

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Vascular Closure Device

Device Trade Name: VASCADE MVP XL Venous Vascular Closure System (VCCS)
Model 800-1014XL

Device Procode: MGB

Applicant's Name and Address: Cardiva Medical, Inc.
1615 Wyatt Dr.
Santa Clara, CA 95054

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P120016/S039

Date of FDA Notice of Approval: March 27, 2026

The original PMA P120016 for the Vascular Closure System (VCS) was approved on January 31, 2013 and is indicated for femoral arterial access site closure while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures using a 5F, 6F, or 7F procedural sheath. The VASCADE VCS is also indicated to reduce time to discharge eligibility in patients who have undergone diagnostic endovascular procedures using a 5F, 6F, or 7F procedural sheath. The SSED to support the indication is available on the CDRH website (https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016b.pdf) and is incorporated by reference here.

The VASCADE MVP Venous Vascular Closure System (VVCS) was approved on November, 27 2018 through supplement P120016/S024 and is indicated for the percutaneous closure of femoral venous access sites while reducing time to ambulation, total post-procedure time, time to hemostasis, and time to discharge eligibility in patients who have undergone catheter-based procedures utilizing 6 – 12F inner diameter (15F maximum outer diameter) procedural sheaths, with single or multiple access sites in one or both limbs. The SSED to support the indication is available on the CDRH website (https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016S024B.pdf) and is incorporated by reference here.

Under P120016/S028, the indications for use were modified to include enabling same day discharge language for VASCADE MVP VVCS Model 800-612C, based on review and analysis of data from retrospective and prospective post-market registries for the VASCADE MVP VVCS Model Number 800-612C.

Under P120016/S029, a line extension was reviewed and approved to increase the size of the deployment disc and increase the collagen mass, adding VASCADE MVP XL VVCS Model Number: 800-1012XL to the VASCADE Family. The bench testing information used to support this line extension is summarized below in Section IX, Summary of Non-Clinical studies, as it was leveraged for the current supplement.

The current supplement was submitted to expand the indication for the VASCADE MVP XL VVCS to include use with a broader range of procedural sheath size, and assign a new device model number, Model 800-1014XL, which replaces the prior model number, Model 800-1012XL.

II. INDICATIONS FOR USE

The VASCADE MVP XL Venous Vascular Closure System (VVCS) Model 800-1014XL is indicated for the percutaneous closure of femoral venous access sites while reducing time to ambulation, total post-procedure time, time to hemostasis, and time to discharge eligibility in patients who have undergone catheter-based procedures utilizing 8 – 14F inner diameter (17F maximum outer diameter) procedural sheaths, with single or multiple access sites in one or both limbs.

The VASCADE MVP XL Venous Vascular Closure System (VVCS) Model 800-1014XL is also indicated for enabling same day discharge in patients who have undergone catheter-based cardiac arrhythmia ablation procedures utilizing 8 – 14F inner diameter (17F maximum outer diameter) procedural sheaths, with single or multiple access sites in one or both limbs.

III. CONTRAINDICATIONS

The VASCADE MVP XL VVCS should not be used in patients with a known allergy to bovine derivatives.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the VASCADE MVP XL VVCS labeling.

V. DEVICE DESCRIPTION

A. Materials and Configuration

The VASCADE MVP XL Venous Vascular Closure System (VVCS) Model 800-1014XL is intended to seal the femoral vein access site(s) at the completion of the procedure. The system consists of a sterile disposable Vascular Closure Catheter which houses a resorbable Collagen Patch, and the VASCADE MVP XL Clip (refer to Figure 1).

The system is designed to deliver a resorbable Collagen Patch, extra-vascularly, at the venotomy site to aid in achieving hemostasis. The patch expands as a result of rehydration in the presence of blood in the tissue tract to provide an extravascular seal. A radiopaque proximal marker band on the Catheter provides means to aid in verifying placement of the patch in the tissue tract adjacent to the femoral venotomy site prior to the release of the patch. A second distal marker band locates the distal tip of the VASCADE MVP XL Disc.

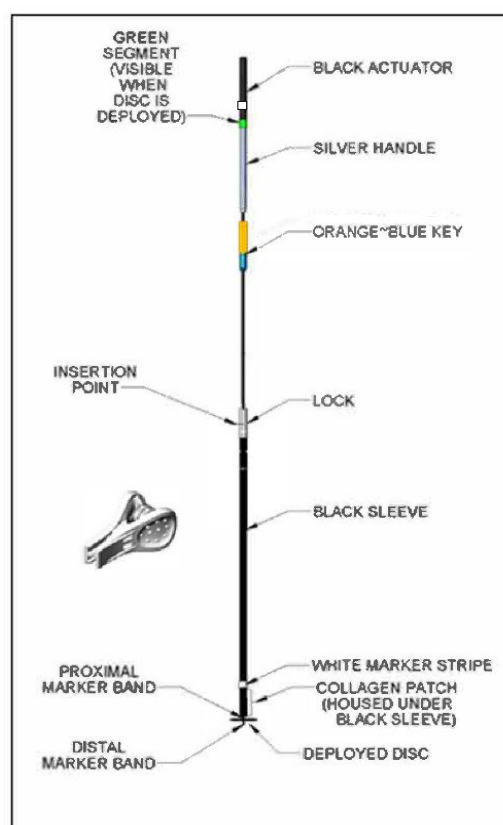


Figure 1: VASCADE MVP XL VVCS

A line extension for the Cardiva Medical VASCADE MVP XL Venous Vascular Closure System (VVCS) device, Model 800-1012XL was approved under P120016/S029, as indicated in Section I above. This product was similar in design to the previous model with the main difference being it was designed to be compatible with 10-14F inner diameter sheaths. The VASCADE MVP XL VVCS Model 800-1014XL, subject of this PMA supplement, is designed to be compatible with 8F-14F inner diameter (ID) sheaths (maximum outer diameter (OD) 17F).

B. Operation

The VASCADE MVP XL VVCS Model 800-1014XL is used with a sheath between 8-14F ID (max 17F OD), and the catheter is inserted into the femoral vessel through the previously placed closure sheath. After insertion, the distal tip of the catheter is deployed, opening and expanding a Nitinol (NiTi) disc within the lumen of the femoral

vein. The sheath is then removed from the vessel over the catheter and the low-profile disc is placed against the inner wall, locating the vessel wall and temporarily sealing the vessel. The position of the device disc against the vessel wall locates the collagen patch in the tissue tract immediately adjacent to the vessel site (extravascular). The collagen patch is then released. The clip is placed on the device shaft at the surface of the skin to hold the device in place during the procedure.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for attaining hemostasis at a venous puncture site post-catheterization, including manual or mechanical compression, percutaneous suture delivery, and PEG-based hemostatic devices. Pressure dressings and sandbags are routinely used in combination with compression methods to control oozing. 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 VASCADE MVP XL Venous Vascular Closure System has been commercially available in the United States since June 2024. It is also commercially available in Japan and the United Arab Emirates and has not been withdrawn from marketing for any reason related to its safety or effectiveness.

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
- Vessel occlusion
- Vessel thrombus
- Arterio-venous fistula
- Bleeding from the puncture site
- Oozing from the puncture site
- Bruising at the puncture site
- Death
- Device failure/malfunction
- Edema
- Embolization (of thrombus, air, calcific debris, or device)
- Pulmonary Embolism
- Hematoma
- Infection
- Inflammatory response
- Intimal tear / dissection

- Laceration of the vessel wall
- Lower extremity ischemia
- Perforation of the vessel wall
- Peripheral nerve injury
- Peripheral nerve irritation
- Pseudoaneurysm
- Retroperitoneal bleeding
- Deep vein thrombosis
- Vascular injury
- Vasovagal response
- Puncture site pain
- Superficial vein thrombosis

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

IX. SUMMARY OF NON-CLINICAL STUDIES

The sponsor has leveraged previous non-clinical testing conducted on the subject device, since the device itself is not changing, only the indications for use. The most recent bench testing was completed in and reviewed under P120016/S029 as a line extension for the VASCADE MVP XL VVCS Model 800-1012XL. The model 800-1014XL, subject of the current submission, leverages the same design, materials and manufacturing as the VASCADE MVP XL device approved through P120016/S029 and subsequent applicable supplements for minor design and process changes (P120016/S033 and P120016/S037). Therefore, completed testing was referenced from these previous PMA supplements under P120016 where such testing were leveraged, and is briefly summarized below.

Summaries of previously reported preclinical studies can also be found in the Summary of Safety and Effectiveness Data (SSED) for the original PMA (https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016b.pdf) and PMA supplement for VASCADE MVP (https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016S024B.pdf)

A. Laboratory Studies

Laboratory studies were leveraged from P120016/S024, and supplemental tests were leveraged from P1200016/S029 to support the Model 800-1014XL line extension in this PMA supplement, since the device has identical design, materials, and manufacturing as the previously approved device, and only the model number is changing, the device is not changing. All of the test results met or exceeded the specified requirements in the product specification and test protocols. The testing leveraged from P1200016/S029 includes the following tests:

Table 1: Laboratory Studies Leveraged from P120016/S029

Purpose	Test	Acceptance Criteria	Result
Device must be compatible with commercially available introducer sheaths.	Overall Device Outer Diameter	$\leq 0.100''$	Pass
	Outer Sleeve Outer Diameter	$0.098'' \pm 0.002''$	Pass
	Tip Outer Diameter at Proximal Sleeve	$\leq 0.086''$	Pass
	Sleeve to grip assembly length	$> 12 \text{ cm}$	Pass
	Catheter tip inserted and removed from introducer sheath	Catheter tip should penetrate the seal of the introducer sheath without damage to the membrane or compromise the integrity of the membrane joint.	Pass
	Distance of the Collagen implant marker from the distal size of the proximal sleeve to the proximal side of the marker	$2.2 \text{ cm} \pm 0.2 \text{ cm}$	Pass
Device must be able to reach the arterial access site it intends to seal	Implant length	$1.5 \text{ cm} \pm 0.2 \text{ cm}$	Pass
	Catheter Working Length	$15.0 \pm 0.5 \text{ cm} (5.9'' \pm 0.2'')$	Pass
	Overall Catheter length	$38.0 \pm 1.0 \text{ cm} (15.0'' \pm 0.4'')$	Pass
Device should be easy to use, simple to deploy, and simple to de-deploy	Disc deployment force	$\leq 3.0 \text{ lb}$	Pass
	Disc de-deployment	$0.5 \text{ lb} \leq x \leq 2.5 \text{ lb}$	Pass
	Deployed Disc Diameter	$0.328'' + 0.013'' / - 0.026''$ (25 Fr +1 Fr / -2 Fr)	Pass
	Clip force	1.0 lb minimum	Pass
	Catheter pull through force	Pull through force: $> 8 \text{ oz}$	Pass
Device shall be able to withstand multiple deployment and de-deployment attempts	Multiple disc deployment	Device should be able to withstand deployment and de-deployment at least 5 consecutive times in 37°C water	Pass

Purpose	Test	Acceptance Criteria	Result
Sterilized membrane shall be able to withstand prolonged deployment	Prolonged Deployment	Deployment time for a period of 1 hours	Pass
Collagen should be of a consistent weight during and after the procedure	Dry weight	19 mg $\pm$ 3 mg	Pass
	Hydrated weight within 30 seconds when submerged in 37 C heparinized blood or plasma	$\leq$ 50 mg	Pass
Implant functionality and position should be maintained until it is ready for deployment	Collagen displacement post inner sleeve retraction when the device tip is dipped in saline and subjected to 5 seconds of pressurized saline followed by 2 minutes of pressurized blood	Outer Sleeve: < 10 oz Inner Sleeve: < 10 oz	Pass
Device should maintain strength throughout the procedure	The tensile strength of the joint between grip and outer sleeve	3.4 lb. minimum	Pass
	Outer Sleeve tubing assembly (distal to proximal) bond joint strength	$\geq$ 1.30 lbs	Pass
	Back stop to catheter shaft bond joint strength		Pass
	Inner Sleeve tubing assembly (distal to proximal) bond joint strength		Pass
	Joint strength of the joint that limits the travel of the outer sleeve over the inner sleeve		Pass
	Back stop to catheter shaft bond joint strength		Pass
	Push rod tubing assembly bond joint strength	$\geq$ 2.25 lbs	Pass

Purpose	Test	Acceptance Criteria	Result
	Catheter shaft with expander to outer handle joint strength		Pass
	Push rod's sidewall lumen to tip house bond joint strength		Pass
	Key fused segment joint strength		Pass
	Proximal braid attachment to the catheter shaft expander and sleeve		Pass
	Actuator to Inner Handle joint strength	≥ 3.00 lbs	Pass
	Pull wire to Inner Handle joint strength		Pass
	Braid tip to pull wire joint strength		Pass
	Inner handle over-molded joint strength		Pass
	Polyimide expander to shaft bond joint strength	≥ 1.3 lbs	Pass

B. Sterilization

The VASCADE MVP XL is sterilized by gamma radiation in the range of 20-35kGy. The packaging system has been demonstrated to be an appropriate sterile barrier and remains intact through the device shelf-life following packaging validation testing reviewed under S029. The sterilization process was validated to deliver a minimum Sterility Assurance Level (SAL) of 10^{-6} for the device and its packaging.

C. Biocompatibility

No new biocompatibility testing was required to support the VASCADE MVP VVCS Model 800-1014XL line extension.

D. Animal Studies

As part of this submission, three new animal studies were performed in porcine animal models to evaluate the performance of the VASCADE MVP XL VVCS Model 800-1014XL in percutaneous closure of venous access sites from 8F ID access sheaths for an acute study and 14F ID Access sheaths for 90 and 120 studies. All three studies used the 19 mg ±3 mg Collagen Patch. Final hemostasis was achieved without complication, and the device was successfully deployed in 100% of access sites evaluated.

Two prior animal studies, reviewed under P120016/S029 to support the safety and effectiveness of the product line extension, were also referenced and leveraged to support P120016/S039. The first study evaluated the device performance in an acute model for 30 days. This study confirmed the collagen demonstrated adequate re-integration in the tissue tract and allowed for reaccess at 30 days. The second study was a similar study performed out to 60 days, and the results were found to be acceptable.

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

The applicant performed a clinical study, entitled AMBULATE EXPAND, to establish a reasonable assurance of safety and effectiveness of percutaneous closure of femoral venous access sites with the VASCADE MVP VVCS Model 800-1014XL in patients who have undergone catheter-based procedures utilizing 16-17F outer diameter procedural sheaths in the US under IDE # G240216. The study device is the VASCADE MVP XL VVCS Model 800-1014XL with 25F Disc (~8.3 mm) and 19 mg collagen implant. 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 February 2025 and July 2025. The database for this Panel Track Supplement reflected data collected through August 2025 (database lock/study completion date of September 8, 2025) and included 77 patients and an additional 8 roll in patients. There were 8 investigational sites. All sites were in the US.

The study was a prospective, multi-center, single-arm clinical study to evaluate the safety and effectiveness of the VASCADE MVP XL Study Device for the management of the femoral venotomy after catheter-based interventions performed utilizing 16-17F OD sheaths. Measures of safety and effectiveness were assessed through 30 ($\pm$ 7) days post-procedure.

An ultrasound sub-study was included as part of this clinical trial at 5 sites utilizing independent analysis of non-invasive duplex ultrasound (DUS) imaging. 29 subjects completed the ultrasound exam. The ultrasound was performed at any point between when successful ambulation was documented (i.e., time to ambulation (TTA)) and 5 calendar days post-procedure. DUS evaluation was utilized to assess the local vascular impact of the VASCADE MVP XL Study Device, along with the development of any iatrogenic vascular complications.

1. Clinical Inclusion and Pre-Operative and Intra-Operative Exclusion Criteria

Pre-Operative

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

- 18 to 80 years of age
- Capable and willing to give informed consent
- Planned non-emergent catheter-based procedure via:
 - Study Limb (Required): The common femoral vein using one 16-17F OD introducer sheath
 - Minimum 10F ID
 - Non-Study Limb (optional): The common femoral vein of the Non-Study Limb using up to three (3) 5-12F ID (max 15F OD) introducer sheaths
- Able and willing to complete a 30 day $\pm$ 7 days follow-up visit

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

- Currently involved in any other investigational clinical trial that may interfere with the outcomes of this study, in the opinion of the Investigator
- Pre-existing immunodeficiency disorder and/or chronic use of high dose systemic steroids
- Known history of bleeding diathesis, bleeding problems following medical procedures, or coagulopathy
- Known baseline hemoglobin < 10 g/dl, hematocrit $< 30\%$, platelet count $< 100,000$ cells/mm³
- Severe co-existing morbidities, with a life expectancy of less than 12 months in the opinion of the Investigator
- Known history of deep vein thrombosis or pulmonary embolism in the last 12 months
- Known allergy/adverse reaction to bovine derivatives
- Active systemic infection, or cutaneous infection or inflammation in the vicinity of the groin
- Unable to ambulate at least 20 ft at baseline
- Pregnant (known or suspected) or lactating
- Extreme morbid obesity (BMI greater than 45 kg/m²) or underweight (BMI less than 20 kg/m²)
- Known planned procedures or known concomitant condition(s) that may extend ambulation attempts beyond 2-3 hours, and/or hospitalization time (e.g., staged procedure, serious co-morbidity), in the opinion of the Investigator
- Femoral vessel closure in either limb with any of the following conditions:
 - Planned femoral access in the next 60 days to reflect the device re-access period
 - Any residual hematoma, significant bruising, or known associated

- vascular complications
 - Use of an intra-vascular closure device within the previous 90 days
 - Access within < 10 days
- Currently known implanted vascular grafts/stents at the access site that would interfere with the planned closure procedure, in the opinion of the Investigator

Intra-Operative Exclusion Criteria

Subjects were excluded from participating in this study if any of the following exclusion criteria occurred prior to initiation of closure of the Study Access Site:

- Administration of low molecular weight heparin (LMWH) within 8 hours before or planned after the procedure
- Uncontrolled systolic hypertension (SBP > 180 mmHg) or hypotension (SBP < 90 mmHg) immediately prior to enrollment
- Subject may be ineligible to ambulate per protocol for any reason, for example:
 - Any procedural complications, medical conditions (e.g., extended diuresis required), or issues with Non-Study Access Site closure that may extend recovery, ambulation and discharge times
 - The subject should not attempt ambulation according to the protocol requirements for any reason, in the opinion of the Investigator
- Any attempted femoral arterial access in either limb during the procedure
- The Investigator deems that a different method should be used to achieve hemostasis of the Study Access Site than stipulated per protocol (e.g., manual compression)
- Disease state or other source of interference that would interfere with the use of the device, in the opinion of the Investigator (e.g., vascular grafts or surgery at the target vessel puncture site)
- The following are exclusions for ALL access sites immediately prior to enrollment unless otherwise noted:
 - Difficult insertion of procedural sheath or needle stick problems at the onset of the procedure (e.g., multiple stick attempts, unintentional vessel stick with hematoma, “back wall stick”) in any of the vessel punctures
 - Access site configurations and procedure sheath size outside of the protocol range:
 - Study Limb (required) – MVP XL Study Device
 - OD: < 16F or > 17F venous or
 - ID: < 10F or
 - More than one access site in the Study Limb
 - Non-Study Limb (optional) – VASCADE Family Commercial Device:

- OD: > 15F or
- ID: < 5F or > 12F venous or
- More than 3 access sites in the Non-Study Limb or
- Non-Study Access site(s) are in the same limb as the Study Limb
- Vessel access site location is noted to be “high” or not at the common femoral vessel (above the inguinal ligament, cephalad to lower half of the femoral head or the inferior epigastric vein origin from the external iliac vein)
- Intra-procedural bleeding around sheath, forming hematoma, and/or suspected vascular complications
- Length of the tissue tract, the distance between the anterior vessel wall and skin, is estimated to be less than 2.5 cm
- Femoral vessel diameter less than 6 mm at access site
- The Non-Study Access Site(s) were not closed successfully with VASCADE commercial device(s) with final hemostasis confirmed prior to Study Access Site closure

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 30 ± 7 days post-procedure.

Preoperatively, patient’s medical history, demographic data, baseline information, and medication regimen were collected. Adverse events and complications were recorded at the follow up exam which occurred $30 (\pm 7)$ days post-procedure. Patients were evaluated for any major or minor complications or adverse events including bleeding, neurological and other potential device or procedure-related adverse effects. Adverse events and complications were recorded pre-discharge and at the $30 (\pm 7)$ days follow up exam.

3. Clinical Endpoints

With regards to safety, the primary safety endpoint was the rate of combined major access site closure-related complications, analyzed on a per-limb basis, through $30 (\pm 7)$ days post-procedure. The secondary safety endpoint was the rate of combined minor access site closure-related complications, analyzed on a per-limb basis, also through the $30 (\pm 7)$ day follow-up period.

The performance goal (PG) for the primary endpoint was set to 10% for the VASCADE MVP XL VVCS Model 800-1014XL Study Device and was derived from a review of published literature (Mohammad M, et al. 2022). The PG was selected at 10% in alignment with the upper bound of a 95% upper confidence interval from this study of venous access sites with 18F OD sheaths, which had

2/67 (3.0%; exact binomial CI upper bound of 10.4%) major complications (2 subjects with transfusion related to vascular access).

The clinical acceptance criterion (CAC) for 30-day minor complication limb incidence rate was set at 3.0% for the VASCADE MVP XL VVCS Model 800-1014XL Study Device and was derived from the minor complication rate (2.4%) reported in the prior AMBULATE Study for the manual compression (MC) arm for the Model 800-612C device, approved under P120016/S024, November 27, 2018.

With regards to effectiveness, the primary endpoint was TTA defined as elapsed time between removal of the final VASCADE MVP XL study device (treatment arm), and time when subject stands and walks 20 feet without evidence of venous re-bleeding from the femoral access sites. The PG for the primary endpoint was the clinically relevant TTA of 6.1 hours, derived from the mean time to ambulation reported in the prior AMBULATE study for the manual compression (MC) arm for the Model 800-612C device, approved under P120016/S024, November 27, 2018.

The secondary effectiveness endpoints were time to hemostasis (TTH), time to discharge eligibility (TTDE), total post-procedure time (TPPT), Device Success, Procedure Success, and time to hospital discharge (TTD). The clinical acceptance criteria for each secondary effectiveness endpoint was derived from the previously reported means + 1 standard deviation in the prior AMBULATE study for the Model 800-612C device study arm, approved under P120016/S024, November 27, 2018.

The primary and secondary endpoint definitions are provided in Table 2 below.

Table 2. Effectiveness Endpoint Definitions.

Primary Effectiveness Endpoint	Time to Ambulation (TTA): elapsed time between Study Device removal and when subject stands and walks 20 feet without evidence of venous re-bleeding from the Study Access Site (per-subject analysis).
Secondary Effectiveness Endpoints	Time to Hemostasis (TTH): elapsed time between Study Device removal and first observed and confirmed venous hemostasis, for the Study Access Site (per-access site analysis).
	Total Post Procedure Time (TPPT): elapsed time between removal of the last procedural device/catheter for the index procedure in the Study Access Site and when subject was able to successfully ambulate based on the Study Access Site (per-subject analysis).
	Time to Discharge Eligibility (TTDE): elapsed time between Study Device removal and when subject is eligible for discharge based solely on the assessment of the Study Access Site (per-subject analysis).

	Time to Discharge (TTD): elapsed time between Study Device removal, and when subject is discharged from the institution (per-subject analysis).
	Procedure Success (PS): Attainment of final hemostasis at all venous access sites and freedom from major venous access site closure-related complications through 30 days (per-subject analysis).
	Device Success (DS): The ability to deploy the delivery system, deliver the collagen, and achieve hemostasis with the Study Device (per-access site analysis).

B. Accountability of PMA Cohort

At the time of database lock, of 77 patients enrolled in the PMA study, [100% (77)] patients were available for analysis at the completion of the study. No subjects were lost to follow up. The required assessments for the follow-up visit were captured for all subjects, and all subjects were evaluated in or after the 30-day follow-up window. A summary of patient accountability is included in Table 3 below.

Table 3: Patient Accountability Summary Table

	Pivotal Subjects (N=77)	
	n	%
Completed Study including Follow-Up	77	100%
Withdrawn, Lost to Follow-Up, or Other Study Exit	0	0%

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a vascular closure study performed in the US. The mean age of subjects was 67.2 ± 9.8 years, the percentage of female subjects was 27.3%, and the mean BMI was 29.3 ± 5.4 kg/m². Table 4 provides a summary of the demographic results.

Table 4: Patient Demographics and Baseline Characteristics

	Pivotal Subjects (N=77)	
	n	%
Age (years)		
Mean	67.2	-
Std Dev	9.8	-
Median	68.0	-
Min	34	-
Max	80	-
Sex Assigned at Birth		
Male	55	71.4%
Female	21	27.3%
Declined to answer	1	1.3%
Gender		
Male	56	72.7%
Female	21	27.3%
Ethnicity		
Not Hispanic or Latino	74	96.1%
Hispanic or Latino	1	1.3%
Unknown	2	2.6%
Race		
White	72	93.5%
Black or African American	4	5.2%
Other: Unknown	1	1.3%
BMI (kg/m²)		
Mean	29.3	-
Std Dev	5.4	-
Median	29.2	-
Min	17.1	-
Max	43.4	-

Medical History

Medical History and Risk Factors are presented in Table 5.

Table 5: Medical History and Risk Factors

	Pivotal Subjects (N=77)	
	n	%
Hypercholesterolemia		
Yes	46	59.7%
No	31	40.3%
Hypertension		
Yes	52	67.5%
No	25	32.5%
Cigarette Smoker		
No history	53	68.8%
Ex-Smoker	20	26.0%
Current	4	5.2%
Diabetes Mellitus		
Yes	9	11.7%
No	68	88.3%
	Pivotal Subjects with Diabetes (N=9)	
Diabetes Treatment		
Oral Hypoglycemics	4	44.4%
Insulin	2	22.2%
Non-insulin injectables	1	11.1%
Insulin & Oral Hypoglycemics	1	11.1%
Other: Glucosamine-Chondroitin	1	11.1%

Anticoagulant and Antiplatelet Medications

Pre-Procedure anticoagulant/antiplatelet administration within the previous 24 hours was captured for all patients, with most subjects taking anticoagulant/antiplatelet medications prior to the procedure (98.7%), with a majority of those subjects on apixaban (82.9%). Intra-Procedural administration of heparin was 100%. Activated Clotting Times (ACTs) were collected at the time of index procedure. The mean clotting time for subjects was reported as 363.65 seconds. Anticoagulant administration is summarized in Table 6 below.

Table 6: Pre-Procedural Anticoagulant/Antiplatelet Medication & Intra-Procedural Administration

	Pivotal Subjects (N=77)			
	n		%	
Subjects Taking Any Pre-Procedural Anticoagulant/Antiplatelet Medication				
Yes	76		98.7%	
No	1		1.3%	
	Number of Meds (N=80)		Subjects on Medication (N=76)*	
	n	%	n	%
Medication				
Apixaban (Eliquis)	63	78.8%	63	82.9%
Aspirin	3	3.8%	3	4.0%
Clopidogrel (Plavix)	3	3.8%	3	4.0%
Dabigatran (Pradaxa)	1	1.3%	1	1.3%
Rivaroxaban (Xarelto)	9	11.3%	9	11.8%
Warfarin (Coumadin)	1	1.3%	1	1.3%
Intra-Procedural Administration				
Intra-procedural administration of heparin				100%
Protamine used (heparinized subjects)				84.4%
Activated clotting time (ACT) (seconds) at the end of the catheterization procedure (heparinized subjects), mean				363.7
*Subjects may have been on more than one medication				

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the cohort of 77 patients/procedures available for the 30-day post procedure evaluation. The key safety outcomes for this study are presented below in Tables 7 and 8.

Table 7 provides an event passed analysis on the Intent-to-Treat (ITT) basis, of the major access site-related complications reported in the AMBULATE EXPAND trial for the VASCADE MVP XL VVCS Model 800-104XL study device during the 30-day post procedure evaluation. There were no major venous access site closure-related complications observed in the 30-day follow-up period. An exact binomial test confirmed the observed complication rate was statistically lower than the PG of 10% ($p=0.0003$). The one-sided upper 97.5% CI was 4.68% which is less than the PG, therefore the primary safety endpoint was successfully met.

Table 7. Major Venous Access Site Closure Related Complications

	Study Limbs (N=77)	
	n	%
Any Major Venous Access Site Closure-Related Complication	0	0%
Access site-related bleeding requiring transfusion	0	0%
Vascular injury requiring surgical repair (via surgery, transcatheter embolization, balloon angioplasty or stent graft)	0	0%
Access site-related infection confirmed by culture and sensitivity, requiring intravenous antibiotics and/or extended hospitalization	0	0%
New onset permanent access site-related nerve injury in the ipsilateral lower extremity (i.e., persisting for 30 days)	0	0%
Pulmonary embolism requiring surgical or endovascular intervention and/or resulting in death, to be confirmed by CT pulmonary angiography or lung ventilation/perfusion scan (VQ scan) or autopsy	0	0%
Pulmonary embolism NOT requiring surgical or endovascular intervention and/or NOT resulting in death, to be confirmed by CT pulmonary angiography or lung ventilation/perfusion scan (VQ scan)	0	0%

The combined rate of minor complications was the secondary safety endpoint. Protocol established minor complications are listed in Table 8. There were no minor venous access site closure-related complications observed in the study. Consequently, the minor complication rate was 0% which is lower than the CAC of 3.0%. Therefore, the minor complication rate is considered acceptable compared to the CAC.

Table 8: Minor Venous Access Site Closure-Related Complications

	Study Limbs (N=77)	
	n	%
Any Minor Venous Access Site Closure-Related Complication	0	0%
Access site-related bleeding requiring > 30 minutes of continuous manual compression to achieve initial venous hemostasis	0	0%
Access site-related hematoma $\geq$ 6 cm documented by ultrasound	0	0%
Late access site-related bleeding requiring non-surgical intervention (following hospital discharge)	0	0%
Ipsilateral deep vein thrombosis, confirmed by ultrasound/imaging	0	0%
Access site-related vessel laceration	0	0%
Localized access site infection confirmed by culture and sensitivity, treated with intramuscular or oral antibiotics	0	0%
Arteriovenous fistula not requiring treatment, documented by ultrasound/imaging	0	0%
Pseudoaneurysm requiring treatment (thrombin/fibrin adhesive injection or ultrasound-guided compression), documented by ultrasound	0	0%
Pseudoaneurysm not requiring treatment, documented by ultrasound	0	0%
New onset transient access site-related nerve injury in the ipsilateral lower extremity (i.e., persisting for < 30 days)	0	0%

Adverse Events that occurred in the PMA clinical study:

A summary of all adverse events not deemed to be major/minor access site closure related complications is reported in Table 9.

Table 9: Summary of All Adverse Events

All Adverse Events	Number of Events (N=29*)		Number of Pivotal Subjects (N=77)	
	n	%	n	%
Any Adverse Event	29*	100%	16*	23.4%
Major or minor access site closure-related complications in the Study Limb	0	0%	0	0%
Major or minor access site closure-related complications in the Non-Study Limb	0	0%	0	0%
Any Venous Access Site Closure-Related Adverse Event in the Study Limb (non-major/minor)	10**	34.5%	8	11.7%
Any Venous Access Site Closure-Related Adverse Event in the Non-Study Limb (non-major/minor)	4	13.8%	1	5.2%
Non-Access Site Events	15	57.1%	10	13.0%
*One subject may have had more than one event in one or more categories. ** Two non-major/minor access site closure related complications were identified through the 29 patient ultrasound substudy and are reflected in the adverse events above. The venous access site closure-related events in the study limb reported included “access site hematoma < 6 cm, measured at widest point” (2), “access site re-bleeding after initial hemostasis confirmed” (3), “vessel thrombus” (1), and “minor peripheral nerve injury” (1), “palpable quarter-size knot in the right groin area” (1), “incision site pain” (1), and “mild bruising and pain” (1).				

2. Effectiveness Results

The analysis of effectiveness was based on the 77 evaluable patients at the 30-day post-operative evaluation time point. Key effectiveness outcomes are presented in Table 10.

A total of 76 of the 77 enrolled patients in the AMBULATE EXPAND Study were evaluated for the Primary Effectiveness Endpoint (TTA) as part of the modified Intent to Treat (mITT) population which was defined as the population which excludes subjects for which primary and secondary effectiveness endpoint durations which were lengthened due to the Non-Study Access Site only. The mITT population was also the population tested for TTDE and TPPT endpoints. The ITT population of 77 patients was used for TTH.

For the primary effectiveness endpoint for TTA, the mean time to ambulation was 3.2 ± 2.8 hours and was significantly shorter than the performance goal (PG) of 6.1 hours (one-sample t-test, $p < 0.0001$). The one-sided upper 97.5% CI was 3.8

hours which is less than the PG (6.1 hours), indicating that the primary effectiveness endpoint was met.

Similarly, the secondary endpoints of TTH, TPPT, and TTDE met predetermined clinical acceptance criteria (CACs). The mean of TTH for the VASCADE MVP XL VVCS when compared to the acceptance criterion of less than or similar to the CAC of 9.8 minutes was -7.1 minutes (2.7 ± 2.7 minutes for the VASCADE MVP XL VVCS). The mean of the TPPT when compared to the to the acceptance criterion of less than or similar to the CAC of 4.4 hours was -1.1 hours (3.3 ± 2.8 hours for the VASCADE MVP XL VVCS). The mean for TTDE when compared to the to the acceptance criterion of less than or similar to the CAC of 4.4 hours was -1.0 hours (3.4 ± 2.8 hours for the VASCADE MVP XL VVCS).

Table 10: Primary and Secondary Effectiveness Endpoints

Endpoint	TTA (hrs)	TTH (mins)	TPPT (hrs)	TTDE (hrs)
Population	mITT	ITT	mITT	mITT
Level	Subject	Access Site	Subject	Subject
n	76	77	76	76
Mean $\pm$ SD	3.2 ± 2.8	2.7 ± 2.7	3.3 ± 2.8	3.4 ± 2.8
Median (min, max)	2.6 (2.0, 23.5)	2.3 (0.0, 14.5)	2.6 (2.1, 23.6)	2.7 (2.0, 23.7)
Acceptance Criteria	Upper bound of one-sided 97.5% CI < PG of 6.1 hours, $p < 0.025$	Less than or similar to CAC of 9.8 minutes	Less than or similar to CAC of 4.4 hours	Less than or similar to CAC of 4.4 hours
One-Side 97.5% CI (upper bound only)	3.8	N/A	N/A	N/A
p-value	<0.0001	N/A	N/A	N/A
Met Acceptance Criteria	Yes	Yes	Yes	Yes

Device Success

Device Success was achieved in 76 of the 77 access sites in which device deployment was attempted (98.7%). The one instance where the device was unsuccessful was attributed to a failure due to a known risk, device pull through. There was no adverse event associated with the issue, and the treatment was converted to manual compression.

Procedure Success

No major access site-related complications were reported in the randomized study group. Procedure success was achieved in all 77 (100%) subjects.

Additional Analyses – Same Day Discharge (SDD)

Outcomes of the additional analysis of Same Day Discharge are included in Table 11 below. Same Day Discharge was achieved in 52/77 patients in the study (67.53%).

Table 11: Additional Analyses - Same Day Discharge*

	Pivotal Subjects (N=77)	
	n	%
Yes	52	67.53%
No	25*	32.47%

*Study did not include inclusion/exclusion criteria related to same day discharge intent. Of the 25 non-SDD subjects, 18 did not have a delay in hospital discharge beyond routine institutional practice. The remaining 7 subjects had discharge delays, including 5 due to medical reasons and 2 due to unknown or other reasons. No major or minor complications per protocol in any of these subjects.

Roll-in Subjects

The roll-in subjects are summarized separately and a summary of their baseline characteristics, effectiveness, and safety endpoints are provided below in Tables 12 – 14. There was nothing concerning related to safety and effectiveness endpoints reported for the roll-in patients when compared to the primary analysis cohort.

Table 12: Roll-in Subjects Demographics and Baseline Characteristics:

	Roll-in Subjects (N=8)	
	n	%
Age (years)		
Mean	72.5	-
Std Dev	6.7	-
Median	75.5	-
Min	64	-
Max	80	-
Sex Assigned at Birth		
Male	4	50%
Female	4	50%
Gender		
Male	4	50%
Female	4	50%
Ethnicity		
Not Hispanic or Latino	7	87.5%
Unknown	1	12.5%

Table 13: Roll-in Subjects Effectiveness Endpoints:

Endpoint	TTA (hrs)	TTH (mins)	TPPT (hrs)	TTDE (hrs)
Level	Subject	Access Site	Subject	Subject
n	7*	8	7*	7*
Mean ± SD	2.7 ± 0.6	3.4 ± 1.5	2.7 ± 0.6	2.8 ± 0.6
Median (min, max)	2.5 (2.1, 3.7)	3.6 (0.8, 5)	2.5 (2.2, 4.0)	4.1 (2.3, 3.9)
*One roll-in subject was unable to complete the ambulation assessment (TTA) due to their clinical condition (which was not access site closure-related). Since an ambulation delay impacts the timing when discharge eligibility is assessed (TTDE) and the overall procedure time (TPPT) per protocol, these two endpoints (TTDE and TPPT) are also unavailable for this subject.				

Table 14: Roll-in Subjects Safety Endpoints:

	Study Limbs (N=8)	
	n	%
Any Major Venous Access Site Closure-Related Complication	0	0%
Any Minor Venous Access Site Closure-Related Complication	0	0%

3. Subgroup Analysis

The following baseline characteristics were evaluated for potential association without outcomes: sex, race, ethnicity, number of non-Study Access Sites, and age. N subgroup variable (sex, race, ethnicity, age, or number of Non-Study Access Sites) showed statistically significant interaction with treatment (all $p \geq 0.15$), indicating no statistically significant difference in TTA for any subgroup.

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 33 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. 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 clinical data from the AMBULATE EXPAND study demonstrate that patients treated with the VASCADE MVP VVCS Model 800-1014XL had a lower mean time to ambulation, total post-procedure time, time to hemostasis, and time to eligibility for hospital discharge compared to the predetermined clinical acceptance criteria (CACs), and that the differences in these times are clinically significant.

B. Safety Conclusions

The risks of the device for the 10-14F sheaths indication were evaluated in nonclinical laboratory and animal studies as well as in the clinical study conducted to support PMA supplement approval as described above. There were no major or minor access site closure-related complications reported for patients treated with VASCADE MVP VVCS Model 800-1014XL in the AMBULATE EXPAND study.

C. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA supplement approval as described above. In summary, the benefits of the VASCADE MXP XL VVCS Model 800-1014XL include lower mean TTA, mean TPPT, Mean TTH, and mean TTDE compared to the predefined performance goals and clinical acceptance criteria.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA supplement approval as described above. The risks of the VASCADE MXP XL VVCS Model 800-1014XL are the following access site-related adverse events: vascular injury, pseudoaneurysm, arteriovenous fistula, nerve injury, nerve irritation, bleeding, hematoma, oozing, venous occlusion, venous thrombus, pulmonary embolism, infection, inflammation, and allergic reaction. There were no major or minor access site closure-related complications in the AMBULATE EXPAND study for the VASCADE MXP XL VVCS Model 800-1014XL device.

Additional factors to be considered in determining probable risks and benefits for the VASCADE MVP XL VVCS 800-1014XL device included: the design of the study, the conduct of the study, the robustness of the analysis of the study results, and the generalizability of the study results. The availability of alternative treatments, and risk mitigation also factored into the overall risk assessment.

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 large bore femoral venous access site closure in patients who have undergone interventional catheter-based 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 indications for reducing time to ambulation, total post-procedure time, time to hemostasis, and time to hospital discharge eligibility in interventional patients when compared to a performance goal and clinical acceptance criteria.

XIV. CDRH DECISION

CDRH issued an approval order on March 27, 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.