SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Vascular Hemostasis Device

Device Trade Name: Perclose ProGlide™ Suture-Mediated Closure System, Perclose™ ProStyle™ Suture-Mediated Closure and Repair System

Device Procode: MGB

Applicant's Name and Address: Abbott Medical
3200 Lakeside Drive
Santa Clara, CA 95054

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P960043/S118

Date of FDA Notice of Approval: June 2, 2023

The original PMA (PMA 960043) was approved on April 30, 1997 and is indicated for the percutaneous delivery of suture for closing the common femoral artery access site of patients who have undergone diagnostic or interventional catheterization procedures using 5 to 8F sheaths. Perclose® ProGlide® 6F Suture-Mediated Closure (SMC) System reduces the time to hemostasis, ambulation (10 feet) and discharge in patients who have undergone diagnostic or interventional catheterization procedures without complicating clinical conditions. The SSED to support the indication is available via FDA's Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 at (240) 402-7500, by referencing the PMA number or Docket # 97M-0274. The SSED to support the indication is available on the CDRH website and is incorporated by reference here.

The indication was expanded in P960043/S080 to include closing femoral artery access sites using sheaths up to 21F in size. The SSED to support the indication is available on the CDRH website (https://www.accessdata.fda.gov/cdrh_docs/pdf/P960043S080B.pdf) and is incorporated by reference here.

The indication was again expanded in P960043/S097 to close femoral vein access sites using sheaths up to 24F. The SSED to support the indication is available on the CDRH website (https://www.accessdata.fda.gov/cdrh_docs/pdf/P960043S097B.pdf) and is incorporated by reference here.

The current supplement was submitted to further expand the indication for the Perclose ProGlide and Perclose ProStyle to include multiple access sites in a single vein.

II. INDICATIONS FOR USE

The Perclose ProGlide Suture-Mediated Closure System/Perclose ProStyle Suture-Mediated Closure and Repair System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access site of patients who have undergone diagnostic or interventional catheterization procedures.

The Perclose ProGlide SMC System/Perclose ProStyle SMCR System is indicated for closing the common femoral vein in single or multiple access sites per limb.

The Perclose ProGlide SMC System/Perclose ProStyle SMCR System is used without or, if required, with adjunctive manual compression.

For access sites in the common femoral artery using 5F to 21F sheaths. For arterial sheath sizes greater than 8F, at least two devices and the pre-close technique are required.

For access sites in the common femoral vein using 5F to 24F sheaths. For venous sheath sizes greater than 14F, at least two devices and the pre-close technique are required."

III. CONTRAINDICATIONS

There are no known contraindications.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Perclose ProGlide and ProStyle device labeling.

V. DEVICE DESCRIPTION

The Perclose ProGlide Suture-Mediated Closure (SMC) System and Perclose ProStyle Suture-Mediated Closure and Repair (SMCR) System are designed to deliver a single monofilament polypropylene suture for use in closing and repairing femoral vessel access sites following diagnostic or interventional catheterization procedures. The Perclose ProStyle Suture-Mediated Closure and Repair (SMCR) System is a design iteration of the Perclose ProGlide Suture-Mediated Closure (SMC) System.

The Perclose ProGlide and Perclose ProStyle devices are composed of a plunger, handle, guide, and sheath. The device tracks over a standard 0.038" (or smaller) guide wire. A hemostasis valve restricts the blood flow through the sheath with or without the guide wire in place. The guide houses the anterior and posterior needles, and the foot with cuffs, and precisely controls the placement of the needles around the access site. The handle is used to stabilize the device during use. The plunger advances the needles and is used to retrieve the suture. A marker lumen is contained within the guide, with the intraluminal port of the lumen positioned at the distal end of the guide. Proximally, the marker lumen exits from the

body of the device. The marker lumen allows a pathway for back-bleeding (obtaining mark) from the femoral vessel to ensure proper device positioning.

A snared knot pusher and a suture trimmer are included in the system. The snared knot pusher and the suture trimmer are designed to position the pre-tied suture knot to the top of the access site. The suture trimmer is also designed to trim the trailing limbs of the suture below the skin.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives used for achieving femoral vein puncture hemostasis post-catheterization. For small sized punctures up to and including 10F, methods used for hemostasis include manual compression, mechanical compression, other vessel closure devices, and surgical closure. For large sized holes up to 21F in size, surgical cutdown provides an alternative to the subject device. 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 Perclose ProGlide Suture-Mediated Closure System has been commercially available in the United States since May 2004. It is also available for sale in over 50 countries outside of the United States including the European Union, Middle East, Asia Pacific, Latin America and Africa. The Perclose ProGlide Suture-Mediated Closure System has not been withdrawn from marketing in any country.

The Perclose ProStyle Suture-Mediated Closure and Repair System has been commercially available in the United States since May 2021. It is also available in several countries outside of the United States including the European Union, Canada, Australia, New Zealand, Japan, Korea, Saudi Arabia and Israel. The Perclose ProStyle Suture-Mediated Closure and Repair System has not been withdrawn from marketing in any 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 reaction or hypersensitivity to device components
- Vascular access complications which may require transfusion or vessel repair, including:
    - Anemia
    - Aneurysm
    - Arteriovenous fistula
    - Bleeding / hemorrhage / re-bleeding
    - Bruising / hematoma
    - Embolism
    - Inflammation

    - Intimal tear / dissection
    - Perforation
    - Pseudoaneurysm
    - Retroperitoneal hematoma / bleeding
    - Scar formation
    - Wound dehiscence
- Cardiac arrhythmias (including conduction disorders, atrial and ventricular arrhythmias)
    - Atrial arrhythmias
    - Ventricular arrhythmias
- Femoral artery / venous complications which may require additional intervention, including:
    - Arterial / venous stenosis
    - Arterial / venous occlusion
    - Arteriovenous fistula
    - Intimal tear / dissection
    - Ischemia distal to closure site
    - Nerve injury
    - Numbness
    - Thrombus formation
    - Vascular injury
- Venous thromboembolism (including deep vein thrombosis, pulmonary embolism, post- procedure pulmonary embolism)
- Infection - local or systemic
- Pain
- Hemodynamic instability:
    - Hypotension / hypertension
    - Vasovagal episode
- Death
- Device complications
- Device failure
- Device malfunction

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

IX. SUMMARY OF NONCLINICAL STUDIES

Nonclinical studies were performed on the Perclose ProGlide and ProStyle devices. Testing was referenced from PMA submission P960043 and related supplements for all nonclinical testing. No additional preclinical studies were conducted to support the proposed indication. A summary of previously reported preclinical studies can be found in the Summary of Safety and Effectiveness Data (SSED) for the original PMA (see section I above).

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of closure of multiple access sites in a single vein with the Perclose ProGlide SMC System or the Perclose ProStyle SMCR System in the US under IDE # G210278. Both the Perclose ProGlide and Perclose ProStyle devices were used in the study, and due to the similarities in device design and function, were considered interchangeable for the purposes of evaluating the study outcomes. 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 September 1, 2021 and May 4, 2022. The database for this Panel Track Supplement reflected data collected through June 24, 2022 and included 36 patients. There were 2 investigational sites.

The study, the Perclose Multi-Access DUS Trial, was a prospective, single-arm, multicenter, descriptive clinical study.

The study utilized an independent Clinical Events Committee (CEC) to adjudicate adverse events, and an independent Echocardiography Core Lab for the interpretation of all echocardiographic data.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the Perclose Multi-Access DUS Trial was limited to patients who met the following inclusion criteria:

   1. Age ≥18 years
   2. Subject was planned to have an ablation procedure that requires multiple sheaths insertion in a single femoral vein
   3. All the access sites were planned to be treated with Perclose SMC
   4. Written informed consent was obtained prior to the procedure

   Patients were not permitted to enroll in the Perclose Multi-Access DUS Trial if they met any of the following exclusion criteria:

   1. Visible vascular thrombus (angiographic or ultrasound) in the ipsilateral leg prior to the ablation procedure
   2. Prior ipsilateral deep vein thrombosis within 6 months
   3. International Normalized Ratio > 3.5 for patients on warfarin
   4. Subject who was not able to ambulate pre-procedure
   5. Women who were pregnant (based on site standard pre-procedure pregnancy test)

6. Had active symptoms and/or a positive test result of COVID-19 or other rapidly spreading -infectious agent within the prior 2 months

2. Follow-up Schedule
   All patients were scheduled to return for follow-up examinations at 30 days postoperatively.

   Preoperatively, patient demographics, risk factors, and chronic concomitant anticoagulants and antiplatelet medications were recorded. Postoperatively, the objective parameters measured during the study included assessment of post-procedure time to mobility and time to ambulation, assessment of symptomatic or visible complications at discharge and 30 day follow-up, and femoral duplex ultrasound (DUS) in the leg or legs in which access sites were closed to detect asymptomatic/non-visible complications. For those subjects with vascular complications detected on femoral DUS at discharge, a repeat femoral DUS was performed at the 30-day visit in the leg or legs in which the vascular complication(s) was (were) found at discharge. Adverse events and complications were recorded at all visits.

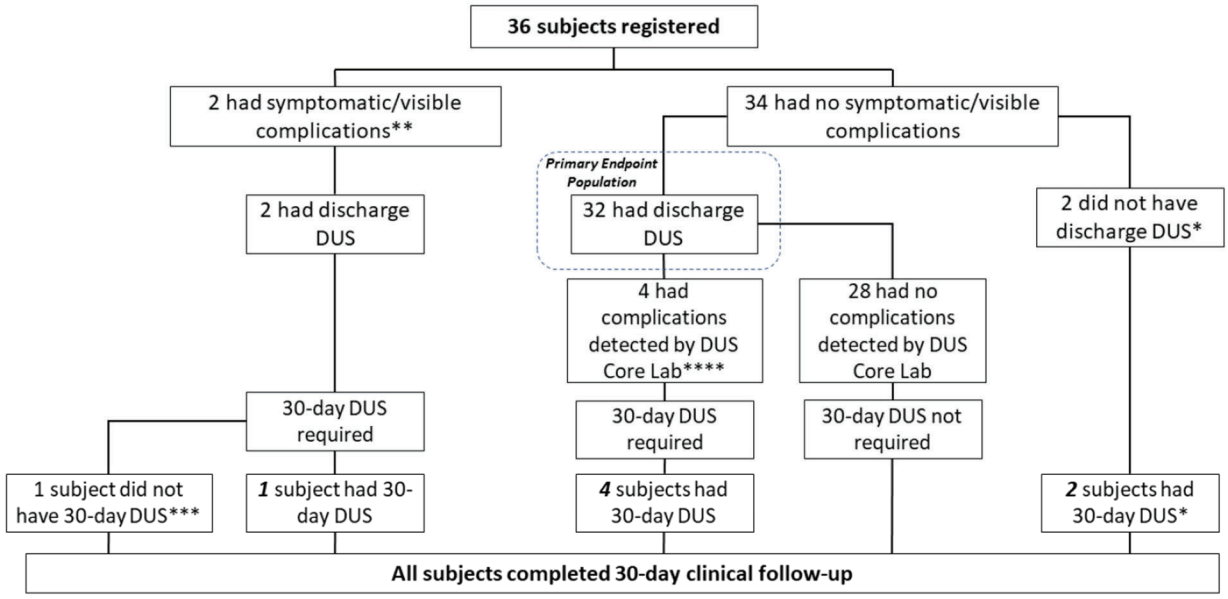
   The key timepoints are shown below in the tables summarizing safety and effectiveness.

3. Clinical Endpoints
   With regards to safety and effectiveness, the primary endpoint of the study was vascular complications detected by scheduled DUS at discharge or 30 days in asymptomatic/non-visible complication subjects.

   With regard to success/failure criteria, a patient was considered successfully treated if successful hemostasis was achieved without surgical conversion, or additional non-study device (adjunctive manual compression and subcutaneous stitch were regarded as the standard of care and not included as failure). The study results were presented descriptively; there were no study success criteria defined.

B. Accountability of PMA Cohort

At the time of database lock, of 36 patients enrolled in the PMA study, 100% of patients are available for analysis at the completion of the study, the 30 day post-operative visit. Patient accountability is summarized in the figure below.



* Subjects US0047-045 and US0047-048 did not have discharge DUS and had 30-day DUS (Subject US0047-045 did not receive study device)
** Subjects US0556-006 and US0556-013 had symptomatic/visible complications
*** Subject US0556-006 did not have 30-day DUS
**** All complications resolved at 30 days

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a vascular closure device study performed in the US.

The mean age of the study population was 62.9 years, and most subjects were male (66.7%), had a mean body mass index (BMI) of 31.25 kg/mm^2, range of 17.9 kg/mm^2 to 43.4 kg/mm^2, and were diagnosed with either Paroxysmal AF (47.2%), Persistent Atrial Fibrillation (30.6%) or Atrial Flutter (16.7%). Major co-morbidities included hypertension (61.1%), dyslipidemia (52.8%), diabetes (33.3%), and coronary artery disease (30.6%). A majority of the subjects (91.7%) were on anticoagulants, primarily Apixaban (86.1%).

D. Safety and Effectiveness Results

1. Safety Results

   The analysis of safety was based on 32 patients in the intent-to-treat cohort who did not have symptomatic or visible complications at discharge, and who did have femoral duplex ultrasound performed at discharge. The key safety outcomes for this study are presented below in Table 1.

Table 1. Vascular Complications at Discharge

	Intent-to-Treat Population (N=36)	Primary Endpoint Population (N=32)
Major Complications by DUS Detection or CEC Adjudication	**0.0% (0/34)**	**0.0% (0/32)**
Minor Complications by DUS Detection or CEC Adjudication	**17.6% (6/34)**	**12.5% (4/32)**
Deep Vein Thrombosis in the Target Limb	11.8% (4/34)	9.4% (3/32)
Venous Bleeding, Retroperitoneal Bleeding	5.6% (2/36)	N/A
Venous Access Site Injury Including Vessel Laceration	5.6% (2/36)	N/A
Hematoma	5.9% (2/34)	3.1% (1/32)
Other Vascular Complication	2.9% (1/34)	3.1% (1/32)
Arterial Stenosis	0.0% (0/34)	0.0% (0/32)
Mobile Perclose Common Femoral Vein*	2.9% (1/34)	3.1% (1/32)

* Linear echodensity or filamentous structure visible in two different planes on DUS was the linear thrombus labeled by the core lab as "mobile Perclose common femoral vein (CFV)".
Note: Major complications are defined as those which requiring surgical or percutaneous repair if not specified. All other complications are considered to be minor complications.
Note: N is the total number of subjects.

Adverse effects that occurred in the PMA clinical study:

A total of 6 adverse events in 4 subjects were reported for the duration of the study. Of those 6, 4 events were vascular disorder. Two non-serious events - one venous bleeding and one rebleeding at the access site were adjudicated by CEC as device and procedure related events. No device/procedure related serious adverse events were reported and no serious adverse events qualified for the CEC adjudication during the study.

2. Effectiveness Results

The analysis of effectiveness was based on the 36 evaluable patients at discharge. Key effectiveness outcomes are presented in Table 2.

Table 2 Procedural Results

	Perclose Device (N=36) (V=56) (AS=126)
PER SUBJECT ANALYSIS	
Type of Ablation Procedure	
Cryoablation only	38.9% (14/36)
Radiofrequency Ablation only	58.3% (21/36)
Both	2.8% (1/36)
Number of Access Site (Based on the number of sheath used)	
Mean ± SD (n)	3.5 ± 0.8 (36)
Median (Q1, Q3)	4.0 (3.0, 4.0)
Range (min, max)	(2, 5)
Number of Perclose Used	
Mean ± SD (n)	3.8 ± 1.3 (36)
Median (Q1, Q3)	4.0 (3.0, 5.0)
Range (min, max)	(0, 5)
Time to Hemostasis (minute)	
Mean ± SD (n) Median (Q1, Q3)	9.5 ± 12.4 (36)
Range (min, max)	6.5 (4.0, 9.5)
	(1, 74)
Heparin Reverse (Protamine)	79.4% (27/34)
PER VEIN ANALYSIS	
Number of Access Site (Based on the number of sheath used)	
Mean ± SD (n)	2.3 ± 0.8 (56)
Median (Q1, Q3)	2.0 (2.0, 3.0)
Range (min, max)	(1, 3)
1	23.2% (13/56)
2	28.6% (16/56)
3	48.2% (27/56)
Number of Perclose Used	
Mean ± SD (n)	2.4 ± 0.7 (56)
Median (Q1, Q3)	2.0 (2.0, 3.0)
Range (min, max)	(0, 4)
1 unit	1.8% (1/56)
2 units	46.4% (26/56)
3 units	46.4% (26/56)
4 units	1.8% (1/56)
PER ACCESS SITE ANALYSIS	

	Perclose Device (N=36) (V=56) (AS=126)
Sheath Size Used	
≥ 15F	1.6% (2/126)
12 - 14F	11.9% (15/126)
8.5 - 11F	37.3% (47/126)
≤ 8F	49.2% (62/126)
Number of Perclose Used*	
1 unit	84.9% (107/126)
2 units	11.1% (14/126)
Number of Perclose Used* per Access Site > 8F	
1 unit	73.4% (47/64)
2 units	21.9% (14/64)
Time to Hemostasis (minute) Mean ± SD (n) Median (Q1, Q3) Range (min, max)	 3.1 ± 7.3 (126) 1.0 (1.0, 3.0) (0, 74)
Success Rate	99.2% (120/121)
POST PROCEDURE INFORMATION	
Time to Ambulation (minute) Mean ± SD (n) Median (Q1, Q3) Range (min, max)	 233.7 ± 188.7 (36) 193.5 (129.5, 275.5) (58, 1199)
Delay >30 minutes	100.0% (36/36)
Time to Discharge (hour) Mean ± SD (n) Median (Q1, Q3) Range (min, max)	 10.92 ± 9.69 (36) 5.95 (4.00, 19.35) (2.4, 43.8)

Note: N is the total number of subjects, V is the total number of Veins, and AS is total numbers of Access Site.
* Subject US0047-45 had two femoral veins, 5 access sites (3 were >8F). None of the 5 access sites was treated by Perclose SMC due to device deficiencies.

3. Subgroup Analyses

The following procedural characteristics were evaluated for potential association with outcomes: use of 2 Perclose devices for access sites greater than 8 French, 3 or 4 access sites in a single vein, sheath size greater than 8 French, and 2 or 3 access sites rather than 4 or greater access sites. A summary of time to hemostasis

for these subgroups is provided in Table 3. As there were no major vascular complications in the study, only minor vascular complications assessed by DUS at discharge are reported as summarized in Table 4.

Table 3 Summary of Time to Hemostasis for Procedural Characteristics Subgroups

	Subgroup 1	Subgroup 2	Subgroup 3		Subgroup 4	
	Subjects Treated with 2 Perclose SMC for Access Sites > 8F Perclose SMC (N=14)	**Subjects having 3 or 4 Access Sites per Vein Perclose SMC (N=27)**	**At least One Sheath > 8F (N=32)**	**All ≤ 8F (N=4)**	**2 or 3 Access Sites (N=16)**	**≥ 4 Access Sites (N=20)**
Time to Hemostasis (minute) – Per Subject Mean ± SD (n) Median (Q1, Q3) Range (min, max)	9.2 ± 6.6 (14) 7.5 (3.0, 16.0) (2, 21)	8.0 ± 6.3 (27) 7.0 (3.0, 10.0) (1, 24)	10.2 ± 13.0 (32) 7.0 (4.0, 10.0) (1, 74)	3.8 ± 3.6 (4) 2.5 (1.5, 6.0) (1, 9)	11.2 ± 17.6 (16) 6.0 (4.0, 9.5) (1, 74)	8.1 ± 6.0 (20) 7.5 (3.5, 12.0) (1, 21)

Table 4 Summary of Minor Vascular Complications for Procedural Characteristics Subgroups

	Subgroup 1	Subgroup 2	Subgroup 3		Subgroup 4	
	Subjects Treated with 2 Perclose SMC for Access Sites > 8F Perclose SMC (N=14)	**Subjects having 3 or 4 Access Sites per Vein Perclose SMC (N=25)**	**At least One Sheath > 8F (N=28)**	**All ≤ 8F (N=4)**	**2 or 3 Access Sites (N=14)**	**≥ 4 Access Sites (N=18)**
Minor Vascular Complications by DUS at discharge	7.1% (1)	12% (3)	14.3% (4)	0% (0/4)	7.1% (1)	16.7% (3)

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

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 9 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.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

A. Study Design

In addition to the IDE clinical study, the applicant also presented real-world evidence consisting of analysis of data from one prospective and two retrospective investigator-sponsored clinical studies conducted by physicians. These studies included the Santa Barbara Cottage Hospital Study (SBCH), conducted at Santa Barbara Cottage Hospital, Santa Barbara, CA; Emory School of Medicine Study (ESM), conducted at the Emory School of Medicine, Atlanta, GA; and VAscular Closure for Cardiac Ablation Registry (VACCAR), conducted at Saint Luke's Hospital, Kansas City, MO.

The ESM study was a prospective trial while both the SBCH and the VACCAR studies were retrospective. The analysis of the three studies was performed by the applicant using datasets provided by the investigators. A total of 1062 subjects underwent an ablation procedure at the three investigational sites between November 2016 and December 2020. Of these 1062 subjects, 647 subjects were treated with the Perclose SMC System. All 572 Perclose SMC System treated subjects in the ESM and SBCH studies were assessed for safety and effectiveness endpoints at 30 days. In the VACCAR study, the 75 subjects treated with the Perclose SMC System were assessed for safety and effectiveness endpoints in-hospital since the VACCAR study did not collect 30 day follow up data.

1. Clinical Endpoints

The primary safety endpoint was freedom from femoral vein access-related major vascular complications at 30-days post procedure, including but not limited to:

- Femoral vein stenosis (> 50%) development at the puncture site related to closure technique;
- Development of deep vein thrombosis in the target limb;
- Significant venous bleeding, retroperitoneal bleeding / hematoma, or hematoma at the access site requiring transfusion or surgical intervention;
- Hematoma that did not require transfusion or surgical intervention;
- Access site-related wound dehiscence or venous access site infection requiring intravenous, intramuscular or oral antibiotics, and / or leading to a prolonged hospitalization;
- Venous access site injury, including vessel laceration, requiring surgical repair, angioplasty, ultrasound-guided compression or thrombin injection;

- Re-bleeding at access site that required treatment or re-hospitalization;
- AV fistula;
- Pseudoaneurysm;
- Access site-related nerve injury;
- Pulmonary embolism

The following additional procedural data were collected:

- Type of ablation procedure
- Number of access sites per subject
- Number of access sites per single vein
- Number of Perclose SMCs used per vein and per access site and per closure procedure
- Number of Perclose SMCs used access site > 8F access sites
- Distribution of sheath size
- Procedure duration
- Success rate
- Anticoagulant and antiplatelet medications
- Use of protamine for heparin reversal

B. Safety and Effectiveness Results

1. Safety Results

The SBCH Study and ESM Study primary safety results were compared to a clinical acceptance criterion of ≥95%. Freedom from major access-site related complications was 99.2% for the SBCH study and 96.2% for the ESM study up to 30 days post index procedure and met the clinical acceptance criterion of ≥95%. A summary of freedom from major access-site related complications in the SBCH Study and ESM Study is provided in Table 5

Table 5 SBCH and ESM Studies Freedom from Major Access-site Related Complications

	SBCH Study Perclose Device (N=519)	ESM Study Perclose Device (N=53)
Freedom from Major Access-site Related Complications	**99.2% (515/519)**	**96.2% (51/53)**
Hematoma	99.8% (518/519)	96.2% (51/53)
Major Bleeding	100.0% (519/519)	96.2% (51/53)
Pseudoaneurysm	99.8% (518/519)	Not reported
Vascular Surgery	99.6% (517/519)	Not reported

The 95% clinical acceptance criterion was not applied to the VACCAR Registry results as it did not have 30-day follow-up. Although the VACCAR study did not have 30-day follow-up, the VACCAR study demonstrated a complete freedom of access site-related major complications (major complications: 0.0%, 0/75) at discharge. Minor complication rate included hematoma (1.3%), pseudoaneurysm (1.3%) and other complications (1.3%).

2. Effectiveness Results

All study results were presented descriptively. In the ESM and VACCAR studies, the mean time to hemostasis was 7.46 minutes and 8.63 minutes respectively and the mean time to ambulation was 167.9 minutes and 157.29 minutes respectively. Time to hemostasis and time to ambulation were not collected in the SBCH study.

3. Subgroup Analyses

The following procedural characteristics were evaluated for potential association with outcomes: use of Perclose devices for closing > 8 French sized access sites with 1 Perclose device, and use of Perclose devices for 2 or 3 access sites rather than 4 or greater access sites.

The outcome of closing > 8 French sized access sites with 1 Perclose device is summarized in Table 6 below. Five-hundred seventeen of the 519 subjects in the SBCH study and 52 of 53 in the ESM study received at least one sheath with size >8F.

Table 6 Major Access-site Related Complications in > 8 French sized access sites closed with 1 Perclose device Subgroup Analysis

	SBCH Study Perclose Device (N=517)	ESM Study Perclose Device (N=52)
Major Access-site Related Complications	0.8% (4/517)	3.8% (2/52)
Hematoma	0.2% (1/517)	3.8% (2/52)
Major Bleeding	0.0% (0/517)	3.8% (2/52)
Pseudoaneurysm	0.2% (1/517)	Not reported
Vascular Surgery	0.4% (2/517)	Not reported

The effect of 2 or 3 access sites rather than 4 or greater access sites was evaluated for potential association with outcomes. The ESM study used both right and left femoral arteries for the ablation procedures while the SBCH study only used right femoral veins

were used for the access sites. A summary of the available data is provided in Table 7 below. The VACCAR study did not report any major in-hospital complications.

Table 7 Major Access-site Related Complications, 2 or 3 vs ≥ 4 Access Sites Subgroup Analysis

	2 or 3 Access Sites		≥ 4 Access Sites	
	SBCH Study Perclose Device (N=212)	**ESM Study Perclose Device (N=39)**	**SBCH Study Perclose Device (N=307)**	**ESM Study Perclose Device (N=14)**
Major Access-site Related Complications	**0.5% (1/212)**	**5.1% (2/39)**	**1.0% (3/307)**	**0.0% (0/14)**
Hematoma	**0.0% (0/212)**	**5.1% (2/39)**	0.3% (1/307)	0.0% (0/14)
Major Bleeding	0.0% (0/212)	**5.1% (2/39)**	0.0% (0/307)	0.0% (0/14)
Pseudoaneurysm	0.0% (0/212)	Not reported	0.3% (1/307)	Not reported
Vascular Surgery	0.5% (1/212)	Not reported	0.3% (1/307)	Not reported

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 of the device are based on data collected in clinical studies conducted to support PMA supplement approval as described above. Time to hemostasis, when assessed, in these studies ranged from an average of 7.46 minutes in the ESM study to 8.63 minutes in the VACCAR study to 9.5 minutes in the IDE study. This duration is comparable to other marketed vascular closure devices.

Effectiveness of the device was also based on the ability to achieve hemostasis. Success rates on a per-access site basis were high when reported, with 98.7% success in the ESM study and 99.2% success in the IDE study.

B. Safety Conclusions

The risks of the device are based on data collected in clinical studies conducted to support PMA supplement approval as described above.

The safety assessments for the Perclose ProGlide SMC device for the closure of multiple access sites in a single vein were based on an assessment of freedom from major vascular complications at 30 days and overall adverse event rates observed within 30 days. The analyses provided to support this panel track supplement suggests that the device use for closure of multiple access sites in a single vein is associated with an acceptably low rate of vascular complications as the rate of freedom from major vascular complications at 30 days was 100% in the IDE study. In addition, the observed rates were 99.2% and 96.2% for the real-world SBCH and ESM studies, respectively, which compared favorably with a 95% clinical acceptance criterion. While the VACCAR study did not report complication rates at 30 days, it also demonstrated a complete freedom of access site-related major complications at discharge. Additionally, adverse events were observed to occur at low and tolerable levels. The risks associated with the use of the device include access site vascular injury that may require surgery, access site related bleeding, pseudoaneurysm, and groin hematoma.

C. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in clinical studies conducted to support PMA supplement approval as described above. The potential benefits of using Perclose ProGlide SMC for closure of multiple access sites in a single vein is that the treatment allows for hemostasis to be achieved within a short period of time (on average, less than 10 minutes) to allow for prompt ambulation.

The probable risks of the device are also based on data collected in clinical studies conducted to support PMA supplement approval as described above. Use of the device to close multiple access sites in a single vein is associated with an acceptably low rate of major vascular complications at 30 days, with the highest rate across the studies provided being 3.8%.

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

In conclusion, given the available information above, the data support that for the following indication:

The Perclose ProGlide Suture-Mediated Closure System/Perclose ProStyle Suture-Mediated Closure and Repair System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access site of patients who have undergone diagnostic or interventional catheterization procedures.

The Perclose ProGlide SMC System/Perclose ProStyle SMCR System is indicated for closing the common femoral vein in single or multiple access sites per limb. The Perclose ProGlide SMC System/Perclose ProStyle SMCR System is used without or, if required, with adjunctive manual compression.

For access sites in the common femoral artery using 5F to 21F sheaths. For arterial sheath sizes greater than 8F, at least two devices and the pre-close technique are required.

For access sites in the common femoral vein using 5F to 24F sheaths. For venous sheath sizes greater than 14F, at least two devices and the pre-close technique are required."

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.

XIV. CDRH DECISION

CDRH issued an approval order on June 2, 2023.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

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.