endovascular abdominal aneurysm repair (EVAR), or thoracic endovascular aneurysm repair (TEVAR), or use of a circulatory assist device or extracorporeal oxygenation using a common femoral arteriotomy created by a 14 to 22 F sheath (arteriotomy up to 26 F).
- 3) Subject is willing and able to provide appropriate study-specific informed consent, follow protocol procedures, and comply with follow-up visit requirements
- 4) Females who are not pregnant or lactating and not planning to become pregnant for the duration of the study.

Patients were not permitted to enroll in the ELITE study if they met any of the following exclusion criteria:

(*Note: The use of a secondary closure device in the same leg was prohibited during this study, and the sponsor instructed investigators that a note to this effect should be entered into the patient's medical records.*)

Baseline exclusion criteria

- 1) Evidence of current systemic bacterial or cutaneous infection, including groin infection,

- 2) Known bleeding diathesis, definite or potential coagulopathy, platelet count < 100,000/ μ L or subjects on long term anticoagulants with an INR >2 within 12 hours prior to index procedure,
- 3) Significant anemia (example: hemoglobin <9 g/dL or hematocrit <27%), within 24 hours prior to index procedure,
- 4) Known type II heparin-induced thrombocytopenia,
- 5) Documented left ventricular ejection fraction <20%,
- 6) Ipsilateral or contralateral lower extremity amputation,
- 7) Previous groin surgery within the region of the ipsilateral access,
- 8) Claudication (Rutherford category 3 or greater), documented untreated iliac or common femoral artery diameter stenosis > 50% or previous bypass surgery/stent placement in the common femoral artery of target leg,
- 9) Known existing nerve damage in the target leg,
- 10) Renal insufficiency (Glomerular Filtration Rate $\leq$ 30 ml/min or baseline serum creatinine >2.5 mg/dl) or on renal replacement therapy,
- 11) Known allergy to any of the materials used in the PerQseal Elite device
- 12) Subject is unsuitable for surgical repair of the target leg access site,
- 13) Subject has undergone a percutaneous procedure greater than 8F sheath in the target leg, within the 90 days prior to index procedure,
- 14) Subject has undergone a percutaneous procedure of 8F sheath or less using an absorbable intravascular closure device for hemostasis, in the target leg, within the 90 days prior to index procedure,
- 15) Subject has undergone a percutaneous procedure of 8F sheath or less using a suture mediated closure device or manual/mechanical pressure for hemostasis in the target leg, within the 30 days prior to index procedure,
- 16) Evidence of marked tortuosity of the femoral or external iliac arteries in the target leg, based on pre-primary procedure CT angiography,
- 17) Evidence of arterial diameter stenosis >20% within 15 mm proximal or distal to arteriotomy site based on pre-primary procedure CT angiography,
- 18) Evidence of anterior wall calcification of the target common femoral artery (other than small, diffuse deposits which in the opinion of the investigator will not impede the vascular closure procedure) within 15 mm proximal or distal to arteriotomy site based on pre-primary procedure CT angiography,
- 19) Target femoral artery diameter is less than 7 mm, based on pre-primary procedure CT angiography,
- 20) Further planned endovascular/catheter-based procedure in the target leg in the 30 days following the index procedure,
- 21) Subject is enrolled in another investigational medical device or drug study,
- 22) Subject has been previously enrolled in this clinical study,
- 23) Current COVID-19 infection (with or without symptoms), recent positive test for COVID-19 within two weeks, or recent exposure to a person with COVID-19 infection within two weeks.

Procedural Exclusion Criteria

The procedure exclusion criteria may not have been known until after the patient had given informed consent and the procedure had started. In this event, the PerQseal Elite

was not used, and the patient was considered excluded from the study and intent-to-treat analysis.

If any Procedural Exclusion Criteria listed below was met, then closure with PerQseal Elite device was not permitted.

- 24) Initial common femoral arterial access achieved with manual palpation or blind arterial stick access, without use of an image guided approach (ultrasound or angiography),
- 25) Difficult dilation during initial target femoral artery access (e.g., that damages or kinks dilators) while step-dilating up to the large-bore device,
- 26) During arterial puncture, the target femoral artery suspected to have experienced a posterior arterial wall needle puncture or underwent > one needle puncture during the primary procedure, with a needle larger than a micro puncture needle (>21 gauge or > Φ 0.819 mm). (Note: not an exclusion if micro puncture technique under ultrasound guidance used for femoral artery access
- 27) Subject has a tissue tract (i.e., estimated distance from skin entry point to arterial anterior surface at arteriotomy) expected to be greater than 8 cm,
- 28) Significant blood loss requiring transfusion of blood products during primary procedure or within 30 days prior to index procedure,
- 29) Activated clotting time (ACT) >300 seconds immediately prior to sheath removal or if ACT measurements are expected to be >300 seconds for more than 24 hours after index procedure,
- 30) Target puncture site is in a vascular graft,
- 31) Target arteriotomy greater than 26 F,
- 32) Target arteriotomy in the profunda femoris or superficial femoral artery or is in common femoral artery, but within 15 mm proximal of the bifurcation of the superficial femoral/ profunda femoris artery, (apex of bifurcation overlying the femoral head),
- 33) Target arteriotomy located at the level or above the inferior epigastric artery and/or beneath or above the inguinal ligament based on bony/arterial landmarks (above femoral head on A-P projection),
- 34) Subjects with an acute hematoma >4 cm diameter, arteriovenous fistula, pseudoaneurysm or intraluminal thrombosis at the target access site identified intra-procedurally,
- 35) Evidence of bleeding around the primary procedure sheath (VARC type 1/BARC type 2 or higher),
- 36) Intra-procedural angiographic evidence of arterial laceration, dissection or stenosis within the femoral artery that would preclude use of the PerQseal Elite device,
- 37) Uncontrolled hypertension (systolic blood pressure >180 mmHg or diastolic blood pressure >110 mmHg) at the time of planned vascular closure,
- 38) Systolic blood pressure <90 mmHg at the time of planned vascular closure.

2. Follow-up Schedule

All patients were scheduled for follow-up examinations at 30 minutes, 1 hour, 12-24 hours, 30 days ($\pm$ 7 days) and 180 days ($\pm$ 30 days) postoperatively to monitor the complete

bioabsorption of the implant. The clinical protocol stipulated that the 30-day and 180-day follow-ups could be completed in the clinic or over the phone. Follow-up evaluations at scheduled visits included lower extremity pulse assessment, targeted physical exam, ankle brachial index (ABI) of both legs, hemoglobin level, a duplex ultrasound of PerQseal Elite and associated vasculature, and an AE assessment.

The key timepoints are shown below in the tables summarizing safety and effectiveness.

3. Clinical Endpoints

Safety Endpoints

Primary Safety Endpoint

The primary safety endpoint was the rate of Major Access Site Complications attributable to the PerQseal Elite device^s through 30 days, as adjudicated by the CEC as study device related. The pre-defined safety endpoint was a composite comprised of the following elements:

- 1) Access site-related bleeding due to a failure of the PerQseal Elite device that requires transfusion of blood product(s); OR
- 2) Device related vascular injury that requires surgical repair or percutaneous stent-graft placement; OR
- 3) Any new and sustained (> 24 hours) device-related ipsilateral lower extremity ischemia, documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram, which causes a threat to the viability of the limb, and/or requires surgical repair or additional percutaneous intervention; OR
- 4) Surgery for device-related nerve injury; OR
- 5) Permanent (lasting to 30 days) device-related nerve injury; OR
- 6) Access site infection requiring intravenous antibiotics, drainage and/or extended hospitalization.

Secondary Safety Endpoint

The Secondary safety endpoint was the incidence of minor access site complications attributable to the PerQseal Elite device^s through 30 days, as classified by an independent CEC as study device related, defined as:

- 1) Non-treated pseudoaneurysm documented by ultrasound; OR
- 2) Pseudoaneurysm treated with ultrasound-guided compression, ultrasound-guided thrombin injection, or ultrasound-guided fibrin adhesive injection; OR
- 3) New non-treated or treated arteriovenous (AV) fistula documented by ultrasound; OR
- 4) Access site hematoma greater than or equal to 10 cm, confirmed by ultrasound; OR
- 5) Late (following hospital discharge) access site-related arterial bleeding; OR
- 6) Ipsilateral lower extremity arterial emboli; OR
- 7) Ipsilateral deep vein thrombosis; OR
- 8) Transient access site-related nerve injury; OR
- 9) Access site infection treated with intramuscular or oral antibiotics.

§**Note:** With respect to the Primary and Secondary endpoints and Other Parameters, “attributable to the PerQseal Elite device” is defined as when an event has a causal relationship with the investigational device or when such causal relationship is reasonably probable, as defined in the *Clinical Event Adverse Event Reporting* procedure.

Effectiveness Endpoints

The primary and secondary effectiveness endpoint definitions are provided in **Table 3** below.

Table 3: Effectiveness Endpoints Definitions

Primary Effectiveness Endpoint	Time to Hemostasis (TTH): defined as elapsed time in minutes from PerQseal Elite (Introducer-sheath and Delivery-device) removal to first observed cessation of common femoral artery (CFA) bleeding, excluding cutaneous or subcutaneous oozing, and in the absence of a developing hematoma. This is assessed at the end of the index procedure prior to discharge.
Secondary Effectiveness Endpoints	Technical Success Rate: defined as the number of PerQseal Elite devices that are deployed and achieve hemostasis (i.e., cessation of arterial bleeding excluding cutaneous or subcutaneous oozing) without need for more than 10 minutes of firm, adjunctive manual compression or alternative treatment (other than adjunctive endovascular ballooning) at target access site, divided by the total number of PerQseal Elite devices where deployment was attempted, within the mITT population. This is a per device endpoint.
	Treatment Success Rate: defined as the number of subjects who meet PerQseal Elite Technical Success without experiencing a device related Major Access Site Complication (based on CEC adjudication) through 30 days, divided by the total number of subjects where PerQseal Elite device deployment was attempted, within the mITT population.
	Time to Device Deployment (TTDD): defined as the time from insertion of the PerQseal Elite delivery device into the PerQseal Elite Introducer sheath to complete removal of the PerQseal Elite (delivery device and introducer-sheath) from the subject following PerQseal Elite deployment.
	Time to Ambulation (TTA): defined as the elapsed time from PerQseal Elite removal from the subject post deployment until the subject can walk 20 feet/6 meters without arterial re-bleeding at the target access site. This endpoint will be evaluated only for subjects who are ambulatory (e.g., not confined to wheelchair or bed) at the time of enrollment.
	Total Closure Time (TCT): TCT is defined as: Time to Hemostasis (TTH) plus Time to Device Deployment (TTDD).

The primary safety and effectiveness endpoints were the principal indicators of study success. Literature searches were used to establish the performance goal (PG) of 0.1405 for the primary safety endpoint, and the primary effectiveness endpoint PG_E of 19.7 minutes.

Specifically, the primary safety performance goal of 0.1405 was derived from a systematic literature review of contemporary peer-reviewed publications on large-bore vascular access site closure, covering both percutaneous vascular closure devices (VCDs) and surgical cutdown techniques. A random-effects meta-analysis was performed on the identified studies, and the resulting literature-derived major complication rates for VCDs and surgical closure were used to calculate the PGs, with an additional margin applied to account for FDA-defined major access site complications not captured within VARC-2/3 definitions.

The primary effectiveness performance goal of 19.7 minutes was derived from a literature review of time to hemostasis data in large-bore catheter-based procedures. A single relevant publication was identified — the PEVAR trial (Nelson et al., *Journal of Vascular Surgery*, 2014) — which reported time to hemostasis outcomes for both percutaneous closure devices and open surgical closure. The mean values from the percutaneous closure and surgical arms of this trial were used to calculate the PGE of 19.7 minutes.

For the secondary safety endpoint, success was defined as the upper bound of the one-sided 97.5% CI falling below a pre-specified Clinical Acceptance Criterion (CAC) of 20%, derived from historical literature on large-bore vascular closure.

B. Accountability of PMA Cohort

Analysis Populations

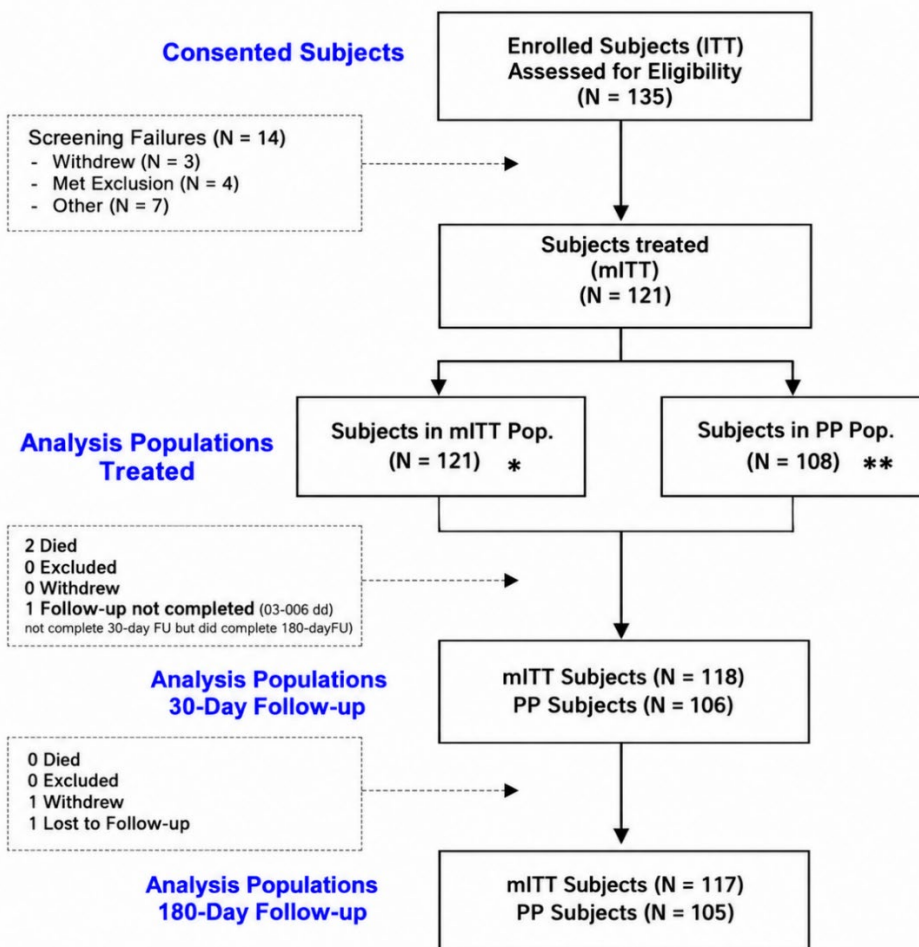
The following analysis populations are defined for this study:

Analysis Population	Definition
Modified Intent-to-Treat (mITT)	The subset of the ITT population who underwent attempted access site closure with the PerQseal Elite device, excluding subjects who met procedural exclusion criteria, required an unrelated intervention at the access site compromising the implant, or had the device intentionally removed prior to deployment
Per-Protocol (PP)	mITT subjects with no major protocol deviations who either experienced the primary safety event or completed the 30-day follow-up evaluation
mITT with 30-day follow-up	mITT subjects who completed the 30-day follow-up evaluation
PP with 30-day follow-up	PP subjects with no major protocol deviations who experienced the safety endpoint or completed the 30-day follow-up evaluation
mITT for Primary Effectiveness	mITT subjects for whom Time to Hemostasis (TTH) was measured
PP for Primary Effectiveness	mITT subjects with no major protocol deviations and for whom Time to Hemostasis (TTH) was measured

Patient Accountability

The Intent-to-Treat (ITT) population included 135 enrolled subjects. Fourteen (14) subjects were excluded prior to treatment (four did not meet eligibility criteria, seven did not receive the investigational device, and three withdrew consent). This resulted in a Modified ITT (mITT) population of 121 subjects who underwent attempted closure with the investigational device.

Within the mITT population, five (5) subjects underwent bilateral closures, resulting in a total of 126 treated access sites. At the 30-day primary safety evaluation point, 118 subjects (97.5%) were available for analysis. Thirteen (13) subjects were excluded from the Per-Protocol (PP) population due to major protocol deviations, yielding 108 subjects for the PP safety analysis and 109 closures for the PP effectiveness analysis. By the conclusion of the study, 117 subjects had completed the final 180-day follow-up. An overview of the subject disposition is shown in **Figure 3**.



* - mITT population included 121 subjects treated, of which (5) five subjects received bilateral closures, resulting in 126 total closures. Of these 126 closures, 13 subjects received alternative closures (no TTH recorded), leaving 113 closures included in the primary effectiveness endpoint analysis.

** - PP population included 108 subjects (121 mITT subjects minus 13 subjects with major protocol deviations), of which (5) five received bilateral closures and (2) two died prior to their 30-day follow-up, resulting in 106 subjects for the primary safety endpoint analysis. For the primary effectiveness endpoint, after excluding (4) four subjects who received alternative closures (no TTH recorded), the PP cohort consisted of 104 subjects with 109 closures.

Figure 3: Subject Disposition in ELITE Study

C. Study Population Demographics and Baseline Parameters

The Modified Intent-to-Treat (mITT) population (n=121) had an average age of 78.2 ($\pm$ 7.4) years, spanning a range from 52 to 90 years. Most subjects were male (70.2%) (Table 4). Hypertension was the most prevalent baseline medical condition, observed in 74.4% of subjects, followed by diabetes in 24.0% of subjects (Table 5). The demographics of the study population are typical for a vascular closure device study.

Table 4: Baseline Demographics – mITT Subjects

Characteristic	Mean $\pm$ SD (N)	% (n/N)
Age (years)	78.2 $\pm$ 7.4 (121)	-
Height (cm)	171.7 $\pm$ 8.60 (121)	-
Weight (kg)	80.1 $\pm$ 13.5 (121)	-
Male	-	70.2% (85/121)
Female	-	29.8% (36/121)

Table 5: Baseline Medical History – mITT Subjects

Condition	% (n/N)
Hypertension	74.4% (90/121)
Diabetes	24.0% (29/121)
Severe acute non-cardiac systemic disease, autoimmune disease or terminal illness	1.7% (2/121)
Clinically significant peripheral vascular disease	0.8% (1/121)
Claudication or rest pain	0.0% (0/121)
Bleeding diatheses	0.0% (0/121)
Previous peripheral vascular surgery involving the aorta or lower extremities	2.5% (3/121)
Previous amputation of either left or right leg	0.0% (0/121)
Previous arterial access performed using the proposed artery	9.9% (12/121)
Antithrombotic medication history	20.7% (25/121)
Pre-existing nerve injury ^a	0.8% (1/121)
Ambulatory	99.2% (120/121)

^a One subject was reported with a neck injury unrelated to the ipsilateral treated leg.

D. Received Treatment and Operative Data

The majority of procedures (72.7%) utilized the right leg for access, with 4.1% (5/121) of subjects undergoing bilateral access. All subjects received local anesthesia at a minimum, with 8.3% (10/121) receiving general anesthesia, 4.1% (5/121) receiving sedation, and

the remainder receiving regional blocks. Intraprocedural anticoagulant or antiplatelet therapy was administered to all subjects (100%). Additional metrics including activated clotting time, estimated blood loss during the primary and index closure procedure, and approximate depth of tissue tract are reported in **Table 6**.

Table 6: Procedural Information – mITT Subjects

Activated Clotting Time (ACT [seconds])	
Mean ± SD (N)	181.8 ± 46.08 (121)
Median (Q1, Q3)	178.0 (147.0, 211.0)
Min, Max	90.0, 300.0
Anticoagulant/antiplatelet therapy given during procedure	100.0% (121/121)
Estimated blood loss during the Primary procedure (cc)	
Mean ± SD (N)	43.5 ± 90.58 (121)
Median (Q1, Q3)	10 (0, 40)
Min, Max	0, 500
Estimated blood loss during the Index closure procedure (cc) [1]	
Mean ± SD (N)	23.5 ± 53.79 (125)
Median (Q1, Q3)	0 (0, 20)
Min, Max	0, 400
Approximate depth of tissue tract (mm) [2]	
Mean ± SD (N)	3.8 ± 1.16 (126)
Median (Q1, Q3)	4.0 (3.0, 4.0)
Min, Max	1.0, 8.0

[1] Refers to blood loss during the index closure procedure.

[2] Subjects may have had procedures in both legs. The N is based on the number of procedures, not the number of subjects.

To accurately reflect the size of the arteriotomy closed by the device, **Table 7** details the outer diameter (OD) of the primary procedure sheaths utilized in the study. The outer diameters ranged from 15 to 26 F, which is the clinically relevant metric for large-bore vascular closure.

Table 7: ELITE Largest Primary Procedure Sheath Used – mITT by Procedure

Outer Diameter of Largest Sheath Used (F)*	Endovascular Aneurysm Repair (EVAR)	Transcatheter Aortic Repair (TAVR)	Total
15	1	0	1
16	11	8	19
18	6	28	34
19	5	4	9
20	7	9	16
22	0	25	25
23	1	0	1
24	0	18	18
26	0	3	3
Total	31	95	126
*For procedures that used sheathless devices (11), OD size reported by site was the arteriotomy size. One (1) treatment PCI+PTSMA+BAV was classed as TAVR and One (1) treatment Arteria iliac communis aneurysm was classed as EVAR.			

E. Safety and Effectiveness Results

1. Safety Results

Primary Safety Endpoint

The primary safety endpoint was the rate of major access site complications attributable to the PerQseal Elite device through 30 days, as adjudicated by the Clinical Events Committee (CEC). To achieve study success, the upper bound of the one-sided 97.5% confidence interval (CI) for the complication rate had to fall below the pre-specified Performance Goal for Safety (PGS) of 14.05% (0.1405), with a corresponding p-value < 0.025.

The primary safety endpoint was met across all analysis populations. In the primary mITT cohort, who completed the 30-day follow-up, the major complication rate was 3.4% (4/118). The upper bound of the one-sided 97.5% CI was 8.45%, which was below the 14.05% performance goal ($p = 0.0001$) (**Table 8**). For the “all mITT” population which consisted of all mITT patients during the time period up to and including the 30-day follow-up, the major complication rate was 3.3% (4/121).

Major access site complications by type are detailed in **Table 9**. The only major complication reported was device-related vascular injury requiring surgical repair or percutaneous stent-graft placement (3.4%, 4/118); no other major complications occurred. The 4 major complications reported as device-related vascular injury requiring surgical repair or percutaneous stent-graft placement were major bleeding, first treated with balloon occlusion and then a stent; 2 complete occlusions of the left external iliac artery, treated with surgical repair; and partial occlusion of the right common femoral artery, treated with 2 stent-grafts.

Table 8: Major Access Site Complication Rates, 97.5% CI, and p-values Across All Analysis Populations

Analysis Population	Complication Rate [97.5% CI]	p-value
mITT with 30-day follow-up (n = 118)	3.4% (4/118) [0.0%, 8.45%]	< 0.001
PP with 30-day follow-up (n = 106)	0.9% (1/106) [0.0%, 5.14%]	< 0.001
All mITT population (n = 121)	3.3% (4/121) [0.0%, 8.25%]	< 0.001
All PP population (n = 108)	0.9% (1/108) [0.0%, 5.05%]	< 0.001

Table 9: Major Access Site Complication Rate Stratified by Type of Complication in mITT Population with 30-day follow-up

	% (n/N)
Access site-related bleeding due to a failure of the PerQseal Elite device that requires transfusion of blood product(s)	0.0% (0/118)
Device related vascular injury that requires surgical repair or percutaneous stent-graft placement	3.4% (4/118)
Any new and sustained (> 24 hrs) device-related ipsilateral lower extremity ischemia, documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram, which causes a threat to the viability of the limb, and/or requires surgical repair or additional percutaneous intervention;	0.0% (0/118)
Surgery for device-related nerve injury	0.0% (0/118)
Permanent (lasting to 30-days) device-related nerve injury	0.0% (0/118)
Access site infection requiring intravenous antibiotics, drainage and/or extended hospitalization	0.0% (0/118)

Secondary Safety Endpoint

The secondary safety endpoint was the incidence of minor access site complications attributable to the PerQseal Elite device through 30 days, as adjudicated by the CEC. Success was defined as the upper bound of the one-sided 97.5% CI falling below the Clinical Acceptance Criterion (CAC) of 20%.

The secondary safety endpoint was met across all analysis populations. The incidence of minor device-related complications was 0.8% (1/118) in the mITT population and 0.9% (1/106) in the PP population, with the upper bounds of the 97.5% CIs remaining significantly below the 20% threshold (**Table 10**).

Minor access site complications by type are detailed in **Table 11**. The only minor complication reported was a pseudoaneurysm treated with ultrasound-guided compression, thrombin injection, or fibrin adhesive injection (0.8%); no other minor complications occurred.

Table 1: Minor Access Site Complication Rates Across All Analysis Populations

Analysis Population	Complication Rate [97.5% CI]	p-value
mITT with 30-day follow-up (n=118)	0.8% (1/118) [0.0000, 0.0463]	< 0.001
PP with 30-day follow-up (n=106)	0.9% (1/106) [0.0000, 0.0514]	< 0.001
All mITT population (n = 121)	0.8% (1/121) [0.0000, 0.0452]	< 0.001
All PP population (n = 108)	0.9% (1/108) [0.0000, 0.0505]	< 0.001

Table 2: Minor Access Site Complication Rate Stratified by Type of Complication in mITT Population with 30-day follow-up

	% (n/N)
Non-treated pseudoaneurysm documented by ultrasound	0.0% (0/118)
Pseudoaneurysm treated with ultrasound-guided compression, ultrasound-guided thrombin injection, or ultrasound-guided fibrin adhesive injection	0.8% (1/118)
New non-treated or treated arteriovenous (AV) fistula documented by ultrasound	0.0% (0/118)
Access site hematoma greater than or equal to 10 cm, confirmed by ultrasound	0.0% (0/118)
Late (following hospital discharge) access site-related arterial bleeding	0.0% (0/118)
Ipsilateral lower extremity arterial emboli	0.0% (0/118)
Ipsilateral deep vein thrombosis	0.0% (0/118)
Transient access site-related nerve injury	0.0% (0/118)
Access site infection treated with intramuscular or oral antibiotics	0.0% (0/118)

Additional Safety Endpoints

Additional safety endpoints evaluated the incidence of major and minor access site complications through 30 days using Valve Academic Research Consortium-3 (VARC-3) definitions.

The device demonstrated a favorable safety profile regarding VARC-3 defined major complications, with a 0.0% event rate across all analysis populations. The incidence of VARC-3 defined minor complications also remained within acceptable clinical thresholds. The minor complication rates were 4.2% (5/118) in the mITT population and 1.9% (2/106) in the PP population.

2. Effectiveness Results

Primary Effectiveness Analysis

The primary effectiveness endpoint was Time to Hemostasis (TTH), defined as the elapsed time in minutes from device removal to the first observed cessation of common femoral artery (CFA) bleeding (excluding cutaneous oozing and in the absence of a developing hematoma). This was assessed at the end of the index procedure prior to discharge.

Of the 126 total closures attempted in the mITT population, 13 required alternative therapy to achieve closure. Therefore, TTH was recorded for 113 closures in the primary mITT effectiveness cohort. The Per-Protocol (PP) effectiveness cohort consisted of 109 closures, excluding those with major protocol deviations.

The primary effectiveness endpoint was met across all analysis populations. The mean TTH was 0.9 minutes for the mITT population and 0.7 minutes for the PP population. For both cohorts, the upper bound of the one-sided 97.5% CI remained significantly below the pre-defined Performance Goal of 19.7 minutes ($p < 0.0001$) (**Table 12**). The median TTH was 0 minutes in both populations, indicating that the majority of subjects achieved immediate hemostasis following device deployment.

Table 3: Time to Hemostasis, Upper 97.5% CI, and p-values Across mITT and PP Populations

Analysis Population	Mean TTH in Mins (SD)	Upper 97.5% CI in Mins	p-value
mITT with TTH* (n=113)	0.9 (2.33)	1.36	<0.001
PP with TTH (n=109)	0.7 (1.77)	1.08	<0.0001

*Primary analysis

Secondary Effectiveness Endpoints

The results of the secondary effectiveness endpoints, including technical success rate, treatment success rate, time to device deployment (TTDD), time to ambulation (TTA), and total closure time (TCT) are provided in **Table 13** below.

Table 4: Secondary Effectiveness Endpoints in ELITE Study

Endpoint	Result
Technical Success Rate (%; n/N)	88.9% (112/126)
Treatment Success rate (%; n/N)	89.0% (105/118)
TTDD in min (Mean $\pm$ SD (N))	2.9 $\pm$ 2.83 (113)
Time to Ambulation in hr (Mean $\pm$ SD (N))	15.5 $\pm$ 10.70 (102)
Total Closure Time in min (Mean $\pm$ SD (N))	3.9 $\pm$ 3.88 (113)

The technical success rate of 88.9% (112/126) is consistent with the 95% confidence interval of [89%; 99%] reported in a meta-analysis of 17 published studies (2017–2024) encompassing 4,276 subjects treated with large-bore closure devices (Prostar® XL, ProGlide®, and MANTA®) in similar patient populations undergoing EVAR, TAVR, and TEVAR procedures. The device demonstrated rapid delivery with an average TTDD of 2.9 minutes and an average total closure time (TCT) of 3.9 minutes. Following the procedure, subjects were able to ambulate in an average of 15.5 hours.

Performance by Procedure

A subgroup analysis was conducted to assess device performance by primary procedure type (EVAR vs. TAVR). The proportion of major access site complications (primary safety) and Time to Hemostasis (primary effectiveness) were compared between the two groups.

As detailed in **Table 14** and **Table 15**, there were no statistically significant differences between the EVAR and TAVR cohorts for either the primary safety outcome ($p = 0.577$) or the primary effectiveness outcome ($p = 0.338$), indicating consistent device performance across procedure types.

Table 5: Primary Safety Outcome Summary Statistics by Procedure – mITT Cohort

	EVAR (n=25)	TAVR (n=93)	p-value
Primary Safety Event?			
No	25 (100%)	89 (95.7%)	0.577
Yes	0 (0%)	4 (4.3%)	

Table 6: Primary Effectiveness Outcome Summary Statistics by Procedure – mITT Cohort

	EVAR (n=28)	TAVR (n=85)	p-value
Time to Hemostasis (mins)			
Mean (SD)	0.6 (1.87)	1.0 (2.46)	0.338
Median [Min, Max]	0 [0, 8.00]	0 [0, 15.0]	

3. Subgroup Analyses

The following baseline characteristics were evaluated for potential association with safety and effectiveness outcomes: sex (gender), age at procedure, race, BMI, study center, procedure type, Sheath to Femoral Artery Ratio (SFAR), Activated Clotting Time (ACT) level at surgery, and medical history/comorbidities including the presence of hypertension, diabetes, severe acute non-cardiac systemic disease, autoimmune disease or terminal illness, bleeding diathesis, peripheral vascular disease, previous peripheral vascular surgery involving the aorta or lower extremities, claudication or rest pain, and previous arterial access procedure using the proposed artery.

For the primary safety endpoint, no significant differences in outcomes were observed across these subgroups, with the exception of Sheath to Femoral Artery Ratio (SFAR). An SFAR > 1.05 was shown to be associated with an increased probability of major access site complications ($p=0.017$), though this finding was based on a very small number of events ($n=2$).

Table 16: Primary Safety Endpoint Subgroup Comparison for SFAR – mITT Population

Sheath to Femoral Artery Ratio (SFAR)	Experienced Primary Safety Endpoint (N = 4)	Did Not Experience Primary Safety Endpoint (N = 114)	p-value*
			0.0172
≤ 1.05	1.8% (2/111)	98.2% (109/111)	
> 1.05	28.6% (2/7)	71.4% (5/7)	

*Calculated via Fisher's Exact Test. Note: Primary safety endpoint includes subjects with at least one major access site complication attributable to the device through 30-days.
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For the primary effectiveness endpoint (Time to Hemostasis), there were no significant differences across subgroups except for study center and previous peripheral vascular surgery. However, the study center difference was biased by a site with only one closure and lost significance when pooled with another small site, while the previous surgery difference was attributed to a small sample size ($n = 4$) and an outlier in the non-surgery group. Ultimately, the data was determined to be evenly distributed and poolable across all evaluated subgroups.

The study was not specifically powered for sex-, age-, race-, ethnicity-, or any other relevant characteristic-specific subgroups.

4. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

XI. FINANCIAL DISCLOSURE

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 9 principal investigators. None of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

XII. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

PATCH Clinical Study

The PATCH study provides additional clinical experience supporting the PerQseal technology platform, including experience in United States patient populations. The trial evaluated earlier iterations of the device (PerQseal and PerQseal+ VCDs), which incorporated similar fundamental technological principles, intended use, and mechanisms of action as the subject device, the PerQseal Elite VCD.

Study Design

The PATCH study was a prospective, multicenter, single-arm adaptive clinical trial conducted in the United States and the European Union, at 15 clinical centers in the US and 3 clinical centers in the EU. The objective was to evaluate the safety and effectiveness of the PerQseal VCD system when used to achieve hemostasis of common femoral arteriotomies created by 12 to 22 F sheaths (arteriotomies up to 26 F) in subjects undergoing percutaneous catheter-based interventional procedures. The patient follow-up schedule (30 minutes, 1 hour, 12-24 hours, 30 days, and 180 days) and the clinical

endpoints were identical to those utilized in the primary ELITE study.

Subject Accountability

The Modified Intent-to-Treat (mITT) population included 128 subjects who underwent attempted access site closure. The Per-Protocol (PP) population consisted of 118 subjects with no major protocol deviations. For the 30-day safety endpoints, 125 mITT subjects and 117 PP subjects were evaluated.

Study Population Demographics and Baseline Parameters

The mITT population (n=128) had an average age of 76.4 ± 8.3 years. The majority of subjects were male (67.2%) and identified as White (63%). Hypertension was the most prevalent baseline medical condition, observed in 81.3% of subjects.

Table 17: Baseline Demographics and Medical History – PATCH mITT Subjects

Characteristic	Value
Age (years), Mean	76.4
Male, % (n/N)	67.2% (86/128)
Hypertension, % (n/N)	81.3% (104/128)
Antithrombotic Medication History, % (n/N)	50.8% (65/128)
Diabetes, % (n/N)	21.9% (28/128)

Safety Results

Primary Safety Endpoint

The primary safety endpoint was the rate of major access site complications attributable to the device through 30 days, as adjudicated by the Clinical Events Committee (CEC). The device demonstrated an acceptable safety profile, with a major complication rate of 4.0% (5/125) for the mITT population, who completed the 30-day follow-up. The upper bound of the 97.95% confidence interval was 9.32%, which remained well below the pre-specified Performance Goal for Safety (PGS) of 14.25%, successfully meeting the endpoint ($p < 0.0001$). For the “all mITT” population which consisted of all mITT patients during the time period up to and including the 30-day follow-up, the major complication rate was 4.7% (6/128).

Table 18: Major Access Site Complication Rates Across Analysis Populations

Analysis Population	Complication Rate % (n/N)	Upper 97.95% CI	p-value
mITT with 30-day follow-up (N = 125)	4.0% (5/125)	9.32%	< 0.0002

Analysis Population	Complication Rate % (n/N)	Upper 97.95% CI	p-value
PP with 30-day follow-up (N = 117)	2.6% (3/117)	7.54%	< 0.0001
All mITT (N = 128)	4.7% (6/128)	10.17%	< 0.0004
All PP (N = 118)	2.5 % (3/118)	7.47%	< 0.0001

Secondary and Exploratory Safety Endpoints

The secondary safety endpoint, incidence of minor access site complications through 30 days, remained well below the pre-specified Clinical Acceptance Criterion (CAC) of 20%. The minor complication rate was 3.2% (4/125) for the mITT population, who completed the 30-day follow-up. Regarding exploratory safety endpoints, the incidence of VARC-3 defined major and minor complications in the mITT population was 1.6% (2/125) and 5.6% (7/125), respectively. For the “all mITT” population which consisted of all mITT patients during the time period up to and including the 30-day follow-up, the minor complication rate was 3.9% (5/128).

Effectiveness Results

Primary Effectiveness Analysis

The primary effectiveness endpoint was Time to Hemostasis (TTH). Hemostasis was achieved in an average of 3.8 ± 6.8 minutes in the mITT population. The upper bound of the 97.95% CI was 5.1 minutes, successfully falling below the pre-defined performance goal of 19.7 minutes ($p < 0.0001$). Similar to the ELITE study, the median TTH was 0 minutes, demonstrating that most subjects achieved immediate hemostasis.

Table 19: Time to Hemostasis (TTH)

Analysis Population	Mean TTH in Mins (SD)	Median	Upper 97.95% CI	p-value
mITT with TTH measured (N = 121)	3.8 (6.8)	0	5.1	< 0.0001
PP with TTH measured (N = 116)	3.5 (5.3)	0	4.5	< 0.0001

Secondary Effectiveness Endpoints

Secondary effectiveness outcomes exhibited robust device performance. The technical success rate and treatment success rate were 91% and 90%, respectively, closely matching the findings of the ELITE study. The device also demonstrated efficient delivery with an average deployment time (TTDD) of 6.2 minutes.

Table 20: Secondary Effectiveness Endpoints (PATCH)

Endpoint	Results
Technical Success Rate (% , n/N)	91% (116/128)
Treatment Success Rate (% , n/N)	90% (115/128)
Time to Device Deployment (TTDD) in min, Mean $\pm$ SD (N)	6.2 $\pm$ 3.1 (121)
Time to Ambulation (TTA) in hr, Mean $\pm$ SD (N)	22.0 $\pm$ 19.0 (114)
Total Closure Time (TCT) in min, Mean $\pm$ SD (N)	10.0 $\pm$ 7.5 (121)

XIII. PANEL MEETING RECOMMENDATION AND FDA’S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIV. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The effectiveness of the PerQseal Elite VCD was based on data collected in the ELITE study, a prospective, multicenter, international, single-arm clinical trial. This was further supplemented by data from the PATCH study, which evaluated earlier iterations of the device platform. The assessment of effectiveness for the ELITE clinical trial was based on mean time to hemostasis (TTH) in the mITT population. Hemostasis was achieved in an average of 0.9 ± 2.33 minutes, successfully meeting the primary effectiveness endpoint. The median TTH was 0 minutes, demonstrating that most subjects achieved immediate hemostasis. This duration compares favorably to other marketed vascular closure devices.

Robust results were also seen in the secondary effectiveness endpoints for the ELITE study, as evidenced by a technical success rate of 88.9% and a treatment success rate of 89.0%. Time to device deployment (TTDD) was on average 2.9 ± 2.83 minutes, demonstrating rapid deployment of the device. Time to ambulation (TTA) was on average 15.5 ± 10.70 hours, indicating that most subjects were able to ambulate within a day after the procedure. Finally, total closure time (TCT) was an average of 3.9 ± 3.88 minutes, reflecting efficient completion of the closure process.

B. Safety Conclusions

The risks of the PerQseal Elite VCD are based on nonclinical laboratory and animal studies as well as data collected in the ELITE clinical study conducted to support PMA approval.

The safety assessments for the PerQseal Elite VCD were based on the primary endpoint of the rate of major access site complications attributable to the device through 30 days, and the secondary endpoint of the rate of minor complications within 30 days, both as adjudicated by the CEC. In the ELITE study, the major complication rate was 3.4% with an upper bound of the one-sided 97.5% confidence interval of 8.45%, which was under the Performance Goal of 0.1405 (14.05%). Therefore, the study met the primary safety endpoint.

The rate of minor access site complications among mITT subjects who had completed the 30-day follow-up assessment was 0.8% (1/118) in the ELITE study. As the upper bound of the one-sided 97.5% CI (4.63%) was below the Clinical Acceptance Criterion (CAC) of 0.20 (20%), the study successfully met the secondary safety endpoint.

C. Benefit-Risk Determination

The probable benefits of the device are based on data collected in the ELITE clinical study conducted to support PMA approval, supplemented with the available data from the PATCH study from earlier iterations of the device (see Section XII). The potential benefits of using the PerQseal Elite VCD for closure of large-bore arterial access sites are that the treatment allows for hemostasis to be achieved promptly (ELITE: 0.9 min), a high technical success rate (ELITE: 88.9%), and a high treatment success rate (ELITE: 89.0%). The device performance is associated with an acceptable major complication rate through 30 days (ELITE: 3.4%).

The probable risks of the device are also based on data collected in the clinical study conducted to support PMA approval. Risks associated with the device include the following access site-related adverse events: vascular injury, pseudoaneurysm, arteriovenous fistula, nerve injury, nerve irritation, bleeding, hematoma, oozing, arterial occlusion, arterial thrombus, lower extremity arterial embolism, lower extremity ischemia, venous thrombus, infection, inflammation, and allergic reaction.

Overall, the data demonstrated a positive benefit-risk profile for the PerQseal Elite VCD. The device provides benefits in terms of safety and effectiveness in hemostasis, with a low incidence of complications and adverse events. These attributes, combined with the absence of new or unexpected risks, affirm the device's safety and effectiveness for the sealing of the common femoral arteriotomy in patients following interventional therapeutic endovascular procedures.

1. Patient Perspective

This submission either did not include specific information on patient perspectives or the information did not serve as part of the basis of the decision to approve or deny the PMA for this device.

In conclusion, given the available information above, the data support that for the percutaneous sealing of a common femoral arteriotomy in patients following interventional therapeutic endovascular procedures, the probable benefits outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. The data support the device's effectiveness in achieving rapid time to hemostasis and its safety in maintaining a low rate of major access site complications in interventional patients when compared to a pre-specified performance goal. Additionally, the data demonstrates a low incidence of minor access site complications when compared to a pre-specified clinical acceptance criterion, alongside favorable secondary outcomes including high technical success, rapid device deployment, and short total closure time.

The totality of the data suggest that the benefits of using the PerQseal Elite VCD outweigh the risks.

XV. CDRH DECISION

CDRH issued an approval order on October 16, 2026. The final clinical conditions of approval cited in the approval order are described below.

The **ELITE ArteREAL Post-Approval Study (PAS)** is a prospective, multi-center, single-arm study designed to characterize the real-world safety and performance of the PerQseal Elite Vascular Closure Device (VCD) in U.S. clinical practice. The study will enroll a minimum of 150 subjects at a minimum of 5 U.S. centers, with subjects followed up to and including 30 days post-procedure regardless of patient status. Data will be collected at baseline, index procedure, prior to hospital discharge, and at 30 days, with the 30-day visit conducted either in-person or via phone/telehealth. The primary endpoint is the rate of major access site closure-related complications attributable to the PerQseal Elite VCD, and key secondary endpoints include the rate of minor access site closure-related complications, device technical success rate, and device deficiencies. Major and minor complications will be independently adjudicated by a Clinical Events Committee (CEC). The study data will be analyzed descriptively, with results compared to the prior studies (e.g. ELITE). Enrollment milestones, as agreed upon with FDA, require the first subject to be enrolled within 6 months, 20% of subjects enrolled within 12 months, 50% within 18 months, and 100% within 24 months of FDA approval of the PAS protocol.

The applicant's manufacturing facility was inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820), which was in effect at the time of the inspection. As of February 2, 2026, the revised part 820, referred to as the Quality Management System Regulation (QMSR), is effective.

XVI. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.