SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Vascular Hemostasis Device

Device Trade Name: AbsorbaSeal 5.6.7F Vascular Closure Device

Device Procode: MGB

Applicant's Name and Address: CyndRx, LLC
205 Powell Place, Suite 124
Brentwood, Tennessee 37027

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P230038

Date of FDA Notice of Approval: June 5, 2026

II. INDICATIONS FOR USE

The AbsorbaSeal 5.6.7F Vascular Closure Device is indicated for use in percutaneous closure of femoral arterial access sites while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional catheterization procedures utilizing 5, 6, or 7F procedural sheaths.

III. CONTRAINDICATIONS

There are no known contraindications.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the AbsorbaSeal 5.6.7F Vascular Closure Device labeling.

V. DEVICE DESCRIPTION

The AbsorbaSeal 5.6.7F Vascular Closure Device (VCD) is designed to achieve rapid femoral artery hemostasis by delivering a fully bioabsorbable sealing mechanism to the vessel puncture site. The AbsorbaSeal 5.6.7F VCD consists of the 1) delivery system, 2) seal assembly, which is composed of two bioabsorbable copolymers, and 3)

the commercially available Galt Medical Micro-Access Elite Hemostasis Valve Introducer Set. The delivery system is comprised of an inserter (which houses the seal assembly), a push tube, and a handle with a deployment slide (Figure 1). The seal assembly, delivered through the Galt Medical 6F Access Sheath (also called the Push Tube) (Figure 3), compresses the puncture site between extravascular components – proximal seal and floating foot, and intravascular components – gasket and distal seal, connected via a stem (Figure 2). The AbsorbaSeal 5.6.7F VCD Delivery System and Seal Assembly are available in a single device size.

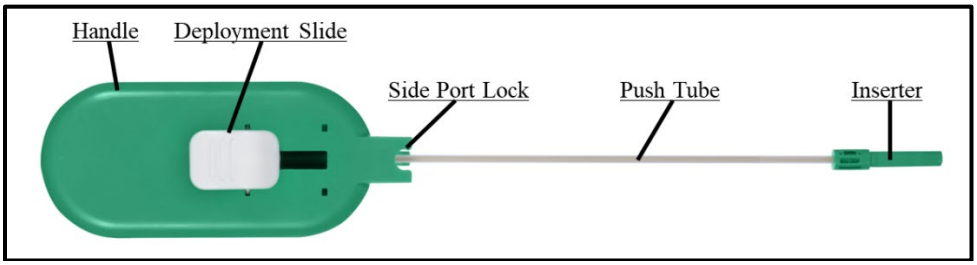

Figure 1: AbsorbaSeal 5.6.7F VCD Delivery System

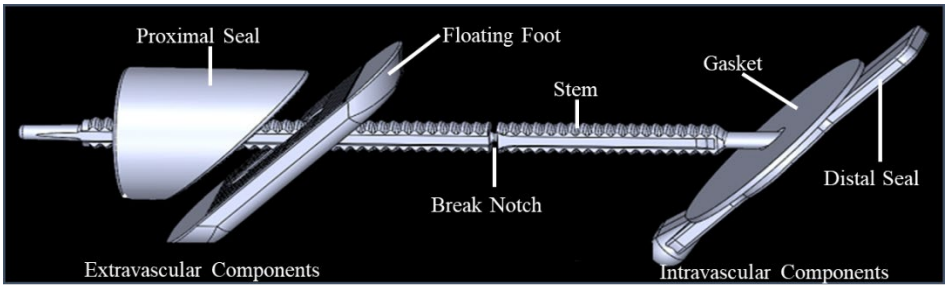

Figure 2: Seal Assembly

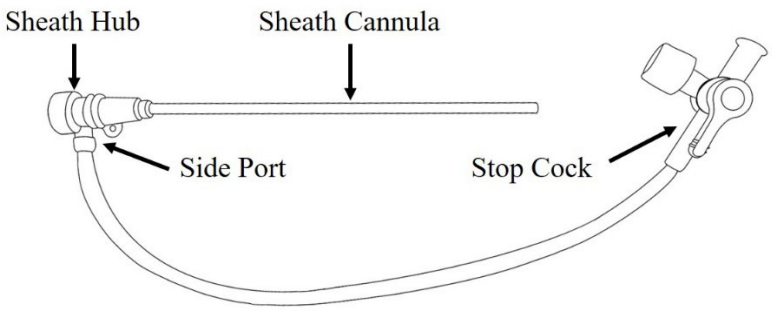

Figure 3: Galt 6F Access Sheath (Push Tube)

Device Deployment Procedure
After completion of the primary procedure, the procedural sheath is exchanged for the Galt Medical 6F Access Sheath. The access sheath dilator and guidewire are removed, and the AbsorbaSeal 5.6.7F VCD Delivery System is inserted into the hub of the Galt Medical 6F Access Sheath until an audible and tactile click is heard– the AbsorbaSeal 5.6.7F VCD Delivery System and Galt Medical 6F Access Sheath are now a single assembly. The implantable Seal Assembly distal seal and gasket have now exited the distal tip of the Galt Medical 6F Access Sheath.

With the AbsorbaSeal 5.6.7F VCD Delivery System handle in the operator's dominant hand, the operator places their first two fingers of their non-dominant hand in front of and behind the Access Sheath, respectively, to stabilize the vessel. The operator slowly retracts the AbsorbaSeal 5.6.7F VCD Delivery System/Galt Medical 6F Access Sheath assembly with their dominant hand along the angle of the puncture tract until resistance of the vessel is felt. This resistance signifies that the distal seal and gasket of the implantable Seal Assembly are positioned against the anterior vessel wall. Temporary hemostasis is achieved at this point. Maintaining light tension on the vessel with the handle, the operator depresses the deployment slide on the handle to unlock the extravascular sealing mechanism and then advances the deployment slide distally until an audible and tactile click occurs signaling deployment of the proximal implantable Seal Assembly and separation of the implantable Seal Assembly from the AbsorbaSeal 5.6.7F VCD Delivery System/Galt Medical 6F Access Sheath. Complete hemostasis is achieved at this time. The AbsorbaSeal 5.6.7F VCD Delivery System/Galt Medical 6F Access Sheath assembly can is then safely removed.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for achieving closure or hemostasis of femoral artery access sites following small-bore catheterization include manual compression, mechanical compression, adjunctive pads and patches for helping to achieve hemostasis, and other vascular closure devices which use a suture or sutures; a collagen sponge or patch; a polymer hydrogel, plug, or patch; an extracellular matrix patch; a nitinol clip; or a stainless-steel implant. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The AbsorbaSeal 5.6.7F Vascular Closure Device has not been marketed in the United States or any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

- Allergic response
- Anemia
- Arterial occlusion
- Arterial thrombus
- Arteriovenous fistula
- Bleeding from the puncture site
- Bruising at the puncture site
- Death
- Device failure/malfunction
- Diminished pulses distal to the closure site
- Edema
- Embolization (thrombus, calcific debris, tissue, device, or air)
- Hematoma
- Infection
- Inflammatory response
- Intimal tear/dissection
- Laceration or perforation of the vessel wall
- Lower extremity ischemia
- Numbness
- Oozing from the puncture site
- Peripheral nerve injury
- Pseudoaneurysm
- Puncture site pain
- Retroperitoneal bleeding
- Vascular injury
- Vasospasm
- Vasovagal response
- Venous thrombus formation
- Wound dehiscence

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

IX. SUMMARY OF NON-CLINICAL STUDIES

A. Laboratory Studies

Design verification testing was conducted on both the AbsorbaSeal 5.6.7F VCD Delivery System and Seal Assembly to ensure the designs met all the required inputs

per the product specifications. The tests are summarized in Table 1 for the AbsorbaSeal 5.6.7F VCD Delivery System and Seal Assembly, respectively.

Table 1. Summary of Device Testing

Test	Purpose	Acceptance Criteria	Result
Dimensional (AbsorbaSeal 5.6.7F VCD Delivery System and Seal Assembly)	Verify the dimensional properties of the device	Ensure the device meets the dimensional requirements	Pass
Breaknotch Maximum force at Break Notch Failure (Seal Assembly)	Verify the connection force of the break notch component	The min break force should be 697 gf and max 1510 gf	Pass
Breaknotch Gasket Outer Diameter (OD) (Seal Assembly)	Verify the dimensional requirements of the component	Average OD of the gasket should measure between 3.4 ± 0.1mm	Pass
Distal Seal Glue Joint (AbsorbaSeal 5.6.7F VCD Delivery)	Verify the strength of the Distal Seal Glue Joint	The min glue joint failure force should be 2000g	Pass
Handle Glue Joint Failure (AbsorbaSeal 5.6.7F VCD Delivery System)	Verify the strength of the handle glue joint	The min glue joint failure is 2000 grams	Pass
Pusher Tube to Ram Glue Joint Failure (AbsorbaSeal 5.6.7F VCD Delivery System)	Verify the strength of the pusher tube to ram glue joint	The min glue joint failure is 1500 grams	Pass
Simulated Use (AbsorbaSeal 5.6.7F VCD Delivery System and Seal Assembly)	Verify the device operates as intended	The device had to pass the following checks while being deployed in a representative model: • Device in locked position • Gasket not stuck in inserter • Device pushes through sheath • Device fires and compresses tubes • Gasket attached between distal seal and tube	Pass

B. Sterilization

The AbsorbaSeal 5.6.7F Vascular Closure Device is sterilized using ethylene oxide (EO) through a process validated per ISO 11135:2014. Results obtained from the sterilization validation demonstrate that the product satisfies a minimum Sterility

Assurance Level (SAL) of 10-6. In addition, the amount of EO residuals and bacterial endotoxins was verified to be within appropriate specification limits.

C. Biocompatibility

Biocompatibility testing on the AbsorbaSeal 5.6.7F VCD Delivery System and implantable Seal Assembly was performed in accordance with ISO 10993-1. The AbsorbaSeal 5.6.7F VCD Delivery System is classified as an externally communicating device that is in contact with circulating blood for limited exposure (less than 24 hours). The Seal Assembly (implant) is classified as an implant device with tissue/bone contact for a permanent duration (greater than 30 days) in direct contact with circulating blood. Per the standard the testing described in Table 2 was conducted on the AbsorbaSeal 5.6.7F VCD.

Table 2. Biocompatibility testing supporting the biological safety of the AbsorbaSeal delivery system and implant

Biocompatibility Endpoint	Specific Test	Result
AbsorbaSeal 5.6.7F VCD Delivery System		
Cytotoxicity	MEM Elution Test	Non-cytotoxic
Sensitization	Guinea Pig Maximization Sensitization Test	Non-sensitizer
Irritation	ISO Intracutaneous Irritation Test	Non-irritant
Acute Systemic Toxicity	Acute Systemic Injection Test	Not inducing significantly greater biological reactions than the control extracts
Hemocompatibility	Direct/Indirect hemolysis and complement activation	Non-hemolytic
Material Mediated Pyrogenicity	Rabbit Pyrogen Test	Non-pyrogenic
In vivo Thrombogenicity	Assessed in animal study	Non-thrombogenic
AbsorbaSeal Seal Assembly		
Cytotoxicity	MEM Elution Test	Non-cytotoxic
Sensitization	Guinea Pig Maximization Sensitization Test	Non-sensitizer
Irritation	ISO Intracutaneous Irritation Test	Non-irritant
Acute Systemic Toxicity	Acute Systemic Injection Test	Not inducing significantly greater biological reactions than the control extracts
Material Mediated pyrogenicity	Rabbit Pyrogen Test	Non-pyrogenic
Implantation	Intramuscular Implantation	No significant local tissue responses to test article
Genotoxicity	AMES	Non-genotoxic
	MLA Assay	Non-genotoxic
Subacute and subchronic systemic toxicity	Assessed in animal study	Acceptable

Carcinogenicity	An assessment of the manufacturing process and device materials and the potential for toxicological exposure was conducted and established a preliminary profile for carcinogenicity and chronic toxicity.	Acceptable
Chronic toxicity		Acceptable

The AbsorbaSeal Seal Assembly (implant) has not been fully evaluated to establish potential for chronic toxicity and carcinogenicity. Prolonged exposure to systemic or carcinogenic toxicants may lead to long term harm and long-term carcinogenic effects. The risks of these potential harms from this specific product have not been established. The Seal Assembly passed all other assessments recommended by ISO 10993-1 supporting the biocompatibility of the device.

D. Degradation

Studies were performed to measure the molecular weight degradation of the AbsorbaSeal Seal Assembly (implant) in vitro using bench top studies. Results were then compared to the in vivo degradation results from a 120-day porcine study and 180-day porcine study (described in Section G. below). The in vitro and in vivo studies demonstrated that the AbsorbaSeal Seal Assembly achieves near complete degradation within 6 months.

E. Packaging

The packaging of the AbsorbaSeal VCD was evaluated in accordance with the requirements of ISO 11607-1. The packaging integrity test samples were subjected to sterilization, environmental conditioning, simulated shipping, and 12-month real-time aging that were in accordance with the applicable ASTM standards. Testing confirmed the sterile barrier integrity and minimum seal strength for the AbsorbaSeal VCD device packaging is maintained per the standard test methods.

F. Shelf-Life

The AbsorbaSeal VCD was evaluated to support a shelf life of 12 months. Devices were sterilized and underwent shipping distribution and environmental conditioning testing prior to real-time ageing in a temperature-controlled area for the full 12-month shelf-life. The testing demonstrated that devices aged for 12 months met the functional, visual, and performance requirements. No anomalies were found during testing. The delivery system was exposed to accelerated aging to a time point of 12 months per ASTM F1980-07. The aged samples met all acceptance criteria.

G. Animal Studies

Two chronic animal studies were performed to characterize the safety and performance of the AbsorbaSeal VCD. Studies were conducted to evaluate the acute

and chronic performance of the AbsorbaSeal 5.6.7F VCD Delivery System and Seal Assembly, as well as the vascular and physiologic responses to the implantable Seal Assembly.

A 120-day Good Laboratory Practices (GLP) compliant study in a porcine abdominal aortic model was performed to evaluate the acute and chronic safety and performance of the AbsorbaSeal VCD. Eight pigs were implanted with three AbsorbaSeal vascular closure devices each for a total of 24 access sites. Two animals were sacrificed at each of the following timepoints: 30 days, 60 days, 90 days and 120 days. The study assessed device deployment, angiography, pathology, in vivo degradation and full histopathology at each timepoint. No major adverse events were reported during the study. Hemostasis was achieved in all 24 access sites in all 8 animals. The average time to hemostasis in the animal study was 21.5 seconds. In vivo device deployment, time to hemostasis, vessel tissue effects, and thrombogenicity met acceptance criteria. The implantable Seal Assembly was not completely degraded by the final sacrifice timepoint (120 days).

A 180-day non-GLP study in a porcine model was conducted to evaluate the chronic safety and complete degradation profile of the Seal Assembly. One pig was implanted with two AbsorbaSeal vascular closure devices in the abdominal aorta and survived to 180 days. There were no major device related adverse events reported in the study. The mean time to hemostasis was 2.0 seconds. The target arteriotomy sites were assessed for complete device degradation and histopathological characteristics. The histological characteristics were consistent with normal healing from the arteriotomy procedure and an acceptably low level of chronic inflammation to the AbsorbaSeal Seal Assembly. The study outcomes support that the device results in minimal chronic inflammation with complete to almost complete device degradation present on histology at 180 days.

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of femoral access vascular closure with the AbsorbaSeal 5.6.7F VCD for closure of femoral artery access sites while reducing time to hemostasis and ambulation in patients who have undergone diagnostic or interventional vascular catheterization procedures in the US under IDE # G210374. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between May 13, 2022 and June 5, 2023. The database for this PMA reflected data collected through July 27, 2023 and included 29 roll-in subjects and 220 pivotal subjects. There were 9 investigational sites in the United

States. Among the 29 roll-in subjects, 10 underwent diagnostic procedures and 19 underwent interventional procedures. Among the 220 pivotal subjects, 102 underwent diagnostic procedures and 118 underwent interventional procedures.

The study was a multi-center, prospective, single-arm clinical study to establish the safety and effectiveness of the AbsorbaSeal 5.6.7F VCD. The study enrolled subjects undergoing diagnostic or interventional endovascular catheterization procedures performed through 5-7F introducer sheaths. The study success was based on meeting the predetermined performance goals (PG) for the primary safety endpoint and the primary effectiveness endpoint. All treated subjects were followed for 30 days. A ultrasound sub-study was performed on up to 55 enrolled subjects to ensure exam completion in at least 50 subjects. In the sub-study, non-invasive duplex ultrasound (DUS) images were obtained at the 30 day follow up of the common femoral artery and veins to assess the implant site for iatrogenic injuries, pseudoaneurysms, hematoma, vessel injury or thrombosis, and arteriovenous fistula. Patients were enrolled at 5 participating sites. A subgroup analysis was performed by age, gender, race, and ethnicity to assess the impact of these parameters. All images were evaluated by an independent Core Laboratory.

The study sample size was based on the safety endpoint. A total of 200 evaluable subjects, i.e., patients with non-missing data, were planned for the primary safety endpoint of treatment-related patient incidence of major access site closure complications to achieve a power of 98% to reject the null hypothesis.

Independent Clinical Events Committee (CEC) and a Data Safety Monitoring Committee (DSMC) were responsible for systematic review and adjudication of any reported deaths, all potential major or minor access site closure-related complications, and all potentially device-related serious adverse events (i.e., events eligible for review). An independent Ultrasound Core Laboratory was used to independently evaluate the ultrasound sub-study imaging.

1. Clinical Inclusion and Exclusion Criteria

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

   1. Age from 18 through 80 years
   2. Provides written informed consent and agrees to 30 ± 7-day follow-up requirements
   3. Acceptable candidate for an elective, non-emergent diagnostic or interventional vascular catheterization procedure using a 5, 6, or 7F introducer sheath via a femoral arterial approach
   4. Acceptable candidate for manual compression and/or emergent vascular surgery if necessary

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

1. Currently involved in any other investigational clinical trial
2. Prior target artery closure with any vascular closure device ≤ 90 days prior to the procedure, or if components of a prior VCD are present in the target artery
3. Known allergy to Poly lactide-co-glycolide (PLGA) and Poly lactide-co-caprolactone (PLACL) or to contrast medium that cannot be adequately pre-medicated
4. Evidence of active systemic infection
5. Known immunodeficiency disorder
6. Known history of bleeding diathesis, bleeding problems following medical procedures, or coagulopathy
7. Known baseline hemoglobin < 10 g/dl, hematocrit < 30%, platelet count < 100,000 cells/mm^3, or baseline INR > 1.8 for subjects on warfarin
8. Known baseline serum creatinine > 2.5 mg/dl
9. Thrombolytic therapy ≤ 24 hours prior to the procedure
10. Administration of low molecular weight heparin (LMWH) within 8 hours of the procedure
11. Unable to ambulate at least 20 feet at baseline
12. Previous target limb amputation below the knee
13. Existing nerve damage in the ipsilateral limb, exclusive of chronic neuropathy that would not confound the ability to detect acute nerve injury in the opinion of the Investigator
14. Life expectancy < 6 months due to severe comorbidities, in the opinion of the Investigator
15. Previous vascular grafts at the target access site
16. Previous vascular surgery or repair in the vicinity of the target access site within past 90 days
17. Planned endovascular or surgical procedure involving the target access site within the next 60 days
18. Use of an intra-aortic balloon pump in the ipsilateral limb ≤ 90 days prior to the procedure
19. Ineligible for vessel closure in the lab
20. More than one arterial femoral sheath is required during procedure
21. Any femoral venous sheath required during procedure
22. Evidence of a pre-existing hematoma, arteriovenous fistula, or pseudoaneurysm at the access site prior to start of the procedure
23. Pregnant (known or suspecting) or lactating
24. Mean body mass index (BMI) < 20 or > 45 kg/m^2

During the endovascular procedure, patients were not permitted to enroll in the study if they met any of the following intra-operative exclusion criteria:

1. Target vessel has a lumen diameter < 5 mm
2. Pre-existing vascular stent within 3 cm of the target access site
3. Fibrotic or severely calcified vessel within 10 mm of the target access site
4. Target access vessel is highly tortuous or requires a sheath length > 10 cm for closure procedure
5. Ipsilateral common femoral artery stenosis > 50%
6. Introducer sheath < 5F or > 7F used during procedure
7. Needle stick problems at onset of the procedure (multiple stick attempts, back wall stick)
8. Difficulty inserting the procedural sheath or evidence of sheath kinking
9. Common femoral artery (CFA) puncture site located above the lowest sweep of the inferior epigastric artery (high stick) or in the target vessel side wall (side wall stick)
10. Procedural sheath placement either in the superficial femoral artery or in the profunda femoris artery, or placement at or distal to the bifurcation of the superficial femoral artery and the profunda femoris artery
11. The puncture site is above the inguinal ligament
12. Forming hematoma or excessive bleeding around the procedural sheath, and/or suspected vascular complications
13. Loss of ipsilateral limb distal pulse during procedure
14. In the Investigator's opinion, any of the following circumstances are present:
    a. A different method should be used to achieve hemostasis of the arterial access site
    b. The subject should not attempt ambulation according to the protocol requirements in the opinion of the Investigator
    c. The subject may not comply with follow-up requirements for any reason
15. ACT > 350 seconds in subjects receiving unfractionated heparin in the absence of glycoprotein IIb/IIIa inhibitor or > 250 seconds in the presence of a glycoprotein IIb/IIIa inhibitor (the Investigator may wait to remove the introducer sheath until the time when the ACT level reaches to or is below the target value)
16. Systemic hypertension (systolic BP > 180 mm Hg) or hypotension (systolic BP < 90 mm Hg) just prior to access site closure
17. Procedures that may extend index hospitalization beyond 12 hours post-procedure (e.g., such as a staged endovascular procedure or a procedure from which a patient is referred directly to CABG surgery)

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 30 ± 7 days post-procedure. The key timepoints and evaluations conducted at all study timepoints are shown in Table 3.

Table 3. Pivotal Study Schedule of Assessments

	Baseline: ≤ 30 days prior to procedure	Index Procedure	Discharge	Follow-up at 30 days[7] (± 7 days)
Informed Consent Signed	X			
Demographics/Medical History	X			
Pre-procedure Inclusion/ Exclusion Criteria assessment[1]	X			
Peripheral nerve injury inquiry	X			
Pulse assessment of the target limb[2]		X		
Rutherford Classification of the target limb[3]	X			
Antiplatelet/anticoagulant medication regimen		X	X	
Access site evaluation		X	X	X
Intra-procedural Exclusion Criteria assessment		X		
Documented SBP 90-180 mmHg		X		
Activated Clotting Time (ACT) for subjects receiving unfractionated heparin		X		
Printed/saved image of sheath placement cine/computed tomography angiography		X		
Enrollment and Treatment		X		
Time to Hemostasis determination		X		
Time to Ambulation determination			X	
Time to Discharge Eligibility determination			X	
Access Site Pain Scale[4]			X	
Time to Discharge determination			X	
Ultrasound exam (sub-study)[5]				X
Adverse Events[6]		X	X	X

[1]All subjects must pass the institution's guidelines for COVID-19 screening prior to the index procedure.

[2]Baseline dorsalis pedis and/or posterior tibial pulses in the ipsilateral/target limb will be documented as present or absent on the day of the procedure, prior commencement of the index procedure, and assessed again just prior to enrollment as defined in the intra-operative exclusion criteria

[3]For subjects with a known history of peripheral vascular disease in the lower extremities, a baseline Rutherford Classification (RCC) will be documented for the target limb.

[4]Subject's assessment of access site pain based on a visual analog scale of 1-10, to be assessed in the peri-ambulation period.

[5]Designated Ultrasound Sub-study sites will perform a DUS exam of the target access site at the 30-day follow-up in subjects who consent to participate, until enrollment in the Sub-study has been fulfilled. DUS images will be recorded and uploaded to an Independent Core Laboratory.
[6]Sites will be required to submit source documents for potential endpoint adverse events that require adjudication by the Data Safety Monitoring Committee (DSMC), including any imaging reports of the access site performed for suspected complications.
[7]The subject's medical records should be reviewed as part of the 30-day follow-up to identify any potential events, even if the subject does not complete the visit.

3. Clinical Endpoints

Primary Safety Endpoint

With regards to safety, the primary safety endpoint was the 30 (± 7) day incidence rate of combined major access site closure-related complications. Major complications were defined as:

- Vascular injury requiring repair (via surgery, ultrasound guided compression, transcatheter embolization or stent graft)
- Access site closure-related bleeding requiring transfusion
- New ipsilateral lower extremity ischemia causing a threat to the viability of the limb and requiring surgical or endovascular intervention, documented by subject symptoms, physical exam and/or a decreased or absent blood flow on lower extremity angiogram
- New onset access site closure-related neuropathy in the ipsilateral lower extremity requiring surgical repair
- Permanent access site closure-related nerve injury (>30 days).
- Access site closure-related infection, confirmed by culture and sensitivity, and requiring intravenous antibiotics and/or extended hospitalization
-

The study was designed to demonstrate that the major access site closure-related complications for the ITT cohort met the Performance Goal (PG). The Performance Goal was set at 6.0% and was based on historical manual compression (MC) data from previous clinical trials for FDA-approved vascular closure devices.

Secondary Safety Endpoints

Secondary safety endpoints included: a) the rate of Combined Major Access Site Closure-Related Complications (listed above) stratified by type of procedure (diagnostic and interventional); and b) the 30-day rate of Combined Minor Access Site Closure-related Complications stratified by type of procedure (diagnostic and interventional). Minor complications were defined as:

- Pseudoaneurysm not requiring treatment
- Pseudoaneurysm requiring thrombin injection or fibrin adhesive injection
- Arteriovenous fistula not requiring treatment, documented by ultrasound
- Access site closure-related vessel laceration
- Access site closure-related hematoma > 6 cm documented by ultrasound

- Access site closure-related bleeding requiring greater than 30 minutes of continual manual compression to achieve initial arterial hemostasis
- Late access site closure-related arterial bleeding (following hospital discharge)
- Ipsilateral lower extremity arterial emboli
- Ipsilateral deep vein thrombosis documented by ultrasound
- New onset of transient access site closure-related neuropathy in the ipsilateral lower extremity that is transient (> 24 hours and < 30 days) and does not require surgical repair
- Access site wound dehiscence
- Localized access site infection, confirmed by culture and sensitivity, and treated with intramuscular or oral antibiotics

Primary Effectiveness Endpoint

With regards to effectiveness, the primary effectiveness endpoint is time to hemostasis (TTH) which is defined as the elapsed time between AbsorbaSeal 5.6.7F Delivery System/Galt Access Sheath assembly removal and first observed arterial hemostasis, exclusive of tissue tract ooze (subsequently confirmed after 5 minutes of observed hemostasis) for the combined cohort (diagnostic and interventional subjects).

- Hypotheses (Primary Analysis - Combined Cohort (Diagnostic and Interventional Subjects)

  H0: population mean AbsorbaSeal 5.6.7F VCD TTH – PG ≥ 0,

  HA: population mean AbsorbaSeal 5.6.7F VCD TTH – PG < 0,

  where PG is specific to each patient's procedure type, 17 minutes for diagnostic procedure (PG-D) and 24 minutes for interventional procedure (PG-I).

The primary TTH analysis was stratified by procedure type. Specifically, PG-D was subtracted from the observed TTH for each diagnostic procedure patient and PG-I was subtracted from the TTH for each interventional procedure patient. A 2-sided t test was then applied to all such differences study-wide, i.e., combining over the two procedure types. The primary effectiveness objective was considered met if this t-test demonstrated a statistically significant mean VCD – PG difference that is <0 at a 1-sided 0.025 level.

The following secondary effectiveness analyses were performed in a gated manner as specified below if the primary TTH PG was met. The secondary TTH analysis

tested the same hypothesis separately for each of diagnostic procedure subjects and interventional procedure subjects.

- Hypotheses (Secondary Analysis):

  Diagnostic Subjects
  H0: population mean AbsorbaSeal 5.6.7F Diagnostic TTH ≥ 17 minutes
  HA: population mean AbsorbaSeal 5.6.7F Diagnostic TTH < 17 minutes

  Interventional Subjects
  H0: population mean AbsorbaSeal 5.6.7F interventional TTH ≥ 24 minutes
  HA: population mean AbsorbaSeal 5.6.7F interventional TTH < 24 minutes

Secondary Effectiveness Endpoint

The secondary effectiveness endpoint was time to ambulation (TTA) defined as elapsed time between AbsorbaSeal 5.6.7F/sheath assembly removal and when subject stands and walks 20 feet without evidence of arterial re-bleeding from the access site.

Additional endpoints were time to discharge eligibility, time to hospital discharge, procedure success, and device success as defined below.

- Time to Discharge Eligibility- Elapsed time between AbsorbaSeal 5.6.7F/sheath assembly removal and when subject's access site is assessed to be hemodynamically stable post-ambulation, as determined by the investigator or his/her designee(s).

- Time to Hospital Discharge- Elapsed time between AbsorbaSeal 5.6.7F/sheath assembly removal and time that subject is actually discharged from the hospital ward.

- Procedure Success- Defined as attainment of final arterial hemostasis using any method and freedom from Major Access Site Closure-Related Complications through 30 ± 7 days.

- Device Success- Defined as the ability to deploy the delivery system, deliver the implant, and achieve arterial hemostasis with the AbsorbaSeal 5.6.7F alone or with post-hemostasis adjunctive compression.

With regard to success/failure criteria, the study will be considered a success if it meets both the AbsorbaSeal 5.6.7F performance goal for the primary effectiveness

analysis and the AbsorbaSeal 5.6.7F performance goal for the primary safety analysis.

B. Accountability of PMA Cohort

At the time of database lock, of 220 pivotal patients enrolled in the PMA study, 219 (99.5%) of subjects were available for analysis at the completion of the study, the 30-day (± 7 days) post-operative visit. The analysis sets were defined as follows:

- The Intent to Treat (ITT) cohort consisted of all enrolled subjects (interventional and diagnostic) in which the AbsorbaSeal 5.6.7F/sheath assembly was inserted, regardless of successful deployment of the AbsorbaSeal 5.6.7F or not.
- Per Protocol (PP) cohort consisted of all enrolled subjects (interventional and diagnostic) who had successful deployment of the AbsorbaSeal 5.6.7F VCD, and no major protocol deviations (defined as inclusion/exclusion violations)

The primary analysis consisted of all ITT subjects. Table 4 below provides an accountability of the ITT cohort.

Table 4. Follow-Up Compliance for ITT Cohort

	Diagnostic (N = 102)	Interventional (N = 118)	Total (N = 220)
30-Day Visit in Window	95.1% (97/102)	84.7% (100/118)	89.5% (197/220)
30-Day Visit Not in Window	3.9% (4/102)	15.3% (18/118)	10.0% (22/220)
Lost to Follow up [1]	1.0% (1/102)	0% (0/118)	0.5% (1/220)

[1] Diagnostic Patient 05-121 was lost to follow-up prior to the 30-day visit.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a VCD study performed in the US. Of the 220 enrolled pivotal subjects, 118 underwent diagnostic procedures and 102 underwent interventional procedures. The mean age was 66.3 ± 10 years. The percentage of male subjects was 57.7%, the percentage of female subjects was 42.3%, and the mean BMI was 29.9 kg/m2. Table 5 below provides the demographics and baseline characteristics of the pivotal subjects.

Table 5. Baseline Demographics of ITT Cohort in Seal to Heal Study

		Diagnostic (N = 102)	Interventional (N = 118)	Total (N = 220)
Age	Mean ± SD	64.1 ± 10.8 years	68.2 ± 8.9 years	66.3 ± 10.0 years
	Median	66 years	69.5 years	68 years
	Range	25 – 80 years	35 – 80 years	25 – 80 years
Male	Percentage	43.1% (44/102)	70.3% (83/118)	57.7% (127/220)

Ethnicity	Hispanic or Latino	7.8% (8/102)	11.0% (13/118)	9.5% (21/220)
	Not Hispanic or Latino	82.4% (84/102)	76.3% (90/118)	79.1% (174/220)
	Unknown	9.8% (10/102)	12.7% (15/118)	11.4% (25/220)
Race	White	87.3% (89/102)	89% (105/118)	88.2% (194/220)
	Black/African American	4.9% (5/102)	7.6% (9/118)	6.4% (14/220)
	American Indian/Alaska Native	2.9% (3/102)	0.8% (1/118)	1.8% (4/220)
	Asian	2.0% (2/102)	1.7% (2/118)	1.8% (4/220)
	Unknown	2.0% (2/102)	0.8% (1/118)	1.4% (3/220)
	Other	1% (1/102)	0% (0/118)	0.5% (1/220)
BMI (kg/m^2)	Mean ± SD	29.8 ± 5.5	29.9 ± 4.9	29.9 ± 5.2
	Median	28.1	29.5	28.8
	Range	20.5 - 47.6	20.2 – 43.3	20.2 – 47.6

The baseline medical history and risk factors of the pivotal subjects are summarized in Table 6 below.

Table 6. Medical History and Risk Factors- ITT Subjects

Characteristic	Diagnostic (N = 102)	Interventional (N = 118)	Total (N = 220)
Hypercholesterolemia/ Hyperlipidemia	69.6% (71/102)	79.7% (94/118)	75% (165/220)
Hypertension	77.5% (79/102)	84.7% (100/118)	81.4% (179/220)
Ever smoker	50.0 % (51/102)	63.6% (75/118)	57.3% (126/220)
Current Smoker	17.6 % (18/102)	18.6% (75/118)	18.2% (40/220)
Diabetes Mellitus	32.4% (33/ 102)	50.0% (22/118)	41.8% (40/220)
Lower Extremity Neuropathy	9.8% (10/102)	20.3% (24/118)	15.5% (34/220)
Peripheral Vascular Disease – lower extremities	11.8% (12/102)	51.7% (61/118)	33.2% (73/220)
Baseline Rutherford Classification (RCC) Index Limb			
0	1.0% (1/102)	4.2% (5/118)	2.7% (6/220)
1	0.0% (0/102)	2.5% (3/118)	1.4% (3/220)
2	2.9% (3/102)	7.6% (9/118)	5.5% (12/220)
3	1.0% (1/102)	19.5% (23/118)	10.9% (24/220)
4	2.0% (2/102)	5.9% (7/118)	4.1% (9/220)
5	4.9% (5/102)	11.0% (13/118)	8.2% (18/220)
6	0.0% (0/102)	0.8% (1/118)	0.5% (1/220)

The characteristics of the index procedures for the pivotal subjects are summarized in Table 7 below.

Table 7. Index Procedure Characteristics- ITT Subjects

Characteristic		Diagnostic (N = 102)	Interventional (N = 118)	Total (N = 220)
Procedure Target	Coronary	64.7% (66/102)	32.2% (38/118)	47.3% (104/220)
	Peripheral	10.8% (11/102)	50.0% (59/118)	31.8% (70/220)
	Lower extremity	10.8% (11/102)	47.5% (56/118)	30.5% (67/220)
	Other peripheral target [1]	0% (0/102)	2.5% (3/118)	1.4% (3/220)
	Other [2]	24.5% (25/102)	17.8% (21/118)	20.9% (46/220)
Target Femoral Artery Site	Right	93.1% (95/102)	63.6% (75/118)	77.3% (170/220)
	Left	6.9% (7/102)	36.4% (43/118)	22.7% (50/220)
Approach	Retrograde	99.0% (101/102)	93.2% (110/118)	95.9% (211/220)
	Antegrade	1.0% (1/102)	6.8% (8/118)	4.1% (9/220)
Procedure Sheath Size	5 French	60.8% (62/102)	27.1% (32/118)	42.7% (94/220)
	6 French	39.2% (40/102)	67.8% (80/118)	54.5% (120/220)
	7 French	0% (0/102)	5.1% (6/118)	2.7% (6/220)
Pre-Deployment Activated Clotting Time (seconds)	Mean ± SD	237.2 ± 49.2	253.4 ± 46.4	252.0 ± 46.6
	Median	244	244.5	244
	Range	161 – 306	156 – 350	156 – 350

[1] Other peripheral target included: Interventional: 1 left common femoral artery, 1 proximal to distal right superficial femoral artery, 1 superior mesenteric artery

[2] Other included: Diagnostic: 22 cerebral, 2 abdominal angiography with bilateral lower extremities, and 1 renal; Interventional: 15 hepatic, 4 prostatic, 1 renal, and 1 uterine

Anticoagulant/Antiplatelet Medications taken by subjects pre- and peri-procedurally are shown in Table 8 below. Pre- and peri-procedural anticoagulant and antiplatelet medications were reported in 79.5% of subjects, with 43.2% of total subjects receiving two oral medications in the ITT cohort.

Table 8. Oral Peri-Procedural Antiplatelet and Anticoagulant Medications for ITT Cohort

Medication	Diagnostic (N = 102)	Interventional (N = 118)	Total (N = 220)
Antiplatelet Medications			
Aspirin	65.7% (67/102)	72.9% (86/118)	69.5% (153/220)
clopidogrel (Plavix)	23.5% (24/102)	55.9% (66/118)	40.9% (90/220)
prasugrel (Effient)	2.0% (2/102)	9.3% (11/118)	5.9% (13/220)
ticagrelor (Brilinta)	2.0% (2/102)	7.6% (9/118)	5.0% (11/220)
ticlopidine (Ticlid)	0% (0/102)	0% (0/118)	0% (0/220)
aspirin-dipyridamole (Asasantin, Aggrenox)	0% (0/102)	0% (0/118)	0% (0/220)
Anticoagulant Medications			
dabigatran (Pradaxa)	0% (0/102)	0% (0/118)	0% (0/220)
edoxaban (Lixiana)	0% (0/102)	0% (0/118)	0% (0/220)
rivaroxaban (Xarelto)	1.0% (1/102)	9.3% (11/118)	5.5% (12/220)

warfarin (Coumadin)	1.0% (1/102)	0.8% (1/118)	0.9% (2/220)
Other (Not Specified)	2.9% (3/102)	5.1% (6/118)	4.1% (9/220)
Any Oral Medication	69.6% (71/102)	88.1% (104/118)	79.5% (175/220)

Intravenous (IV) and Subcutaneous Peri-Procedural Antiplatelet and Anticoagulant Medications for ITT Cohort are presented in **Table 9** below. The mean activated clotting time (ACT) in subjects receiving unfractionated heparin was 237.2 seconds for diagnostic subjects and 253.4 seconds for interventional subjects.

Table 9. Intravenous (IV) and Subcutaneous Peri-Procedural Antiplatelet and Anticoagulant Medications for ITT Cohort

Medication	Diagnostic (N = 102)	Interventional (N = 118)	Total (N = 220)
Antiplatelet Medication			
Any glycoprotein (GP) IIb/IIIa inhibitor (intravenous)	0% (0/102)	1.7% (2/118)	0.9% (2/220)
eptifibatide (Integrilin)	0% (0/102)	0.8% (1/118)	0.5% (1/220)
tirofiban (Aggrastat)	0% (0/102)	0.8% (1/118)	0.5% (1/220)
Anticoagulant Medication			
Unfractionated heparin (intravenous)	8.8% (9/102)	82.2% (97/118)	48.2% (106/220)
Low molecular weight heparin (subcutaneous)	0% (0/102)	0.8% (1/118)	0.5% (1/220)
Any IV/Subcutaneous Medication	8.8% (9/102)	83.1% (98/118)	48.6% (107/220)
No Medications	91.2% (93/102)	16.9% (20/118)	51.4% (113/220)
Protamine given (to reverse heparin)	1.0% (1/102)	4.2% (5/118)	2.7% (6/220)

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the intent to treat (ITT) cohort of 219 evaluable patients who completed the 30-day follow up visit. The key safety outcomes for this study are presented below in Tables 10 to 12.

The primary safety endpoint was the rate of combined major access site closure-related complications within 30 ± 7 days post-procedure on a per patient basis. The major access site closure-related complication rate for ITT pivotal subjects was 0.0% (0/219). The upper limit of the 2 sided 95% confidence interval for total (diagnostic and interventional) major access site closure-related complications is 1.7% and therefore, the performance goal of 6.0% was met ($p<0.0001$).

Secondary Safety Endpoint Results

The rate of Combined Major Access Site Closure-Related Complications stratified by type of procedure) were 0/101 (0.0%) for diagnostic subjects and 0/118 (0.0%) for interventional subjects, respectively.

The rate of Combined Minor Access Site Closure-related Complications stratified by type of procedure through 30 days is presented in Table 10. The Clinical Acceptance Criteria (CACs) for total minor access site closure-related complications were based on historical manual compression data and were 5.0% for diagnostic procedures and 6.0% for interventional procedures. The minor complication rates observed in the study were 0/101 (0.0%) for diagnostic subjects and 1/118 (0.8%) for interventional subjects in the ITT population. The observed rates are numerically less than the predetermined CACs of 5.0% for diagnostic procedures and 6.0% for interventional procedures. There was only one reported minor complication in an interventional subject which was a new onset of transient (≥ 24 hours and ≤ 30 days) access site closure-related neuropathy in the ipsilateral lower extremity. Surgical repair was not required.

Table 10. Incidence of Minor Complications in ITT Cohort"

Description of Event	Diagnostic (N = 101)	Interventional (N = 118)	Total (N = 219)
Pseudoaneurysm not requiring treatment, documented by ultrasound	0% (0/101)	0% (0/118)	0% (0/219)
Pseudoaneurysm requiring thrombin injection or fibrin adhesive injection, documented by ultrasound	0% (0/101)	0% (0/118)	0% (0/219)
Arteriovenous fistula not requiring treatment, documented by ultrasound	0% (0/101)	0% (0/118)	0% (0/219)
Access site closure-related vessel laceration	0% (0/101)	0% (0/118)	0% (0/219)
Access site closure-related hematoma ≥ 6 cm documented by ultrasound	0% (0/101)	0% (0/118)	0% (0/219)
Access site closure-related bleeding requiring > 30 minutes of continual manual compression to achieve initial arterial hemostasis	0% (0/101)	0% (0/118)	0% (0/219)
Late access site closure-related arterial bleeding (following hospital discharge)	0% (0/101)	0% (0/118)	0% (0/219)
Ipsilateral lower extremity arterial emboli	0% (0/101)	0% (0/118)	0% (0/219)
Ipsilateral deep vein thrombosis documented by ultrasound	0% (0/101)	0% (0/118)	0% (0/219)
New onset of transient access site closure-related neuropathy in the ipsilateral lower extremity that is transient (≥ 24 hours and	0% (0/101)	0.8% (1/118)	0.5% (1/219)

≤ 30 days) and does not require surgical repair			
Access site wound dehiscence	0% (0/101)	0% (0/118)	0% (0/219)
Localized access site infection, confirmed by culture and sensitivity, and treated with intramuscular or oral antibiotics	0% (0/101)	0% (0/118)	0% (0/219)
Total Minor Access Site Closure-Related Complications	0% (0/101)	0.8% (1/118)	0.5% (1/219)
Clinical Acceptance Criteria *for Diagnostic and Interventional Patients* for Total Minor Access Site Closure-Related Complications	5.0%	6.0%	

The rate of total minor access site closure related complications is less than the respective CACs. In the 30-day ultrasound sub-study, a total of 53 subjects had ultrasound exams. The Ultrasound Core Laboratory reported one new finding of a sub-clinical hematoma < 6 cm in diameter in one diagnostic subject. No other adverse findings were noted by the Ultrasound Core Laboratory.

Re-bleeding events, defined as arterial bleeding from the puncture site occurring after initial hemostasis has been confirmed for 5 minutes, occurred in 14 subjects (1 diagnostic and 13 interventional subjects). Three subjects experienced more than one re-bleeding event. These re-bleeding events were treated with manual compression and in one case a manual compression device. Table 11 summarizes the re-bleeding events.

Table 11. Re-bleeding Events in ITT Cohort

	Diagnostic (N = 102)	**Interventional (N = 118)**	**Total (N = 220)**
Number and Percentage of Patients with Re-bleeding Events	1.0% (1/102)	11.0% (13/118)	6.4% (14/220)
Timing of Onset of Re-bleeding Events			
Before Ambulation	0.0% (0/102)	7.6% (9/118)	4.0% (9/220)
During Ambulation	1.0% (1/102)	1.7% (2/118)	1.3% (3/220)
After Ambulation and Before Hospital Discharge	0.0% (0/102)	1.7% (2/118)	1.0% (2/220)
After Hospital Discharge	0.0% (0/102)	0% (0/118)	0.0% (0/220)
Re-bleeding Event Frequency			
Number of Pts With 1 Event	0.0% (0/102)	8.5% (10/118)	4.5% (10/220)
Number of Pts with 2 Events	1.0% (1/102)	1.7% (2/118)	1.4% (3/220)
Number of Pts with 3 Events	0% (0/102)	0.8% (1/118)	0.5% (1/220)

Adverse effects that occurred in the PMA clinical study:

A total of 39 adverse events were reported in 28/220 (12.7%) of the AbsorbaSeal 5.6.7F VCD subjects. Of these 39 adverse events, 3 were classified as serious adverse events. There were no device related Serious Adverse Events nor were there procedure related Serious Adverse Events. Adverse events with a potential relationship to the device or procedure included hematomas less than 6 centimeters in diameter (7 events), rebleeding 5 minutes after arterial closure (see Table 11 for complete details), oozing into the tissue tract (4 events), groin pain (1 event), fever (1 event) and vasovagal syncope (2 events), and one case of new onset of transient access site closure-related neuropathy in the ipsilateral lower extremity that is transient (minor complication reported in Table 10).

2. Effectiveness Results

The analysis of effectiveness was based on the 220 evaluable ITT subjects at discharge. The key effectiveness outcomes are presented in Table 12 and 13. The primary effectiveness endpoint was time to hemostasis (TTH) which is defined as the elapsed time between AbsorbaSeal 5.6.7F Delivery System/Galt Access Sheath assembly removal and first observed arterial hemostasis, exclusive of tissue tract ooze (subsequently confirmed after 5 minutes of observed hemostasis) for all subjects. The primary effectiveness analysis was to test the null hypothesis H0, TTH - PG > 0. Combined over the two procedure types, the overall mean TTH-PG was -19.04 minutes (95% CI: -19.78, -18.30) and the null hypothesis was rejected ($p<0.0001$). The t-test demonstrated a statistically significant mean VCD – PG difference less than 0 at a 1-sided 0.025 level; thus the primary analysis for the primary effectiveness endpoint was met. The secondary analysis for the primary effectiveness endpoint was performed and was stratified based on procedure type.

The performance goal for diagnostic procedures was pre-specified at 17 minutes and 24 minutes for interventional procedures based on historical manual compression data from previous clinical trials. The performance goals were met. The vast majority of subjects (92.2% (94/102) of diagnostic and 83.1% (98/118)

of interventional subjects) experienced TTH at the time of device deployment. All subjects achieved TTH within 30 minutes.

Table 12. Primary Effectiveness Endpoint TTH Results (ITT Cohort)

	Primary Analysis (Combined Cohort)	Secondary Analysis (Stratified by Procedure Type)	
Time to Hemostasis (minutes)	**N=220**	**Diagnostic (N = 102)**	**Interventional (N = 118)**
Mean ± Standard Dev	1.71 ± 4.95	0.85 ± 3.14	2.46 ± 6.01
[95% C.I.]	[1.06, 2.37)]	[0.23, 1.46]	[1.37, 3.56]
P-value	P < 0.0001[1]	P < 0.0001	P < 0.0001
Performance Goal	20.8 min[2]	17 min.	24 min.
Performance Goal Met?	Yes	Yes	Yes

[1]The p-value is nominal and was not adjusted for multiple comparisons

[2]Performance goal is calculated based upon the distribution of interventional and diagnostic patient

The key secondary effectiveness endpoint is summarized in Table 13. The secondary safety endpoint was time to ambulation (TTA) defined as elapsed time between AbsorbaSeal 5.6.7F/sheath assembly removal and when subject stands and walks 20 feet without evidence of arterial re-bleeding from the access site. The secondary effectiveness endpoint was TTA and compared to a pre-established performance goal of 6 hours for diagnostic procedures and 11 hours for interventional procedures. The mean TTA for the diagnostic subjects was 1.82 hours (95% CI: 1.72-1.92) and mean TTA for the interventional subjects was 3.15 hours (95% CI: 2.71-3.59). These mean TTA values for the AbsorbaSeal 5.6.7F met the diagnostic and interventional PGs. Time to ambulation (TTA) was achieved in ≤ 4 hours by 94.1% of subjects, and in ≤ 4 hours by 94.1% of subjects.

Table 13. Key Secondary Endpoint Results (ITT Cohort)

Time to Ambulation (hours)	Diagnostic (N = 101)	Interventional (N = 118)	Total (N = 219)[1]
Mean ± Standard Dev	1.82 ± 0.50	3.15 ± 2.41	2.54 ± 1.92
[95% C.I.]	[1.72, 1.92]	[2.71, 3.59]	[2.28, 2.79]
p-value	<0.0001 [1]	<0.0001 [1]	<0.0001 [1]
Performance Goal	6 hrs.	11 hrs.	9.1*

1 Subject 12-122 could not be assessed for Time to Ambulation

2 The p-value is nominal and was not adjusted for multiple comparisons

* Performance goal is calculated based upon the distribution of interventional and diagnostic patients.

The secondary effectiveness endpoints included TTD, procedure success and device success. Time to discharge eligibility (TTDE) was achieved by 93.2% of all subjects in ≤ 4 hours. All subjects were eligible for discharge within 24 hours. Time to discharge (TTD) was achieved by 92.3% of all subjects in ≤ 6 hours. The rate of procedure success was 100% and the overall device success rate was 93.6% (205/219). Device success was achieved in 96.1% (98/102) of diagnostic subjects and 91.5% (108/118) of interventional subjects. In the 14 cases where the device was not successful, these cases were attributed to user error resulting in incomplete deployment of the AbsorbaSeal VCD in 4 diagnostic and 10 interventional patients.

3. Duplex Ultrasound (DUS Sub Study)

A duplex ultrasound subgroup study was prospectively designed to evaluate a minimum of 50 evaluable ultrasounds at up to 5 study sites. The sub-study enrolled a total of 53 patients (21 diagnostic and 32 interventional subjects). Subjects completed the follow-up ultrasound exam at the 30 ± 7 days to assess for access site-related complications. The images were uploaded to an independent Ultrasound Core Laboratory for analysis. Of the 53 subjects enrolled with evaluable ultrasounds, abnormal findings were observed in 2 cases for an event rate of 3.8%. The abnormal findings were one hematoma and one arterial thrombus (which the investigator stated was pre-existing). Overall, these results supported the safe use of the AbsorbaSeal VCD.

Table 14. Abnormal Findings Noted on 30-Day Ultrasound Exams Per Ultrasound Core Lab in Pivotal Patients in AbsorbaSeal VCD Clinical Study[1]

Abnormal Finding	Diagnostic (N = 21)	Interventional (N = 32)	Total (N = 53)
Pseudoaneurysm	0% (0/21)	0% (0/32)	0% (0/53)
Arteriovenous fistula [2]	0% (0/21)	0% (0/29)	0% (0/50)
Dissection	0% (0/21)	0% (0/32)	0% (0/53)
Laceration/Perforation	0% (0/21)	0% (0/32)	0% (0/53)
Hematoma [3]	4.8% (1/21)	0% (0/32)	1.9% (1/53)
Embolism	0% (0/21)	0% (0/32)	0% (0/53)
Arterial thrombus [4]	0% (0/21)	3.1% (1/32)	1.9% (1/53)
Venous thrombus [2]	0% (0/21)	0% (0/29)	0% (0/50)
Total Abnormal Findings	4.8% (1/21)	3.1% (1/32)	3.8% (2/53)

[1] Event-based (based on number of events)

[2] Three (3) interventional patients (Patients 02-104, 02-105, and 02-108) could not be evaluated for arteriovenous fistula or venous thrombus since they had an ultrasound exam without venous images being captured in the exam. Thus the denominator is smaller.

[3] Sub-clinical hematoma was noted in Diagnostic Patient 05-137 and was 3.95 cm in diameter per the Ultrasound Core Lab.

[4] Arterial thrombus was noted in Interventional Patient 02-114 in the proximal superficial femoral artery. The investigator stated that this thrombus was pre-existing, having been noted on pre-index procedure ultrasound and at the time of access during the index procedure.

4. Subgroup Analyses

   The study was not specifically powered for sex, age, race, or ethnic subgroups. The study enrolled 24.1% females and 75.9% males. There were no notable differences in the time to hemostasis between female and male patients. The majority of the subjects (93.1%) enrolled in the study identified as white and there was insufficient evidence to conduct a meaningful subgroup analysis with respect to race and ethnic subgroups.

5. 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 17 investigators of which none were full-time or part-time employees of the sponsor and 2 had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: 0
- Significant payment of other sorts: 0
- Proprietary interest in the product tested held by the investigator: 0
- Significant equity interest held by investigator in sponsor of covered study: 2

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

XII. 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.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The assessment of effectiveness for the AbsorbaSeal 5.6.7F VCD was based on mean time-to-hemostasis (TTH). The study met the primary effectiveness performance goal of 17 minutes for diagnostic procedures and 24 minutes for interventional procedures. In the pivotal ITT cohort, on average, TTH was achieved in 0.85 minutes (95% confidence interval 0.23-1.46 minutes) for diagnostic subjects and 2.46 minutes (95% confidence interval 1.37-3.56 minutes) for interventional subjects. The vast majority of subjects (92.2% (94/102) of diagnostic and 83.1% (98/118) of interventional subjects) experienced TTH at the time of device deployment. Hemostasis was achieved with the AbsorbaSeal without the need for adjunctive methods in 87.7% (220-27/119) of subjects. Manual compression was used in 12.3% (27/119) of subjects, with 6.8% (7/119) for diagnostic procedures and 16.9% (20/x) for interventional procedures. Reasons for light pressure being held were reported primarily as active/persistent oozing noted at the access site in 5/7 (71%) diagnostic subjects and in 16/20 (80%) interventional subjects. No oozing/investigator discretion was the reported reason for the remainder.

The mean time to ambulation was 1.82 hours (95% confidence interval 1.72-1.92 hours) for diagnostic procedures and 3.15 hours (95% confidence interval 2.71-3.59 hours). Time to discharge eligibility was achieved in ≤ 4 hours by 93.2% of subjects. The procedure success rate of 100% and the device success rate was 93.6% in cases where device deployment was attempted.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory and/or animal studies as well as data collected in the clinical study conducted to support PMA approval as described above. The safety assessments for the AbsorbaSeal 5.6.7F device were based on the primary safety endpoint defined as freedom from major complications of the target limb access site within 30 days post-procedure. The primary safety endpoint was the rate of combined major access site closure-related complications within 30 ± 7 days post-procedure on a per patient basis. The major access site closure-related complication rate for ITT pivotal subjects was 0.0% (0/219). The upper limit of the 2 sided 95% confidence interval for total (diagnostic and interventional) major access site closure-related complications was 1.7% and therefore, the performance goal of 6.0% was met ($p<0.0001$).

The secondary safety endpoints provided additional evidence to support safety. The Clinical Acceptance Criteria (CACs) for total minor access site closure-related complications were based on historical manual compression data and were 5.0% for

diagnostic procedures and 6.0% for interventional procedures. The minor complication rates observed in the study were 0/101 (0.0%) for diagnostic subjects and 1/118 (0.8%) for interventional subjects in the ITT population. Comparing the two procedure groups did not note any clinically meaningful differences between the two procedure types.

C. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The potential benefits of using the AbsorbaSeal include hemostasis to be achieved in around one minute for the majority of subjects and a technical success rate of 93.6% (procedural success rate of 100%). The device performance is associated with an acceptable patient-based rate of major complications through 30 days of 0% and an acceptable patient-based rate of minor complications through 30 days of 0.5%.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. Even though no major adverse events were noted in the clinical trial, risks associated with the device include major vascular injury, access site bleeding, ipsilateral lower extremity ischemia, nerve injury, and access site infection. Additional risks include minor pseudoaneurysm, arteriovenous (AV) fistula, access site hematoma, late access site bleeding, lower extremity arterial emboli, vein thrombosis, transient access site nerve injury, access site wound dehiscence, and access site infection.

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 closure of the common femoral artery and vein access sites of patients who have undergone either diagnostic or interventional catheterization procedures using 5F to 7F introducer sheaths, 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. As discussed in the previous sections, the benefits of potential reduced time-to-hemostasis coupled with low rates of access site-related complications suggest that the benefits of using the AbsorbaSeal device outweigh the risks.

XIV. CDRH DECISION

CDRH issued an approval order on June 5, 2026. 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.

XV. 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.

XVI. REFERENCES

N/A