SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Vascular Hemostasis Device

Device Trade Name: Quick-Close® Vascular Suturing System

Applicant's Name and Address: Interventional Therapies LLC,
1 Gorham Island,
Westport, CT 06880

Date of Panel Recommendation: none

Premarket Approval Application (PMA) Number: P080029

Date of FDA Notice of Approval: April 8, 2010

Expedited: Not applicable

II. INDICATIONS FOR USE

The Quick-Close® Vascular Suturing System is indicated to close femoral artery access sites and to reduce time-to-hemostasis and time-to-ambulation in patients who have undergone diagnostic or interventional endovascular procedures utilizing a 5, 6, 7, or 8 French procedural sheath. Additionally, the Quick-Close® Vascular Suturing System is indicated to reduce time-to-hemostasis in patients who have undergone interventional endovascular procedures, utilizing a 5, 6, 7, or 8 French procedural sheath, who have received intraprocedural glycoprotein IIb/IIIa inhibitor therapy.

III. CONTRAINDICATIONS

There are no known contraindications to the use of the Quick-Close Vascular Suturing System.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Quick-Close Vascular Suturing System labeling.

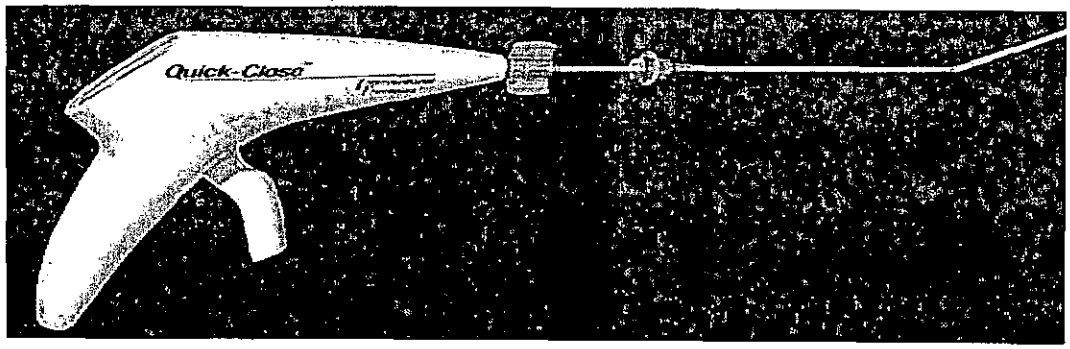
V. DEVICE DESCRIPTION

The Quick-Close® System consists of two separate devices that are supplied together in a single blister pack:

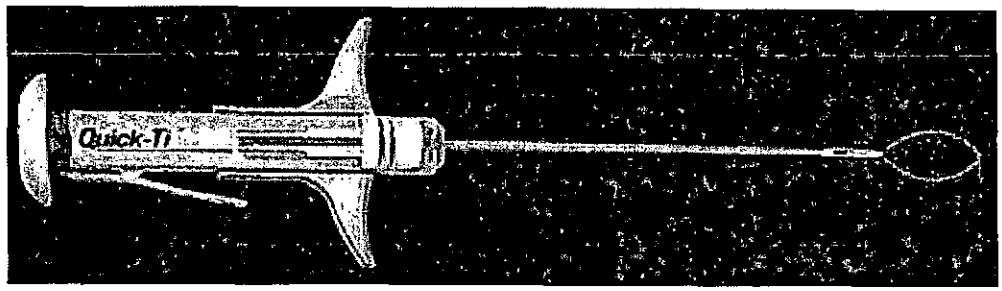
- Suture delivery mechanism (Quick-Close® Suture Applier)

- Suture closure (cinching) apparatus (Quick-Ti® Cinch Applier).

Quick-Close® Suture Applier: The Quick-Close® Suture Applier has a pistol-grip configuration and shaft for gaining access to the femoral artery wound site. The applier houses a single strand of polybutester (Novafil™) suture fitted with stainless steel ferrules at either end. Using manual control, and relying on tactile feedback, the device is used to place one end of the suture through one edge of the arterial wound. The applier is then re-positioned and the other end of the suture is placed through the opposite edge of the wound site. As the applier is withdrawn from the wound site, the 24" length of suture is deployed out of its housing within the applier.



Quick-Ti® Cinch Applier: The Quick-Ti® Cinch Applier has a syringe-type configuration with an extended shaft. The device is used to gather the two ends of the suture so as to allow for tissue approximation. The applier places a stainless steel cinch that acts in place of a knot to secure the suture in a closed, hemostatic position.



Principles of Operation

Closure of vascular wounds by means of suture is a basic technique of surgery. The use reflects the principle that wound edges held in close approximation will heal more quickly and with less scar tissue formation. However, use of a suture mediated closure of the femoral artery following coronary access procedures presents special challenges. The tiny size of the wound site in the groin precludes standard, manually performed, suture placement. On the other hand, extending the groin incision site to allow manually-performed suture placement defeats the minimally invasive nature of the access procedure.

The Quick-Close® System is designed to allow for such suture mediated closure without the need for wound site extension. As described below, the device places a single stitch of standard, non-absorbable suture through opposite edges of the femoral artery puncture site. The Quick-Ti® Cinch Applier is then inserted to the level of the vessel, which causes the suture to gently tighten in order to place the wound edges in close approximation. The minimal access through the groin to the arterial puncture site prevents the use of a standard suture knot. Instead the Quick-Close® device secures the two ends of the suture by means of an "artificial knot" in the form of a stainless steel cinch. Following placement of the cinch, the extraneous suture material is clipped immediately distal to (i.e., above) the cinch and removed. The suture, along with its stainless steel cinch, will remain in place throughout the healing period; post-procedural removal of the cinch is not required. The intra-vascular segment of the suture is minimal in length (approximately 1 mm or less) and held snug to the vessel wall to preclude a nidus for thrombus formation. To minimize the potential for infection, no externally communicating materials are left in place. Likewise, no materials other than the non-absorbable suture and stainless steel cinch are left in place. The device relies solely on suture mediation to create and maintain wound closure.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative practices and procedures for attaining hemostasis at the femoral artery puncture site post-catheterization include mechanical compression, manual compression, percutaneous delivery of sutures at the femoral access site, collagen-based hemostasis devices and staples.

VII. MARKETING HISTORY

The Quick-Close® System 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 Quick-Close® System.

- Vascular repair or the need for vascular repair
- Transient access site-related nerve injury
- Permanent access site-related nerve injury
- Surgery for access site-related nerve injury
- Access site-related hemorrhage requiring > 30 minutes to achieve hemostasis
- Access site-related hemorrhage requiring transfusion
- Late access site-related hemorrhage (i.e., following hospital discharge)
- Access site hematoma
- Access site hematoma requiring extended hospitalization
- Access site-related infection requiring oral, intramuscular, or intravenous antibiotics and/or extended hospitalization

- Pseudoaneurysm
- Arteriovenous fistula
- Ipsilateral lower extremity arterial emboli
- Ipsilateral lower extremity ischemia
- Transient loss of ipsilateral lower extremity pulse
- Ipsilateral deep vein thrombosis
- Access site-related vessel laceration
- Access site wound dehiscence
- Access site pain and/or swelling
- Ipsilateral leg pain

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

IX. SUMMARY OF PRECLINICAL STUDIES

Engineering

The suture which the subject device delivers is manufactured by U.S. Surgical (North Haven, CT) and is sold under their Novafil trademark. The Novafil™ suture delivered by the Quick-Close® System meets the requirements established by the United States Pharmacopoeia (USP) for nonabsorbable surgical sutures. Novafil™ is legally marketed for vascular closure under P840041, K896946 and K990952. Interventional Therapies does not modify the Novafil™ suture for use in the Quick-Close® Suture Applier. Consequently, bench testing was limited to the delivery device and the cinch which replaces a standard surgical knot.

Mechanical testing was performed to assess the mechanical integrity and functionality of the Quick-Close® Suture Applier, Quick-Ti® Cinch Applier, and component subassemblies. This testing was conducted to confirm that the Quick-Close® Suture Applier and Quick-Ti® Cinch Applier and subassembly components were mechanically and physically designed to withstand the forces anticipated in vivo. These tests included:

- Needle-Ferrule engagement: An Instron device was used to test the force required to separate needles and ferrules of the QuickClose™ device following firing. The results of the test were then compared to the analogous U.S. Pharmacopoeia requirement for needle to suture attachment. The U.S.P. requirement for needle attachment for size 3-0 non-absorbable suture is an average of 0.45kg with no individual sample below 0.23kg. The device passed.

  Testing of the Quick Close™ suture-needle attachment showed an average attachment force of 1.37kg and no sample below 0.70kg (n=45). As demonstrated by this test, the needle to ferrule attachment force is significantly higher the U.S.P. requirement for suture needle retention for 3-0 non-absorbable suture.

- Suture deployment force: An Instron device was used to determine the force required to deploy the suture from the interior of the Suture Applier following firing. This testing showed an average payout force of 33gm with no sample requiring more than 43gm.

- Loop Pull testing: This involved measuring the average force required to separate the suture from the ferrule. Design input required no more than 1.32 lbf. Test results showed mean pull force of 1.15 kgf, meeting the pass/fail criteria.

The results of the mechanical testing confirm that the mechanical performance of the Quick-Close® System met established specifications.

Sterilization & Shelf Life

The Quick-Close® Vascular Suturing System is packaged in a PETG (polyethylene terephthalate glycol) tray with Tyvek-coated cover. All of the components are manufactured in a clean-room environment and the final product is sterilized using radiation sterilization.

The Sterilization process was validated using the Sterilization Standards: ISO 11137-1&2:2006 Sterilization of health care products – Radiation – Part 1 & Part 2: Requirements for development, validation and routine control of a sterilization process for medical devices & establishing the sterilization dose, respectively.

The product has passed 6 month shelf life testing including non-accelerated aging for the device and accelerated aging for the packaging as well as meeting ASTM and ISO standards for drop testing, vehicle stacking and vehicle vibration.

Biocompatibility

The biocompatibility of all patient-contacting device materials were verified in accordance with ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing". The information and test data provided supports the biocompatibility of the Quick-Close® Suture Applier, Quick-Ti® Cinch Applier and NovaFil™ suture material for their intended use. Test items submitted for biocompatibility testing were component subassemblies, components, or materials. Subassemblies and components were manufactured in accordance with standard manufacturing practices. All test items were gamma irradiated. Biocompatibility test results for those patient-contacting components or materials of the Quick-Close® Suture Applier and Quick-Ti® Cinch Applier shafts for which testing was required are listed in Tables 1 through 3.

Table 1. Biocompatibility Information for the Quick-Close® Suture Applier Sheath

Component	Test Report	Test Method	Summary Of Results
Inner Sheath Tubing	NAMSA V0014_130	**Cytotoxicity** ISO 10993-5: Tests for Cytotoxicity: *in vitro* Methods	Under the conditions of this study, the 1x MEM test extract showed no evidence of causing cell lysis or toxicity.
	NAMSA T1251_800	**Irritation** ISO10993-10: Selection of Tests for Irritation and Sensitization	Under the conditions of this study, there was no evidence of significant irritation from the extracts injected intracutaneously into rabbits.
	NAMSA T1261_300	**Sensitization** ISO 10993-10: Selection of Tests for Irritation and Sensitization	Under the conditions of this study, the SC and SO test article extracts showed no significant evidence of causing delayed dermal contact sensitization in the guinea pig.
	NAMSA TU012_500	**Systemic Toxicity** ISO 10993-11: Tests for Systemic Toxicity (ISO).	Under the conditions of this study, there was no mortality or evidence of systemic toxicity from the extracts.
	NAMSA V0020_000	**Coagulation** *ISO 10993-4: Selection of Tests for* Interactions with Blood.	The average recalcification time of the plasma after exposure to the test article was equivalent to the recalcification time for the negative and plasma controls. Under the conditions of this study, it was concluded that the test article had no significant effect on recalcification time.
	NAMSA V0019_100	**Hemolysis** ISO 10993-4: Selection of Tests for Interactions with Blood.	Under the conditions of this study, the mean hemolytic index for the test article extract was 0%. The test article extract was nonhemolytic.
Outer Sheath Tubing	STS GLP-2000-0479	**Cytotoxicity** ISO 10993-5: Tests for Cytotoxicity: in vitro Methods	Under the conditions of this study, the 1x MEM test extract did not induce cell lysis or toxicity.
	STS GLP-2000-0476	**Irritation** ISO10993-10: Selection of Tests for Irritation and Sensitization	Under the conditions of this study, there was no evidence of significant irritation from the extracts injected intracutaneously into rabbits.
	STS GLP-2000-0481	**Sensitization** ISO 10993-10: Selection of Tests for Irritation and Sensitization	Under the conditions of this study, the SC and SO test article extracts showed no signs of sensitization in the guinea pig.
	STS *GLP-2000-0477*	**Systemic Toxicity** *ISO 10993-11: Tests for Systemic* Toxicity (ISO).	Under the conditions of this study, there was no mortality or evidence of systemic toxicity *from the extracts.*
	STS GLP-2000-0480	**Hemolysis** ISO 10993-4: Selection of Tests for Interactions with Blood.	Under the conditions of this study, the mean hemolytic index for the test article extract was below the 5% hemolysis limit for the test. The test article extract met the test requirements.

Table 2. Biocompatibility Information for the Quick-Close® Suture Applier Monorail

Test Report	Test Method	Summary Of Results
NAMSA V0014_130	**Cytotoxicity** ISO 10993-5: Tests for Cytotoxicity: *in vitro* Methods.	Under the conditions of this study, the 1x MEM test extract showed no evidence of causing cell lysis or toxicity.
NAMSA T1251_800	**Irritation** ISO 10993-10: Selection of Tests for Irritation and Sensitization.	Under the conditions of this study, there was no evidence of significant irritation from the extracts injected intracutaneously into rabbits.
NAMSA T1261_300	**Sensitization** ISO 10993- 10: Selection of Tests for Irritation and Sensitization.	Under the conditions of this study, the SC and SO test article extracts showed no significant evidence of causing delayed dermal contact sensitization in the guinea pig.
NAMSA test report TU012_500	**Systemic Toxicity** ISO 10993-11: Tests for Systemic Toxicity (ISO).	Under the conditions of this study, there was no mortality or evidence of systemic toxicity from the extracts.
NAMSA test report V0019_100	**Hemolysis** ISO 10993-4: Selection of Tests for Interactions with Blood.	Under the conditions of this study, the mean hemolytic index for the test article extract was 11%. The test article extract was moderately hemolytic. The negative and positive controls performed as anticipated.
NAMSA test report V0020_000	**Coagulation** ISO 10993-4: Selection of Tests for Interactions with Blood.	The average recalcification time of the plasma after exposure to the test article was equivalent to the recalcification time for the negative and plasma controls. The negative and plasma controls performed as anticipated. Under the conditions of this study, it was concluded that the test article had no significant effect on recalcification time.

Table 3. Biocompatibility Information for the Quick-Ti® Cinch Applier Tip

Material	Test Report	Test Method	Summary Of Results
Tip	Cell Culture Toxicity Test Data Sheet	**Cytotoxicity** Cell Culture (systemic) Toxicity USP (Extraction) Elution Method	Not cytotoxic
	Well Laboratories Laboratory No. W92-2612	**Intracutaneous Reactivity** USP XXII Section (88)	This sample meets the requirements of the USP Class V-B, Intracutaneous Test at 70° C.
	STS GLP-1992-658	**Irritation** Mucosal Irritation Test	Nonirritating to mucosal tissue.
	STS GLP-1993-016	**Sensitization** Guinea Pig Maximization (Kligman) Test	Not considered to elicit contact dermal allergenicity.
	STS GLP-1993-053	**Hemolysis** Hemolysis Test – Saline Extract Method	The average hemolysis induced by the test sample extract is below the 5% hemolysis limit. The test article meets the test requirements.
	STS GLP-1992-649	**Coagulation** ISO 10993-4: Selection of Tests for Interactions with Blood.	The average recalcification time of the plasma after exposure to the test article was equivalent to the recalcification time for the negative and plasma controls. The negative and plasma controls performed as anticipated. Under the conditions of this study, it was concluded that the test article had no significant effect on recalcification time.
Coating	STS GLP-2002-0288	**Irritation** ISO 10993-10: Selection of Tests for Irritation and Sensitization	The test article has a negligible primary irritation response for all extracts.
	STS GLP-2002-0304	**Sensitization** ISO 10993- 10: Selection of Tests *for Irritation and Sensitization*	Under the conditions of this study, the SC and SO test article extracts are not considered to elicit delayed dermal contact sensitization in the guinea pig.
	STS GLP-2002-0295	**Systemic Toxicity** ISO 10993-11: Tests for Systemic Toxicity (ISO)	The test article meets the requirements of the test.
	STS GLP-2002-0282	**Hemolysis** ISO 10993-4: Selection of Tests *for Interactions with Blood*	The average hemolysis induced by the test sample extract is below the 5% hemolysis limit. The test article meets the test requirements.

Animal Studies

The Quick-Close® System was tested in porcine and canine animal models. However, while some favorable results were obtained, the information gained was not conclusive due to differences in the anatomy of the femoral arteries between animals and humans.

Cadaver Studies

Quick-Close® System prototypes were tested in cadavers. Based upon the results of this testing it was concluded that the Quick-Close® System can function as required.

X. SUMMARY OF PIVOTAL CLINICAL STUDY

The applicant performed a clinical study *to establish a reasonable assurance of safety and effectiveness of arterial closure with the* Quick-Close® System intended for closure of the femoral artery following arterial access in the US under IDE G020017. 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

The clinical investigation for the Quick-Close Vascular Suturing System (VSS), the STITCHES II Study, was a prospective, multicenter randomized study carried out at 8 medical centers in the United States. The first patient was enrolled in the study on 2/10/05 and the final patient was enrolled on 5/3/07. The clinical study follow-up was complete as of 5/29/07.

The Quick-Close VSS clinical study enrolled patients in 2 separate phases: lead-in and pivotal study. Each center enrolled a series of Quick-Close device lead-in patients to provide training and ensure investigator familiarity with the device.

In the Quick-Close VSS clinical study there were 77 lead-in Quick-Close device patients and 367 randomized patients who were randomized into Quick-Close device patients and manual compression (control) patients in a 2:1 Quick-Close device/manual compression ratio. The randomized patients were stratified based on the type of catheterization procedure so that each group included close to 50% diagnostic procedures and close to 50% interventional procedures.

Among the 77 lead-in Quick-Close device patients in the clinical study, the percentages of diagnostic and interventional patients were not provided. Of the 367 randomized patients, there were 243 Quick-Close device patients (66.2%) and 124 manual compression control patients (33.8%). Of the 243 randomized Quick-Close device patients, there were 136 diagnostic patients (56.0%) and 107 interventional patients (44.0%). Of the 124 manual compression control patients, there were 70 diagnostic patients (56.5%) and 54 interventional patients (43.5%).

Inclusion Criteria

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

- Patient is ≥ 21 years of age
- Patient has undergone a 5 to 8 Fr diagnostic or interventional procedure performed percutaneously via the femoral artery
- Female patient of childbearing age has had a negative pregnancy test at the time of treatment
- Patient provides written informed consent
- Patient agrees to return to the investigative site for all follow up

Exclusion Criteria

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

- ineligible for in-catheterization lab arterial sheath removal.

- has a pre-existing (defined as at the time of randomization/ enrollment) hematoma (visual and/or palpable), arterio-venous fistula, or pseudoaneurysm; or bleeding during the procedure
- has had treatment with another suture or collagen vascular hemostasis device at the access site within the previous 3 months
- has a Dacron graft or patch at the access site
- has more than one arterial puncture site during this intervention
- has puncture sites in the profunda femoris or superficial femoral artery or at the bifurcation of the arteries
- has fluoroscopically visible calcium at the femoral artery puncture site
- the diameter of the target femoral artery is < 4 mm
- the posterior wall of the intended artery was thought to have been punctured during the interventional procedure
- has a history of bleeding diathesis, coagulopathy, or a blood dyscrasia
- is morbidly obese [defined as abdominal panniculus hangs below the level of the groin or obesity precludes the use of a standard introducer needle (i.e. Seldinger Needle)]
- the introducer sheath insertion prior to the interventional procedure was difficult due to scarring of the vessel wall
- has a venous sheath
- has a hemoglobin level < 10.5 g/dl
- has angiographic evidence of common femoral artery stenosis >50% at the access site
- has absence of distal pulses in the access site leg
- has received thrombolytic therapy within 48 hours prior to procedure; unless patient has an Activated Clotting Time (ACT) within the reasonable and usual practice standard for ACT levels that are applied to vascular hemostasis devices at the institution
- ACT levels do not meet the reasonable and usual practice standard for ACT levels that are applied to vascular hemostasis devices at the institution.
- has had the same artery punctured in the previous 14 days. [It is acceptable to include patients who have had a prior procedure if a different artery can be used (i.e., the contralateral femoral artery)]
- is known to be ineligible for same day ambulation
- is known to require an extended hospitalization (e.g., patients undergoing coronary bypass surgery)
- has known allergy to any of the materials used in the device
- is a female patient known to be pregnant or lactating
- has a severe noncardiac systemic disease or illness with a life expectancy of less than one year
- has evidence of systemic or cutaneous infection
- there has been use of an intra-aortic balloon pump through the arterial puncture site

- is currently enrolled in another investigational drug or device trial and has not reached the study end-point or completed the required follow-up period
- has already participated in this trial

Follow-up Schedule

Follow-up assessments were made at the following times post-procedure:

- 24 hours ± 6 hours
- 30 days ± 7 days

All patients were contacted 24 hours after their interventional or diagnostic procedure to assess clinical events. Those patients that remained in the hospital overnight were assessed at 24 hours or hospital discharge, whichever was first. All patients returned to the investigative site for a clinical visit to monitor clinical events at 30 days post-procedure.

Table 4. Pre-Procedure & Post-Procedure Evaluation Schedule

	CLINICAL LAB TESTS	CLINICAL EXAM	ADVERSE EVENTS
Pre-treatment	CBC, PT, PTT, INR[1]	X[1]	X
Treatment	ACT[2]		X
Post-treatment	CBC[3]	X	X
24 Hours		X[4]	X
30 Days		X	X

Any patients who were seen 24 hours post-procedure and all patients who were seen 30 days post-procedure underwent a physical exam, to include

- Auscultation for femoral bruit at the access site and
- Examination of the posterior tibial and dorsalis pedis pulses in the access site leg.

The patients were also evaluated for:

- Hematoma (visible and palpable),
- AV-fistula,
- Pseudoaneurysm,
- Infection,
- Loss of motor or sensory function in the lower extremities,
- Access site pain and/or swelling, and
- Leg pain, parasthesia, and/or paralysis.

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

Primary and Secondary Endpoints

The objective of the Quick-Close VSS clinical study was to evaluate the safety and effectiveness of the Quick-Close device to achieve hemostasis of the femoral artery access sites in patients undergoing percutaneous diagnostic or interventional endovascular procedures using a 5, 6, 7, or 8 French sheath. The objective for the safety endpoints of the study was to demonstrate non-inferiority to the control group, and the objective for the effectiveness endpoints of the study was to demonstrate superiority to the control group. The primary safety endpoint was the combined rate of major complications within 30 ± 7 days following the catheterization procedure. The secondary safety endpoint was the combined rate of minor complications within 30 ± 7 days following the catheterization procedure. The primary effectiveness endpoints were time-to-hemostasis and time-to-ambulation. The secondary effectiveness endpoints were time-to-dischargeability, procedure success, and device success.

All primary analyses comparing the 2 randomized groups were based on an intent-to-treat (ITT) analysis, in which patients were assigned to the treatment group to which they were randomized. The ITT populations were the randomized patients.

B. Accountability of PMA Cohort

Of the 243 randomized Quick-Close device patients in the pivotal Quick-Close VSS clinical study, 15 patients (6.2%) were lost to follow-up. Of the 124 randomized manual compression patients in the clinical study, 8 patients (6.5%) were lost to follow-up. Thus, of the 367 randomized patients in the clinical study, 23 patients (6.3%) were lost to follow-up. In addition, of the 367 randomized patients, 5 patients (1.4%) were unable or unwilling to return for the 30-day follow-up visit, 3 patients (0.8%) withdrew their consent to be in the clinical study, and 1 patient (0.3%) was inadvertently not contacted to return for follow-up. These 9 patients who did not have follow-up and the 23 patients who were lost to follow-up result in 32 patients (8.7%) who did not have complete follow-up and 335 patients (91.3%) who had complete follow-up among the 367 randomized patients. This 91.3% patient compliance represents good patient compliance.

C. Study Population Demographics and Baseline Parameters

Table 5. Baseline Demographics of Total Patients in ITT Populations in Quick-Close VSS Clinical Study

Demographic		Quick-Close (N = 243)	Manual Compression (N = 124)	P Value[1]
Age	Mean ± SD	64.2 ± 10.93 years	65.1 ± 10.54 years	0.4424
	Median	65.3 years	64.7 years	---
	Range	38.6 – 86.5 years	40.7 – 89.2 years	---

Sex		Men: 67.9% (165/243)	Men: 61.3% (76/124)	0.2451
		Women: 32.1% (78/243)	Women: 38.7% (48/124)	---

[1] P value based on tests for superiority, using ANOVA model for continuous variable and Fisher Exact Test for categorical variable.

Table 6. Baseline Characteristics of Total Patients in ITT Populations in Quick-Close VSS Clinical Study

Characteristic		Quick-Close (N = 243)	Manual Compression (N = 124)	P Value[1]
Weight (pounds)	Mean ± SD	188.7 ± 37.20	179.5 ± 33.29	0.0204
	Median	185.0	178.5	---
	Range	104.0 – 271.0	110.0 – 265.0	---
Height (inches)	Mean ± SD	68.1 ± 4.15	67.4 ± 4.38	0.1837
	Median	69.0	68.0	---
	Range	56.0 – 81.0	59.0 – 79.0	---
Systolic Blood Pressure (mm Hg)	Mean ± SD	141.7 ± 21.69	139.0 ± 19.38	0.2393
	Median	141.0	138.0	---
	Range	85.0 – 216.0	82.0 – 189.0	---
Diastolic Blood Pressure (mm Hg)	Mean ± SD	75.6 ± 13.02	72.7 ± 12.68	0.0431
	Median	75.0	74.0	---
	Range	42.0 – 109.0	37.0 – 100.0	---
Peripheral Vascular Disease		5.8% (14/243)	4.0% (5/124)	0.6210

[1] P value based on tests for superiority, using ANOVA model for continuous variables and
Fisher Exact Test for categorical variable.

Table 7. Baseline Anticoagulant and Antiplatelet Medication Information for Total Patients in ITT Populations in Quick-Close VSS Clinical Study[1]

Characteristic		Quick-Close (N = 238)	Manual Compression (N = 124)	P Value [2]
Intra-Procedural Anticoagulant and Antiplatelet Medications	All Meds			0.4126
	Anticoagulant	42.4% (101/238)	42.7% (53/124)	---
	Antiplatelet	8.0% (19/238)	4.0% (5/124)	---
	GP IIb/IIIa	13.9% (33/238)	13.7% (17/124)	---

[1] Per Protocol patients
[2] P value based on test for superiority, using Chi-square test.

Safety and Effectiveness Results

Safety Results

Table 8. Incidence of Major Complications in Total Patients in ITT Populations in Quick-Close VSS Clinical Study[1]

Description of Event	Quick-Close (N = 243)	Manual Compression (N = 124)	P Value [2]
Vascular repair or the need for vascular repair	0.0% (0/243)	0.8% (1/124)	0.3379
Any new ipsilateral lower extremity ischemia defined by a 1-class change in Rutherford score	0.0% (0/243)	0.0% (0/124)	NA [3]
Permanent groin-related nerve injury or surgery for groin-related nerve injury	0.0% (0/243)	0.0% (0/124)	NA
Groin-related transfusion	0.8% (2/243)	0.0% (0/124)	0.5526
> 20% drop in hemoglobin requiring transfusion	0.0% (0/243)	0.8% (1/124)	0.3379
Retroperitoneal hemorrhage	0.0% (0/243)	0.8% (1/124)	0.3379
Hematoma requiring extended hospitalization	0.4% (1/243)	0.0% (0/124)	1.0000
Device failure with adverse consequences to the patient	0.4% (1/243)	0.0% (0/124)	1.0000
Groin-related infection requiring IV antibiotics and/or extended hospitalization	0.0% (0/243)	0.0% (0/124)	NA
Myocardial infarction	0.4% (1/243)	0.0% (0/124)	1.0000
Death	0.0% (0/243)	0.0% (0/124)	NA
Total complications	2.1% (5/243) 1.6% (4/243) [4]	2.4% (3/124)	1.0000

[1] Event-based

[2] P value based on test for lower or higher complication rates of device (exact test for comparing 2 Poisson rates, using StatXact – 8).

[3] NA = Not Applicable

[4] Excluding myocardial infarction event

Table 9. Incidence of Major Complications in Diagnostic Patients in ITT Populations in Quick-Close VSS Clinical Study[1]

Description of Event	Quick-Close (N = 136)	Manual Compression (N = 70)	P Value [2]
Vascular repair or the need for vascular repair	0.0% (0/136)	0.0% (0/70)	NA [3]
Any new ipsilateral lower extremity ischemia defined by a 1-class change in Rutherford score	0.0% (0/136)	0.0% (0/70)	NA
Permanent groin-related nerve injury or surgery for groin-related nerve injury	0.0% (0/136)	0.0% (0/70)	NA
Groin-related transfusion	0.0% (0/136)	0.0% (0/70)	NA
> 20% drop in hemoglobin requiring transfusion	0.0% (0/136)	0.0% (0/70)	NA
Retroperitoneal hemorrhage	0.0% (0/136)	0.0% (0/70)	NA
Hematoma requiring extended hospitalization	0.7% (1/136)	0.0% (0/70)	1.0000
Device failure with adverse consequences to the patient	0.7% (1/136)	0.0% (0/70)	1.0000
Groin-related infection requiring IV antibiotics and/or extended hospitalization	0.0% (0/136)	0.0% (0/70)	NA
Myocardial infarction	0.0% (0/136)	0.0% (0/70)	NA
Death	0.0% (0/136)	0.0% (0/70)	NA
Total complications	1.5% (2/136)	0.0% (0/70)	0.5513

[1] Event-based

[2] P value based on test for lower or higher complication rates of device (exact test for comparing 2 Poisson rates, using StatXact – 8).

[3] NA = Not Applicable

Table 10. Incidence of Major Complications in Interventional Patients in ITT Populations in Quick-Close VSS Clinical Study[1]

Description of Event	Quick-Close (N = 107)	Manual Compression (N = 54)	P Value [2]
Vascular repair or the need for vascular repair	0.0% (0/107)	1.9% (1/54)	0.3354
Any new ipsilateral lower extremity ischemia defined by a 1-class change in Rutherford score	0.0% (0/107)	0.0% (0/54)	NA [3]
Permanent groin-related nerve injury or surgery for groin-related nerve injury	0.0% (0/107)	0.0% (0/54)	NA
Groin-related transfusion	1.9% (2/107)	0.0% (0/54)	0.5542
> 20% drop in hemoglobin requiring transfusion	0.0% (0/107)	1.9% (1/54)	0.3354
Retroperitoneal hemorrhage	0.0% (0/107)	1.9% (1/54)	0.3354
Hematoma requiring extended hospitalization	0.0% (0/107)	0.0% (0/54)	NA
Device failure with adverse consequences to the patient	0.0% (0/107)	0.0% (0/54)	NA
Groin-related infection requiring IV antibiotics and/or extended hospitalization	0.0% (0/107)	0.0% (0/54)	NA
Myocardial infarction	0.9% (1/107)	0.0% (0/54)	1.0000
Death	0.0% (0/107)	0.0% (0/54)	NA
Total complications	2.8% (3/107) 1.9% (2/107) [4]	5.6% (3/54)	0.6708

[1] Event-based
[2] P value based on test for lower or higher complication rates of device (exact test for comparing 2 Poisson rates, using StatXact – 8).
[3] NA = Not Applicable
[4] Excluding myocardial infarction event

The above 3 tables show that in the total (diagnostic and interventional), diagnostic, and interventional randomized ITT populations, patients treated with the Quick-Close device had incidences of major complications at 30 days post-procedure which are not clinically significantly different from the incidences of major complications at 30 days post-procedure for patients treated with manual compression.

Table 11. Incidence of Minor Complications in Total Patients in ITT Populations in Quick-Close VSS Clinical Study [1]

Description of Event	Quick-Close (N = 243)	Manual Compression (N = 124)	P Value [2]
Pseudoaneurysm documented by ultrasound	0.0% (0/243)	0.8% (1/124)	0.3379
AV fistula documented by ultrasound	0.0% (0/243)	0.0% (0/124)	NA [3]
Hematoma > 6 cm	1.2% (3/243)	1.6% (2/124)	1.0000
Groin-related bleeding requiring > 30 min to achieve hemostasis	4.5% (11/243)	8.9% (11/124)	0.1177
Late groin-related bleeding	0.4% (1/243)	0.0% (0/124)	1.0000
Ipsilateral lower extremity arterial emboli	0.0% (0/243)	0.0% (0/124)	NA
Transient loss of ipsilateral lower extremity pulse	0.0% (0/243)	0.0% (0/124)	NA
Ipsilateral deep vein thrombosis	0.0% (0/243)	0.0% (0/124)	NA
Transient groin-related nerve injury	0.0% (0/243)	0.0% (0/124)	NA
Groin-related vessel laceration	0.0% (0/243)	0.0% (0/124)	NA
Groin wound dehiscence	0.0% (0/243)	0.0% (0/124)	NA
Localized groin-related infection treated with intramuscular or oral antibiotics	0.0% (0/243)	0.0% (0/124)	NA
Other serious	0.0% (0/243)	0.0% (0/124)	NA
Total complications	6.2% (15/243)	11.3% (14/124)	0.1161

[1] Event-based

[2] P value based on test for lower or higher complication rates of device (exact test for comparing 2 Poisson rates, using StatXact – 8).

[3] NA = Not Applicable

Table 12. Incidence of Minor Complications in Diagnostic Patients in ITT Populations in Quick-Close VSS Clinical Study[1]

Description of Event	Quick-Close (N = 136)	Manual Compression (N = 70)	P Value [2]
Pseudoaneurysm documented by ultrasound	0.0% (0/136)	0.0% (0/70)	NA [3]
AV fistula documented by ultrasound	0.0% (0/136)	0.0% (0/70)	NA
Hematoma > 6 cm	0.0% (0/136)	1.4% (1/70)	0.3398
Groin-related bleeding requiring > 30 min to achieve hemostasis	0.7% (1/136)	2.9% (2/70)	0.5557
Late groin-related bleeding	0.7% (1/136)	0.0% (0/70)	1.0000
Ipsilateral lower extremity arterial emboli	0.0% (0/136)	0.0% (0/70)	NA
Transient loss of ipsilateral lower extremity pulse	0.0% (0/136)	0.0% (0/70)	NA
Ipsilateral deep vein thrombosis	0.0% (0/136)	0.0% (0/70)	NA
Transient groin-related nerve injury	0.0% (0/136)	0.0% (0/70)	NA
Groin-related vessel laceration	0.0% (0/136)	0.0% (0/70)	NA
Groin wound dehiscence	0.0% (0/136)	0.0% (0/70)	NA
Localized groin-related infection treated with intramuscular or oral antibiotics	0.0% (0/136)	0.0% (0/70)	NA
Other serious	0.0% (0/136)	0.0% (0/70)	NA
Total complications	1.5% (2/136)	4.3% (3/70)	0.3450

[1] Event-based

[2] P value based on test for lower or higher complication rates of device (exact test for comparing 2 Poisson rates, using StatXact – 8).

[3] NA = Not Applicable

Table 13. Incidence of Minor Complications in Interventional Patients in ITT Populations in Quick-Close VSS Clinical Study[1]

Description of Event	Quick-Close (N = 107)	Manual Compression (N = 54)	P Value [2]
Pseudoaneurysm documented by ultrasound	0.0% (0/107)	1.9% (1/54)	0.3354
AV fistula documented by ultrasound	0.0% (0/107)	0.0% (0/54)	NA [3]
Hematoma > 6 cm	2.8% (3/107)	1.9% (1/54)	1.0000
Groin-related bleeding requiring > 30 min to achieve hemostasis	9.3% (10/107)	16.7% (9/54)	0.2267
Late groin-related bleeding	0.0% (0/107)	0.0% (0/54)	NA
Ipsilateral lower extremity arterial emboli	0.0% (0/107)	0.0% (0/54)	NA
Transient loss of ipsilateral lower extremity pulse	0.0% (0/107)	0.0% (0/54)	NA
Ipsilateral deep vein thrombosis	0.0% (0/107)	0.0% (0/54)	NA
Transient groin-related nerve injury	0.0% (0/107)	0.0% (0/54)	NA
Groin-related vessel laceration	0.0% (0/107)	0.0% (0/54)	NA
Groin wound dehiscence	0.0% (0/107)	0.0% (0/54)	NA
Localized groin-related infection treated with intramuscular or oral antibiotics	0.0% (0/107)	0.0% (0/54)	NA
Other serious	0.0% (0/107)	0.0% (0/54)	NA
Total complications	12.1% (13/107)	20.4% (11/54)	0.2787

[1] Event-based

[2] P value based on test for lower or higher complication rates of device (exact test for comparing 2 Poisson rates, using StatXact – 8).

[3] NA = Not Applicable

The above 3 tables show that in the total (diagnostic and interventional), diagnostic, and interventional randomized ITT populations, patients treated with the Quick-Close device had incidences of minor complications at 30 days post-procedure which are not clinically significantly different from the incidences of minor complications at 30 days post-procedure for patients treated with manual compression.

Table 14. Incidence of Major Complications in Interventional Patients With GP IIb/IIIa Inhibitor Therapy in ITT Populations in Quick-Close VSS Clinical Study[1]

Description of Event	Quick-Close (N = 31)	Manual Compression (N = 17)	P Value [2]
Vascular repair or the need for vascular repair	0.0% (0/31)	0.0% (0/17)	NA [3]
Any new ipsilateral lower extremity ischemia defined by a 1-class change in Rutherford score	0.0% (0/31)	0.0% (0/17)	NA
Permanent groin-related nerve injury or surgery for groin-related nerve injury	0.0% (0/31)	0.0% (0/17)	NA
Groin-related transfusion	6.5% (2/31)	0.0% (0/17)	0.5425
> 20% drop in hemoglobin requiring transfusion	0.0% (0/31)	5.9% (1/17)	0.3542
Retroperitoneal hemorrhage	0.0% (0/31)	0.0% (0/17)	NA
Hematoma requiring extended hospitalization	0.0% (0/31)	0.0% (0/17)	NA
Device failure with adverse consequences to the patient	0.0% (0/31)	0.0% (0/17)	NA
Groin-related infection requiring IV antibiotics and/or extended hospitalization	0.0% (0/31)	0.0% (0/17)	NA
Myocardial infarction	3.2% (1/31)	0.0% (0/17)	1.0000
Death	0.0% (0/31)	0.0% (0/17)	NA
Total complications	9.7% (3/31) 6.5% (2/31) [4]	5.9% (1/17)	1.0000

[1] Event-based
[2] P value based on test for lower or higher complication rates of device (exact test for comparing 2 Poisson rates, using StatXact – 8).
[3] NA = Not Applicable
[4] Excluding myocardial infarction event

The above table shows that in the interventional randomized ITT population among patients receiving GP IIb/IIIa inhibitor therapy, patients treated with the Quick-Close device had incidences of major complications at 30 days post-procedure which are not ***clinically*** significantly different from the incidences of major complications at 30 days post-procedure for patients treated with manual compression (although among patients receiving GP IIb/IIIa inhibitor therapy, groin-related transfusion is ***statistically*** worse in device patients).

Table 15. Incidence of Minor Complications in Interventional Patients With GP IIb/IIIa Inhibitor Therapy in ITT Populations in Quick-Close VSS Clinical Study[1]

Description of Event	Quick-Close (N = 31)	Manual Compression (N = 17)	P Value [2]
Pseudoaneurysm documented by ultrasound	0.0% (0/31)	0.0% (0/17)	NA [3]
AV fistula documented by ultrasound	0.0% (0/31)	0.0% (0/17)	NA
Hematoma > 6 cm	9.7% (3/31)	5.9% (1/17)	1.0000
Groin-related bleeding requiring > 30 min to achieve hemostasis	6.5% (2/31)	23.5% (4/17)	0.1946
Late groin-related bleeding	0.0% (0/31)	0.0% (0/17)	NA
Ipsilateral lower extremity arterial emboli	0.0% (0/31)	0.0% (0/17)	NA
Transient loss of ipsilateral lower extremity pulse	0.0% (0/31)	0.0% (0/17)	NA
Ipsilateral deep vein thrombosis	0.0% (0/31)	0.0% (0/17)	NA
Transient groin-related nerve injury	0.0% (0/31)	0.0% (0/17)	NA
Groin-related vessel laceration	0.0% (0/31)	0.0% (0/17)	NA
Groin wound dehiscence	0.0% (0/31)	0.0% (0/17)	NA
Localized groin-related infection treated with intramuscular or oral antibiotics	0.0% (0/31)	0.0% (0/17)	NA
Other serious	0.0% (0/31)	0.0% (0/17)	NA
Total complications	16.1% (5/31)	29.4% (5/17)	0.5104

[1] Event-based
[2] P value based on test for lower or higher complication rates of device (exact test for comparing 2 Poisson rates, using StatXact – 8).
[3] NA = Not Applicable

The above patient table shows that in the interventional randomized ITT population among patients receiving GP IIb/IIIa inhibitor therapy, patients treated with the Quick-Close device had incidences of minor complications at 30 days post-procedure which are not ***clinically*** significantly different from the incidences of minor complications at 30 days post-procedure for patients treated with manual compression (although among patients receiving GP IIb/IIIa inhibitor therapy, hematoma > 6 cm is ***statistically*** worse in device patients).

Effectiveness Results

Table 16. Effectiveness Results for Total Patients in ITT Populations in Quick-Close VSS Clinical Study

Patient Group	Measure	Quick-Close	Manual Compression	P Value
Time-to-Hemostasis	Mean ± SD (min.)	10.4 ± 38.50	23.4 ± 29.56	< 0.0001[1]
	Median (min.)	1.0	20.0	---
	Range (min.)	0.0 – 386.0	5.0 – 310.0	---
	Number	243	124	---
Time-to-Ambulation	Mean ± SD (hrs.)	4.4 ± 3.73	6.9 ± 5.45	< 0.0001[1]
	Median (hrs.)	3.3	5.0	---
	Range (hrs.)	1.0 – 22.1	1.7 – 46.5	---
	Number	242	122	---
Time-to-Dischargability	Mean ± SD (hrs.)	11.7 ± 11.85	11.9 ± 11.87	0.8999[1]
	Median (hrs.)	5.7	6.1	---
	Range (hrs.)	1.1 – 79.8	2.0 – 74.5	---
	Number	242	122	---
Procedure Success	Percentage	97.9% (238/243)	97.6% (121/124)	1.0000[2]
Device Success	Percentage	97.9% (238/243)		---

[1] P value based on test for superiority using the log-rank test for the survival curve analysis.
[2] P value based on 2-sided Fisher exact test.

The above table shows that the total patients treated with the Quick-Close device had a lower mean time-to-hemostasis and a lower mean time-to-ambulation than the corresponding times for those patients treated with manual compression, and that the differences in these times are statistically and clinically significant. The table also shows that the total patients treated with the Quick-Close device had a mean time-to-dischargeability that is not statistically or clinically significantly different from the corresponding time for those patients treated with manual compression.

Table 17. Effectiveness Results for Diagnostic Patients in ITT Populations in Quick-Close VSS Clinical Study

Patient Group	Measure	Quick-Close	Manual Compression	P Value
Time-to-Hemostasis	Mean ± SD (min.)	3.5 ± 6.52	16.6 ± 11.97	< 0.0001[1]
	Median (min.)	1.0	15.0	---
	Range (min.)	0.0 – 44.0	5.0 – 100.0	---
	Number	136	70	---
Time-to-Ambulation	Mean ± SD (hrs.)	2.8 ± 1.96	4.8 ± 5.59	< 0.0001[1]
	Median (hrs.)	2.2	4.1	---
	Range (hrs.)	1.0 – 15.5	1.7 – 46.5	---
	Number	135	68	---
Time-to-Dischargeability	Mean ± SD (hrs.)	5.4 ± 8.65	6.7 ± 9.97	0.0062[1]
	Median (hrs.)	2.7	4.7	---
	Range (hrs.)	1.1 – 79.8	2.0 – 74.5	---
	Number	135	70	---
Procedure Success	Percentage	98.5% (134/136)	100% (70/70)	0.5491[2]
Device Success	Percentage	97.8% (133/136)		---

[1] P value based on test for superiority using the log-rank test for the survival curve analysis.
[2] P value based on 2-sided Fisher exact test.

The above table shows that the diagnostic patients treated with the Quick-Close device had a lower mean time-to-hemostasis, a lower mean time-to-ambulation, and a lower mean time-to-dischargeability than the corresponding times for those patients treated with manual compression, and that the differences in these times are statistically and clinically significant.

Table 18. Effectiveness Results for Interventional Patients in ITT Populations in Quick-Close VSS Clinical Study

Patient Group	Measure	Quick-Close	Manual Compression	P Value
Time-to-Hemostasis	Mean ± SD (min.)	19.1 ± 56.51	32.3 ± 41.22	< 0.0001[1]
	Median (min.)	2.0	26.5	---
	Range (min.)	0.0 – 386.0	5.0 – 310.0	---
	Number	107	54	---
Time-to-Ambulation	Mean ± SD (hrs.)	6.3 ± 4.46	9.5 ± 4.01	0.0010[1]
	Median (hrs.)	5.0	8.7	---
	Range (hrs.)	1.2 – 22.1	2.3 – 18.7	---
	Number	107	54	---
Time-to-Dischargeability	Mean ± SD (hrs.)	19.6 ± 10.53	18.9 ± 10.60	0.0822[1]
	Median (hrs.)	19.4	16.9	---
	Range (hrs.)	1.6 – 67.7	5.0 – 64.0	---
	Number	107	52	---
Procedure Success	Percentage	97.2% (104/107)	94.4% (51/54)	0.4038[2]
Device Success	Percentage	98.1% (105/107)		---

[1] P value based on test for superiority using the log-rank test for the survival curve analysis.
[2] P value based on 2-sided Fisher exact test.

The above table shows that the interventional patients treated with the Quick-Close device had a lower mean time-to-hemostasis and a lower mean time-to-ambulation than the corresponding times for those patients treated with manual compression, and that the differences in these times are statistically and clinically significant. The table also shows that the interventional patients treated with the Quick-Close device had a mean time-to-dischargeability that is not statistically or clinically significantly different from the corresponding time for those patients treated with manual compression.

Table 19. Effectiveness Results for Interventional Patients with GP IIb/IIIa Inhibitor Therapy in ITT Populations in Quick-Close VSS Clinical Study

Patient Group	Measure	Quick-Close	Manual Compression	P Value[1]
Time-to-Hemostasis	Mean ± SD (min.)	13.1 ± 35.85	43.6 ± 70.38	0.0015
	Median (min.)	1.0	20.0	---
	Range (min.)	0.0 – 193.0	10.0 – 310.0	---
	Number	31	17	---
Time-to-Ambulation	Mean ± SD (hrs.)	8.0 ± 6.09	8.0 ± 4.14	0.9053
	Median (hrs.)	5.5	7.0	---
	Range (hrs.)	1.6 – 22.1	2.3 – 18.7	---
	Number	31	17	---

[1] P value based on test for superiority using the log-rank test for the survival curve analysis.

The above patient table shows that in the interventional randomized ITT population, among patients receiving GP IIb/IIIa inhibitor therapy, patients treated with the Quick-Close device had a lower mean time-to-hemostasis than the corresponding time for those patients treated with manual compression, with the difference in this time being statistically and clinically significant, but patients treated with the Quick-Close device had a mean time-to-ambulation that is statistically and clinically the same as (i.e., no better than) the corresponding time for those patients treated with manual compression.

Table 20. Effectiveness Results by Post-Procedure Time Interval for Diagnostic Patients in ITT Populations in Quick-Close VSS Clinical Study

Parameter	Patient Group	Post-Procedure Time Interval							
Percentage of Patients Achieving Hemostasis Within Time Interval		*≤ 1 min*	*≤ 5 min*	*≤ 10 min*	*≤ 15 min*	*≤ 20 min*	*≤ 30 min*	*≤ 60 min*	*≤ 120 min*
	Quick-Close	**58.1%** (79/136)	**83.8%** (114/136)	**89.7%** (122/136)	**94.1%** (128/136)	**96.3%** (131/136)	**99.3%** (135/136)	**100%** (136/136)	**100%** (136/136)
	Manual Comp	**0.0%** (0/70)	**2.9%** (2/70)	**28.6%** (20/70)	**57.1%** (40/70)	**81.4%** (57/70)	**97.1%** (68/70)	**98.6%** (69/70)	**100%** (70/70)
Percentage of Patients Ambulating Within Time Interval		*≤ 2 hrs*	*≤ 3 hrs*	*≤ 4 hrs*	*≤ 5 hrs*	*≤ 6 hrs*	*≤ 12 hrs*	*≤ 18 hrs*	*≤ 24 hrs*
	Quick-Close	**43.4%** (59/136)	**68.4%** (93/136)	**80.9%** (110/136)	**89.0%** (121/136)	**93.4%** (127/136)	**98.5%** (134/136)	**99.3%** (135/136)	**99.3%** (135/136)
	Manual Comp	**7.1%** (5/70)	**27.1%** (19/70)	**41.4%** (29/70)	**75.7%** (53/70)	**90.0%** (63/70)	**92.9%** (65/70)	**95.7%** (67/70)	**95.7%** (67/70)
Percentage of Patients Eligible for Discharge Within Time Interval		*≤ 2 hrs*	*≤ 3 hrs*	*≤ 4 hrs*	*≤ 5 hrs*	*≤ 6 hrs*	*≤ 12 hrs*	*≤ 24 hrs*	*≤ 48 hrs*
	Quick-Close	**24.3%** (33/136)	**54.4%** (74/136)	**67.6%** (92/136)	**76.5%** (104/136)	**83.1%** (113/136)	**89.0%** (121/136)	**94.9%** (129/136)	**98.5%** (134/136)
	Manual Comp	**1.4%** (1/70)	**20.0%** (14/70)	**28.6%** (20/70)	**58.6%** (41/70)	**84.3%** (59/70)	**92.9%** (65/70)	**95.7%** (67/70)	**98.6%** (69/70)

Table 21. Effectiveness Results by Post-Procedure Time Interval for Interventional Patients in ITT Populations in Quick-Close VSS Clinical Study

Parameter	Patient Group	Post-Procedure Time Interval							
Percentage of Patients Achieving Hemostasis Within Time Interval		*≤ 1 min*	*≤ 5 min*	*≤ 10 min*	*≤ 15 min*	*≤ 20 min*	*≤ 30 min*	*≤ 60 min*	*≤ 120 min*
	Quick-Close	**45.8%** (49/107)	**69.2%** (74/107)	**77.6%** (83/107)	**85.0%** (91/107)	**86.0%** (92/107)	**89.7%** (96/107)	**93.5%** (100/107)	**94.4%** (101/107)
	Manual Comp	**0.0%** (0/54)	**3.7%** (2/54)	**11.1%** (6/54)	**22.2%** (12/54)	**40.7%** (22/54)	**83.3%** (45/54)	**94.4%** (51/54)	**98.1%** (53/54)
Percentage of Patients Ambulating Within Time Interval		*≤ 2 hrs*	*≤ 3 hrs*	*≤ 4 hrs*	*≤ 5 hrs*	*≤ 6 hrs*	*≤ 12 hrs*	*≤ 18 hrs*	*≤ 24 hrs*
	Quick-Close	**8.4%** (9/107)	**18.7%** (20/107)	**31.8%** (34/107)	**49.5%**(53/107)	**62.6%** (67/107)	**89.7%** (96/107)	**96.3%** (103/107)	**100%** (107/107)
	Manual Comp	**0.0%** (0/54)	**3.7%** (2/54)	**5.6%** (3/54)	**14.8%** (8/54)	**18.5%** (10/54)	**72.2%** (39/54)	**98.1%** (53/54)	**100%** (54/54)
Percentage of Patients Eligible for Discharge Within Time Interval		*≤ 2 hrs*	*≤ 3 hrs*	*≤ 4 hrs*	*≤ 5 hrs*	*≤ 6 hrs*	*≤ 12 hrs*	*≤ 24 hrs*	*≤ 48 hrs*
	Quick-Close	**0.9%** (1/107)	**1.9%** (2/107)	**4.7%** (5/107)	**7.5%** (8/107)	**9.3%** (10/107)	**17.8%** (19/107)	**81.3%** (87/107)	**98.1%** (105/107)
	Manual Comp	**0.0%** (0/54)	**0.0%** (0/54)	**0.0%** (0/54)	**1.9%** (1/54)	**1.9%** (1/54)	**11.1%** (6/54)	**87.0%** (47/54)	**92.6%** (50/54)

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(2) 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.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Safety Conclusions

The adverse effects of the device are based on data collected in clinical studies conducted to support PMA approval as described above. The primary safety endpoint was the combined rate of major complications within 30 ± 7 days following the catheterization procedure. The secondary safety endpoint was the combined rate of minor complications within 30 ± 7 days following the catheterization procedure. The data showed that in the total (diagnostic and interventional), diagnostic, and interventional randomized ITT populations, patients treated with the Quick-Close device had incidences of major and minor complications at 30 days post-procedure which are not clinically significantly different from the incidences of major and minor complications at 30 days post-procedure for patients treated with manual compression.

B. Effectiveness Conclusions

The primary effectiveness endpoints were time-to-hemostasis and time-to-ambulation. The secondary effectiveness endpoints were time-to-dischargeability, procedure success, and device success. The clinical data shows that the total patients treated with the Quick-Close device had a lower mean time-to-hemostasis and a lower mean time-to-ambulation than the corresponding times for those patients treated with manual compression, and that the differences in these times are statistically and clinically significant. The table also shows that the total patients treated with the Quick-Close device had a mean time-to-dischargeability that is not statistically or clinically significantly different from the corresponding time for those patients treated with manual compression

C. Overall Conclusions

The data provided in PMA Application P080029 support the safety and effectiveness of the Interventional Therapies Quick-Close Vascular Suturing System when used in patients who have undergone diagnostic or interventional endovascular procedures utilizing a 5, 6, 7, or 8 French procedural sheath. The data support the claims of improved time-to-hemostasis and time-to-ambulation in diagnostic and interventional patients, improved time-to-dischargeability in only diagnostic patients, and improved time-to-hemostasis but not time-to-ambulation in interventional patients receiving GP IIb/IIIa inhibitor therapy. Approval of PMA Application P080029 is recommended.

XIII. CDRH DECISION

CDRH issued an approval order on April 8, 2010.

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

XIV. 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.

XV. REFERENCES

None