SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Iliac stent (Product Code: NIO)
Device Trade Name:	Absolute Pro® Vascular Self-Expanding Stent System
Applicant's Name and Address:	Abbott Vascular 3200 Lakeside Drive Santa Clara, CA 95054
Premarket Approval (PMA) number:	P110028
Date of Panel Recommendation:	None
Date of FDA Notice of Approval:	February 22, 2012
Expedited:	Not Applicable

II. INDICATIONS FOR USE

The Absolute Pro® Vascular Self-Expanding Stent System is indicated for improving luminal diameter in patients with *de novo* or restenotic atherosclerotic lesions in the native common iliac artery and native external iliac artery with reference vessel diameters between 4.3 mm and 9.1 mm and lesion lengths up to 90 mm.

III. CONTRAINDICATIONS

There are no known contraindications.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Absolute Pro Vascular Self-Expanding Stent System labeling.

V. DEVICE DESCRIPTION

The Absolute Pro Vascular Self-Expanding Stent System includes:

- A self-expanding nickel titanium stent (Figure 1) that is pre-mounted on an over-the-wire (OTW) Delivery System. The stent delivery system is compatible with a 0.035" (0.89 mm) guide wire and comes in lengths of 80 cm and 135 cm;

- A total of 12 (6 at each end) markers made of a radiopaque nickel-titanium alloy located at the ends of the stent. The system also includes radiopaque markers that identify the stent location.
- A delivery catheter comprised of a retractable sheath that covers the stent during delivery and a radiopaque tip. Rolling back the thumbwheel on the delivery system handle deploys the stent. The locking mechanism is located on top of the Absolute Pro handle (Figure 2).

Figure 1: Absolute Pro Vascular Self-Expanding Stent

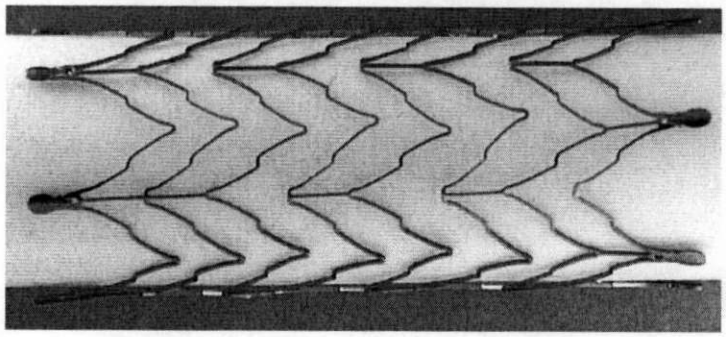
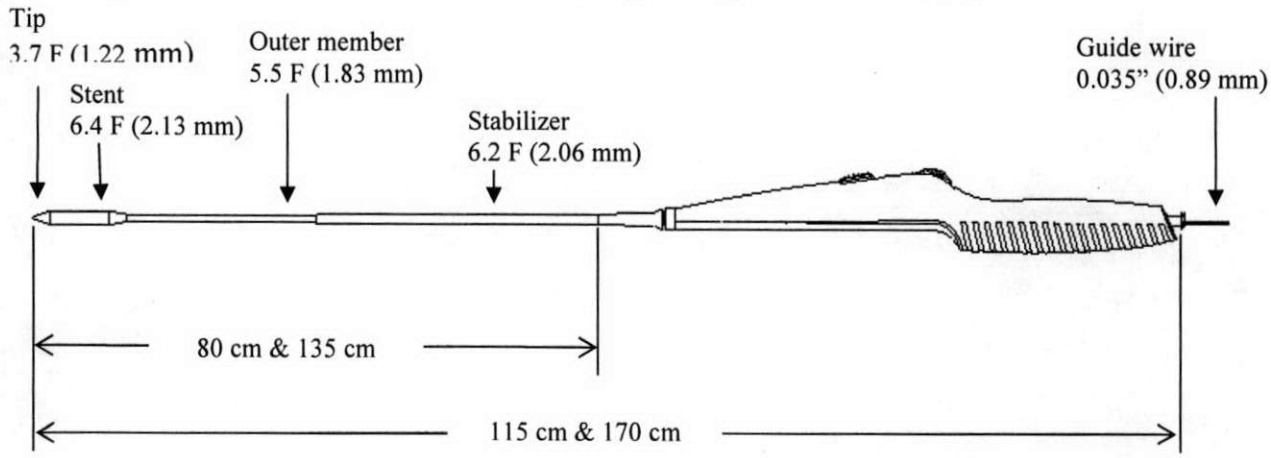


Figure 2: Absolute Pro Vascular Self-Expanding Stent Delivery System



The Absolute Pro stent system is available in diameters of 6.0-10.0 mm in 1.0 mm increments. The stent comes in lengths of 20, 30, 40, 60, 80, and 100 mm. **Table 1** lists the stent sizes.

Table 1: Absolute Pro Vascular Self-Expanding Stent System Product Information

Stent Diameter	Product Length									
	80 cm					135 cm				
	Stent Length					Stent Length				
	20mm	40mm	60mm	80mm	100mm	20mm	40mm	60mm	80mm	100mm
6.0 mm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
7.0 mm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
8.0 mm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9.0 mm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10.0 mm	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative practices and procedures for treatment of Peripheral Vascular Disease (PVD) include percutaneous transluminal angioplasty (PTA), stenting with another stent for which there is an approved indication, bypass surgery, exercise therapy, and pharmacotherapy. Atherosclerotic risk factors may be reduced through lifestyle modifications such as cessation of smoking, weight reduction, lipid control, blood pressure control, and diabetes management.

VII. MARKETING HISTORY

The Absolute Pro has been commercially available in the United States and its territories as a biliary stent since September 29, 2008. The same device labeled as the Absolute Pro Peripheral Stent System is commercially available in over 80 countries outside the United States including countries in the European Union, Middle East, Asia Pacific, Latin America and Africa. The Absolute Pro has not been withdrawn from marketing in any country for any reason.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

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

- Acute myocardial infarction
- Allergic reaction (contrast medium, drug, or stent material)
- Aneurysm, pseudoaneurysm, or arteriovenous fistula
- Angina or coronary ischemia
- Arrhythmias, with or without the need for a temporary pacemaker
- Bleeding complications from anticoagulant or antiplatelet medication requiring transfusion or surgical intervention
- Death
- Detachment and/or implantation of a component of the system
- Embolization, arterial or other (air, tissue, plaque, thrombotic material, stent)
- Emergent or urgent surgery to perfuse limb or remove stent

- Fever
- Hematoma or hemorrhagic event
- Hypotension or hypertension
- Infection, local or systemic, including bacteremia or septicemia
- Ischemia or infarction of tissue or organ
- Pain (limb or catheter insertion site)
- Pulmonary embolism
- Renal failure or insufficiency secondary to contrast medium
- Restenosis of vessel in stented segment
- Stent malapposition or migration
- Stent strut fracture
- Stent thrombosis or occlusion
- Stroke, cerebrovascular accident (CVA), or transient ischemic attack (TIA)
- Target limb loss (amputation of toe, foot, and/or leg)
- Vascular thrombosis or occlusion at puncture site, treatment site, or remote site
- Vessel dissection, perforation, or rupture
- Vessel spasm or recoil
- Worsening claudication or rest pain

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

IX. SUMMARY OF PRECLINICAL STUDIES

A series of non-clinical laboratory studies related to the Absolute Pro Vascular Self-Expanding Stent System was performed. Studies included those performed on the stent, the delivery system, or the entire device (stent mounted on delivery system). In all cases, test samples were sufficiently representative of the as-manufactured final product.

A. *In Vitro* Bench Testing

In vitro bench testing was performed to assess the functional characteristics of the Absolute Pro Vascular Self-Expanding Stent System. This testing was consistent with the guidelines outlined in the *FDA Guidance for Industry and FDA Staff – Non-clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems* (April 18, 2010). **Table 2** below summarizes the bench testing performed on the Absolute Pro Vascular Self-Expanding Stent System. The test results support the safety and effectiveness of the device.

Table 2: Summary of *In Vitro* Testing

Test	Test Purpose	Acceptance Criteria	Results
Stent Dimensional and Functional Testing			
Material Composition	To verify that the stent material conforms to the requirements of ASTM F2063-05, and to measure the chemical composition and depth of the passivation layer.	The chemical composition of the nitinol tubing must meet ASTM F2063-05 requirements. Surface characterization studies showed the depth of the passivation layer to be at least 54 Å, and that the chemical composition consisted of predominately titanium dioxide.	Pass
Shape Memory and Superelasticity	To describe the Austenite finish transition temperature (Af) and the mode of action for the stent.	The stent must transition to the specified size and shape at 37° C after deployment in the body by superelasticity.	Pass
Pitting and Crevice Corrosion: Single Stent and Overlapped Stents after Radial Fatigue	To document the potential for pitting and crevice corrosion of the stent.	Cyclic potentiodynamic polarization testing was performed on single and overlapped stents after radial fatigue testing to determine the breakdown potential. The mean difference between the breakdown and rest potential (Eb – Er) must be at least 600 mV, the minimum difference between the breakdown and rest potentials (Eb – Er) for a single data point must be at least 300 mV, and the minimum breakdown potential (Eb) must be at least 200 mV with respect to SCE.	Pass
Fretting Corrosion: Overlapped Stents after Radial Fatigue	To document the potential for fretting corrosion for overlapped stents.	Absolute Pro stents deployed in an overlapped configuration underwent 10 year equivalent radial fatigue conditioning in a simulated physiologic environment. This study was conducted for informational purposes only, therefore there were no acceptance criteria. No fretting corrosion evidence was found after inspection of the stents.	Pass
Galvanic Corrosion	To document the potential for galvanic corrosion in overlapped stents of dissimilar materials.	The maximum mass loss rate for single stents must be less than 9500 ng/cm^{2}day.	Pass
Dimensional Verification	To characterize the dimensions of the stent.	Stent total length must be ± 4 mm of the nominal length and the unconstrained stent OD must be no more than 0.8 mm larger than the labeled diameter.	Pass
Foreshortening	To determine the stent length change after deployment.	Stent foreshortening was calculated by measuring the difference in undeployed and deployed stent lengths. The maximum foreshortening for all stents met the acceptance criteria and was ≤ 7%..	Pass
Stent Integrity	To provide assurance that the stent has no clinically significant defects or flaws after deployment.	Visual examination of the stent after deployment was conducted. All Absolute Pro Stents must be free of broken struts, microcracks along the entire side wall and misaligned struts.	Pass
Radial Outward	The radial outward force	The acceptance criteria vary by stent length.	Pass

Test	Test Purpose	Acceptance Criteria	Results
Force	exerted by the stent against the vessel wall after deployment was measured at both minimum and maximum oversizing.	For minimum reference vessel diameters, all stents must be ≥ 2 N. For maximum reference vessel diameters, all stents must be ≤ 39 N.	
Mechanical Properties	To characterize the stent material for the purpose of developing parameters for a finite element analysis of the stent.	Plateau strength, ultimate tensile strength, permanent set, and maximum elongation of the stent material were determined.	Pass
Stress/Strain and Fatigue Analysis	Using Finite Element Analysis, the stresses acting upon the stent during manufacturing, deployment and implantation were determined, and the durability and integrity of the stent under physiologic conditions was verified.	The Finite Element Analysis must show alternating strain values that are below the allowable constant life limit and a Factor of Safety value greater than 1.00 for overlapped stents for 10 years of radial fatigue.	Pass
Accelerated Durability Testing: Radial Fatigue	To evaluate the long term fatigue resistance (10 year real time equivalent) of the Absolute Pro stent in an overlapped state in a physiologically simulated environment with accelerated dynamic radial loading.	Stents were subjected to 400 million cycles of radial fatigue and then examined for fractures. No stent must have higher than a Type II fracture and there can be no detachment of any part of the stent. Any stent that suffers a Type I or Type II strut fracture must still meet the radial force specification.	Pass
Magnetic Resonance Imaging	To evaluate the response of the Absolute Pro Stent to MR scanning conditions.	Rf induced heating, image distortion, magnetic force and torque for single and overlapped Absolute Pro stents in lengths up to 290 mm were measured under MR field strengths of 1.5 and 3.0 Tesla. Test results must show that the Absolute Pro stents are rated MR Conditional per ASTM 2503.	Pass
Radiopacity	To assess the radiopacity of the Absolute Pro Stent System in a simulated clinical setting.	The radiopacity of the Absolute Pro Stent System was evaluated *in vivo* in an acute porcine model. Visibility during delivery and deployment and after retraction must be rated as clinically acceptable.	Pass
Crush Resistance	To demonstrate the ability of the Absolute Pro stent to recover its desired size and shape after application and removal of external loads.	Stents must recover to at least 95% of the initial diameter after application of external loads.	Pass
Kink Resistance	To evaluate the kink resistance of the Absolute Pro stent when bent in a radius of curvature that is clinically relevant to the intended implant site.	The average diameter of all Absolute Pro stents must not decrease by more than 50% when bent around a clinically relevant bend radius.	Pass
Delivery System Dimensional and Functional Testing			
Delivery System	To measure various	The working length and total length of the	Pass

Test	Test Purpose	Acceptance Criteria	Results
Dimensional Verification	dimensional characteristics of the Absolute Pro Delivery Catheter.	delivery catheters must meet the labeled dimensions ± 4 cm.	
Crossing Profile	To evaluate the maximum diameter (crossing profile) of the delivery catheter.	The delivery catheters must have a crossing profile of less than or equal to .084 in.	Pass
Delivery, Deployment, Retraction, Coating Integrity	To assess the performance of the device in a simulated clinical setting, to evaluate the functional attributes of delivery, deployment, retraction and coating integrity of the device.	Absolute Pro Stent Systems were evaluated in a simulated clinical model. All test articles must be delivered, deployed and retracted without damage to the stent. Additionally, the guide wire lumen must be compatible with .035 in guide wires and the catheter shaft coating must allow for delivery and retraction of the devices.	Pass
Catheter Bond Strength and Tip Pull Test	To determine the bond strength at all locations on the Absolute Pro Delivery Catheter where a joint is present was performed.	Each bond was pulled on a tensile tester until failure. Catheter bond strengths must be $\geq$ 2.25 lbf or > 4.0 lbf depending on the location of the bond.	Pass
Flexibility and Kink Test	To evaluate the ability of the Absolute Pro Delivery Catheter to withstand flexural forces typical of clinical use.	Absolute Pro Stent Systems were tracked through a series of incrementally smaller bend radii until the catheter kinked. The minimum radius that the catheter can be placed in without kinking must be $\leq$ 13.0 mm.	Pass
Torque Strength	To determine the ability of the Absolute Pro Delivery Catheter to withstand torsional forces typical of clinical use.	The catheter shaft was locked in a fixture and the catheter was rotated until failure. The catheter shaft must rotate greater than 180° before failure.	Pass

B. Sterilization

The Absolute Pro Vascular Self-Expanding is sterilized by means of e-beam radiation in accordance with ANSI/AAMI/ISO 11137-1:2006, Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices,.

Results obtained from sterilization studies show that the Absolute Pro Stent System will meet a Sterility Assurance Level (SAL) of 10^{-6} when sterilized at a minimum dose of 25kGy.

C. Packaging and Product Shelf Life

Packaging Validation testing conducted in compliance with ISO 11607-1/-2 demonstrated that the packaging system for the Absolute Pro Vascular Self-Expanding Stent System is robust and acceptable for use during normal and worst case production processes for the labeled shelf life of the product. The aging test results indicate that the Absolute Pro Vascular Self-Expanding Stent System will maintain functional characteristics for the labeled shelf life of 1 year.

D. *In Vivo* Animal Studies

In vivo animal testing was conducted to demonstrate the safety of the Absolute Pro Vascular Self-Expanding Stent System. A total of five studies were carried out in a non-atherosclerotic swine model at multiple time points to determine the safety of the stent in an *in vivo* animal model. An acute animal study with the Absolute Pro Vascular Self-Expanding Stent System assessed the functional performance of the device. Safety studies evaluating the chronic vascular response at 28, 90, 180, and 360 days were conducted in the peripheral vasculature of healthy swine. A description of the studies and results is provided in **Table 3**. The results all support the safety and adequate performance of the device.

Table 3: Summary of Animal Studies Performed

Test Type	Number of Animals, Implant Location / Number of Stents	Testing Summary
Design Validation, Acute	5 swine Ilio-femoral arteries 17 stents plus controls	The study evaluated the acute functional performance of the Absolute Pro Stent System in healthy porcine arteries. Acute performance requirements were met and all test devices were rated as clinically acceptable.
Multiphased Single Stent Study, 28 days	20 swine Femoral arteries 10 stents	The study characterized the vascular histological response to the stents. In the porcine femoral arterial model, the stents demonstrated safety, successfully meeting all angiographic and histological acceptance criteria.
90-day Study	8 swine Iliac arteries 8 overlapped pairs of stents	The study evaluated the safety after implantation of overlapped pairs of stents in the porcine iliac artery for 90 days. All arteries remained patent, no stent fractures were observed, endothelialization was complete and that injury, inflammation and granuloma scores were comparable to previous animal studies with bare metal stents.
180-day Study	8 swine Iliac arteries 8 overlapped pairs of stents	The study evaluated the safety after implantation of overlapped pairs of stents in the porcine iliac artery for 180 days. All arteries remained patent, no stent fractures were observed, endothelialization was complete and that injury, inflammation and granuloma scores were comparable to previous animal studies with bare metal stents.

Test Type	Number of Animals, Implant Location / Number of Stents	Testing Summary
360-day Study	8 swine Iliac arteries 8 overlapped pairs of stents	The study evaluated the safety after implantation of overlapped pairs of stents in the porcine iliac artery for 360 days. All arteries remained patent, no stent fractures were observed, endothelialization was complete and that injury, inflammation and granuloma scores were comparable to previous animal studies with bare metal stents.

E. Biocompatibility

Biocompatibility testing according to ISO 10993-1 was conducted on the Absolute Pro stent which is in contact with cardiovascular tissue and circulating blood with a permanent duration of contact (> 30 days), or on the associated Delivery Catheter, an externally communicating device having contact with circulating blood for a limited (< 24 hours) exposure. The test results indicated that the materials and processes used to manufacture the Absolute Pro Vascular Self-Expanding Stent System are biocompatible and suitable for their intended use. **Tables 4 and 5** summarize the testing that was successfully completed.

Table 4: Biocompatibility Test Summary for the Absolute Pro Stent

Test Name	Test Purpose	Acceptance Criteria	Results
Cytotoxicity ISO 10993-5: Elution Test (MEM Extract)	To determine the potential for cytotoxicity.	The sample is considered non-cytotoxic if the grade assigned from the Cytotoxicity Scale is less than or equal to grade 2 (mild).	Pass
Sensitization ISO 10993-10: Guinea Pig Maximization Test for Delayed Hypersensitivity	To evaluate the potential for delayed dermal contact sensitization.	Skin reaction scores received by the test group which are greater than the scores received by the negative control group, are considered to represent significant sensitization.	Pass
Intracutaneous Reactivity ISO 10993-10: Intracutaneous (Intradermal) Reactivity	To assess possible contact hazards from chemicals released from medical devices that may produce skin and mucosal irritation, eye irritation and delayed	The requirements of the test are met if the difference between the mean score for the sample extract and the mean score for the corresponding blank is 1.0 or less (negligible or slight)	Pass

Test Name	Test Purpose	Acceptance Criteria	Results
	contact hypersensitivity.		
Systemic Toxicity ISO 10993-11: ISO Acute Systemic Toxicity Test	To determine the potential for systemic toxicity.	The requirements of the test are met if none of the animals treated with the sample extract show a significantly greater biological reactivity than the control animals over the 72 hour test period..	Pass
Material-Mediated Pyrogenicity ISO 10993-11: 2009	To determine whether an extract of the test article induced a pyrogenic response following injection in rabbits.	If no rabbit shows an individual rise in temperature of 0.5°C or more above its respective control temperature, the test article meets the requirements for the absence of pyrogens.	Pass
Hemocompatibility / Hemolysis ISO 10993-4: Hemolysis, Indirect and Direct	To determine whether the presence of any leachable chemical from the test article or direct contact with the test article would cause *in vitro* red blood cell hemolysis.	The test article is considered non-hemolytic if the hemolytic index is less than 2%.	Pass
Complement Activation (C3a & SC5b-9)	To determine if the test article has the potential for activation of the complement system.	The test article must not demonstrate activation of the classical or alternate pathways of the complement system at all three timepoints, when compared to the negative control.	Pass
Implantation ISO 10993-6: 90-Day	To evaluate the histopathological effects of implantation	No gross evidence of local irritancy.	Pass
Genotoxicity ISO 10993-3: *S. Typhimurium* and *E. coli* Reverse Mutation Assay ISO 10993-3: Chromosomal	To evaluate the mutagenic and clastogenic potential	Non-mutagenic and/or non-clastogenic	Pass

Test Name	Test Purpose	Acceptance Criteria	Results
Aberration Assay ISO 10993-3: CHO/HGPRT Forward Mutation Assay ISO 10993-3: Rodent Bone Marrow Micronucleus Assay (90 Animals)			

Table 5: Biocompatibility Test Summary for the Absolute Pro Delivery Catheter

Test Name	Test Purpose	Acceptance Criteria	Results
Cytotoxicity ISO 10993-5: Elution Test (MEM Extract)	To determine the potential for cytotoxicity.	The sample is considered non-cytotoxic if the grade assigned from the Cytotoxicity Scale is less than or equal to grade 2 (mild).	Pass
Sensitization ISO 10993-10: Guinea Pig Maximization Test for Delayed Hypersensitivity	To evaluate the potential for delayed dermal contact sensitization.	Skin reaction scores received by the test group which are greater than the scores received by the negative control group, are considered to represent significant sensitization.	Pass
Intracutaneous Reactivity ISO 10993-10: Intracutaneous (Intradermal) Reactivity	To assess possible contact hazards from chemicals released from medical devices that may produce skin and mucosal irritation, eye irritation and delayed contact hypersensitivity.	The requirements of the test are met if the difference between the mean score for the sample extract and the mean score for the corresponding blank is 1.0 or less (negligible or slight)	Pass
Systemic Toxicity ISO 10993-11: ISO Acute Systemic Toxicity Test	To determine the potential for systemic toxicity.	The requirements of the test are met if none of the animals treated with the sample extract show a significantly greater biological reactivity than the control animals over the	Pass

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Test Name	Test Purpose	Acceptance Criteria	Results
		72 hour test period.	
Pyrogenicity ISO 10993-11: Material Mediated Rabbit Pyrogen	To determine whether an extract of the test article induced a pyrogenic response following injection in rabbits.	If no rabbit shows an individual rise in temperature of 0.5°C or more above its respective control temperature, the test article meets the requirements for the absence of pyrogens.	Pass
Hemocompatibility / Hemolysis ISO 10993-4: Hemolysis, Direct and Indirect (ASTM method)	To determine whether the presence of any leachable chemical from the test article or direct contact with the test article would cause *in vitro* red blood cell hemolysis.	The test article is considered non-hemolytic if the hemolytic index is less than 2%.	Pass
Complement Activation (C3a & SC5b-9)	To determine if the test article has the potential for activation of the complement system.	The test article must not demonstrate activation of the classical or alternate pathways of the complement system at all three timepoints, when compared to the negative control.	Pass

X. SUMMARY OF PRIMARY CLINICAL STUDY

A clinical study (MOBILITY) was conducted in the United States under IDE G080171 to establish a reasonable assurance of safety and effectiveness of iliac artery stenting using the Absolute Pro Vascular Self-Expanding Stent System for the treatment of subjects with atherosclerotic *de novo* and restenotic iliac artery disease. The data from the clinical study related to the Absolute Pro Stent System were the basis for the PMA approval decision. A summary of the clinical study related to the Absolute Pro Stent System is presented below. The data are from all enrolled subjects in the Absolute Pro System arm of the MOBILITY study. Additional data from a clinical study (BRAVISSIMO) conducted in Belgium and Italy was used to establish a reasonable assurance of safety and effectiveness of iliac artery stenting using the 6.0 mm Absolute Pro Vascular Self-Expanding Stent System for the treatment of subjects with atherosclerotic *de novo* and restenotic iliac artery disease (Section E – Additional Clinical Data).

A. Study Design

The MOBILITY study (IDE #G080171) is a prospective, non-randomized, two-arm, multicenter study. One of the two arms was designed to assess the

safety and effectiveness of the Absolute Pro Stent System in the treatment of atherosclerotic *de novo* or restenotic iliac artery disease. The other arm of the study has no relation to the evaluation of the Absolute Pro Stent System.

The objective of the Absolute Pro arm of the study was to demonstrate that the Absolute Pro Stent System is safe and effective for treatment of iliac artery disease by comparing the primary endpoint result to the prespecified Objective Performance Criterion (OPC) of 19.5% MAE rate at 9 months.

Subjects were treated between March 23, 2009 and May 17, 2010. There were a total of 33 clinical sites that enrolled subjects. The data monitoring committee last reviewed data on June 7, 2011 when 150 subjects had been treated and followed for 9 months.

1 Clinical and Angiographic Inclusion and Exclusion Criteria

Enrollment in the MOBILITY study was limited to subjects who met all the inclusion criteria. Subjects were not permitted to enroll in the MOBLITY study if they met any of the exclusion criteria.

Clinical Inclusion Criteria:

- Subject must be at least 18 and < 90 years of age.
- Subject has been informed of the nature of the study, agrees to its provisions, and has signed the informed consent form.
- Subject must agree to undergo all protocol-required follow-up examinations and requirements at the investigational site.
- History of symptomatic claudication (Rutherford Becker (RB) clinical category 2-3) or ischemic rest pain (RB clinical category 4).
- Female subject of childbearing potential must have had a negative pregnancy test (serum HCG) within 14 days before treatment, and must not be nursing at the time of treatment, and agree at time of consent to use birth control during participation in this study up to and including the follow-up at 9 months.

Angiographic Inclusion Criteria:

- Up to two bilateral *de novo* or restenotic (defined as non-stented or not previously treated with brachytherapy, laser, atherectomy, surgical bypass, or endarterectomy) lesions of the native common iliac artery and/or native external iliac artery may be treated (one per side)
- Common iliac artery lesion visually estimated to be ≥ 50% stenosis and ≤ 100% stenosis (total occlusion)
- External iliac artery lesion visually estimated to be ≥ 50% stenosis and ≤ 99% stenosis
- Lesion length for stenosis of the common or external iliac artery visually estimated to be ≥ 10 mm and ≤ 90 mm

- Lesion length for total occlusion of the common iliac artery visually estimated to be ≤ 40 mm
- Target vessel reference diameter visually estimated to be ≥ 3.6 mm and ≤ 9.1 mm
- On the treatment side(s), patent superficial femoral and popliteal arteries and at least one patent distal outflow artery with in-line distal vessel flow to the foot as confirmed by arteriography. Patent is defined as < 50% stenosis

Clinical Exclusion Criteria:

- Subject is unable to walk
- Subject has had recent major surgery (last 3 months) e.g., abdominal surgery, coronary artery bypass graft surgery, thoracic surgery
- Subject has received, or is on the waiting list for a major organ transplant (heart, lung, kidney, liver)
- Subject is diagnosed as RB clinical category 0, 1, 5, or 6.
- Subject has ulcers or lesions on the lower extremity(ies) of the target lesion side(s)
- Subject has elevated serum creatinine > 2.0 mg/dl
- Subject has uncontrolled diabetes mellitus (serum glucose > 400 mg/dl)
- Subject has had a MI within the previous 30 days
- Subject has had a stroke within the previous 30 days and/or has deficits from a prior stroke that limits the subject's ability to walk
- Subject has unstable angina defined as rest angina with ECG changes
- Subject has a groin infection, or an acute systemic infection that is currently under treatment
- Subject has acute thrombophlebitis or deep vein thrombosis in either extremity
- Subject requires any planned procedure within 30 days after the index procedure that would necessitate the discontinuation of aspirin, clopidogrel or ticlopidine following the procedure. If the subject is enrolled into the study and then subsequently requires a medical procedure within 30 days after the index procedure which would necessitate the discontinuation of these medications, then the subject is to resume protocol required medications as soon as possible after the medical procedure
- Subject has other medical illnesses (e.g., cancer or congestive heart failure) that may cause the subject to be non-compliant with protocol requirements, confound the data interpretation or is associated with limited life-expectancy (i.e., less than 2 years)
- Subject is currently participating in an investigational drug or device study that has not completed the primary endpoint follow-up or that clinically

interferes with the current study endpoints. (Note: Studies requiring extended follow-up for products that were investigational, but have since become commercially available, are not considered investigational studies.)

- Subject is unable to understand or unwilling to cooperate with study procedures or is unwilling or unable to return to the treatment center for follow-up visits
- Subject has known hypersensitivity or contraindication to nickel, titanium, or platinum; subject has known hypersensitivity or contraindication to standard intraprocedure anticoagulant(s); subject has sensitivity to contrast which cannot be adequately pre-treated with medication
- Subject has known allergy or contraindication to aspirin or clopidogrel (Plavix®); if allergy or contraindication is to clopidogrel, subject is unable to tolerate ticlopidine (Ticlid®)
- Subject has known bleeding disorder or hypercoagulable disorder, or will refuse blood transfusions
- Subject has suffered a gastrointestinal (GI) bleed within 30 days before the index procedure that would interfere with antiplatelet therapy
- Requirement of general anesthesia or spinal block for the procedure
- Presence of contralateral limb amputation that was performed to treat any non-traumatic disease in that limb, e.g. atherosclerotic, vascular, neuropathic
- Presence of bypass conduit in any outflow vessel, i.e. SFA, popliteal, anterior tibial, posterior tibial, peroneal, ipsilateral to the target lesion.
- Subject requires a concomitant percutaneous endovascular procedure in another vessel, e.g. coronary.
- Target lesion is in an iliac artery that has been previously stented

Angiographic Exclusion Criteria:

- Subject has a totally occluded (100% stenosis) external iliac artery ipsilateral to the target lesion
- Subject has a totally occluded (100% stenosis) SFA ipsilateral to the target lesion
- Target lesion is within or adjacent to an aneurysm
- Lesion is located within or beyond a vessel that contains a bypass graft
- Lesion(s) requires atherectomy (or ablative devices) to facilitate stent delivery
- Subject has a history of aortic revascularization or has an abdominal aortic aneurysm > 3 cm
- Lesion extends beyond the inguinal ligament

- Subject has angiographic evidence of thrombus in the target disease segment or vessel that is unresponsive to anti-thrombotic therapies
- Subject has multilevel disease in the target extremity that requires other staged procedures within 30 days before or after the procedure
- On the treatment side(s), subject is without patent superficial femoral and popliteal arteries and at least one patent distal outflow artery with in-line distal vessel flow to the foot as confirmed by arteriography. Patent is defined as < 50% stenosis.
- Requirement for >1 stent to treat full length of lesion.

2 Follow-up Schedule

All subjects were scheduled to return for follow-up examinations at 30 days and 9 months. Subsequent follow-up visits at the investigational sites will be at 2 years and 3 years. In addition, telephone contact rather than an office visit is scheduled at 18 months.

Table 6 provides a summary of the required clinical assessments for subjects at each scheduled follow-up.

Table 6: Schedule of Follow-up Visits

Contact Period	Follow-up
1 month (-7 days / +14 days)	Medication review, clinical assessment, hemodynamic assessment (Thigh brachial index (TBI) and ankle brachial index (ABI)) for the treated limb(s), Walking Impairment Questionnaire (WIQ), Quality Of Life (SF-12®) (QOL), RB clinical category, duplex ultrasound, adverse events
9 months (- 21 days, +56 days)	Medication review, clinical assessment, hemodynamic assessment (TBI/ABI) for the treated limb(s), WIQ, QOL, RB clinical category, duplex ultrasound, adverse events. If the duplex ultrasound is unreadable, an arteriogram is required.
18 months (± 28 days)	Telephone contact: Medication review and adverse events
2 years and 3 years (± 28 days)	Medication review, clinical assessment, hemodynamic assessment (TBI/ABI) for the treated limb(s), WIQ, QOL, RB clinical category, duplex ultrasound, adverse events

3 Clinical Endpoints

The primary endpoint was a composite major adverse event (MAE) rate at 9 months, defined as: death due to any causes, myocardial infarction, clinically-driven target lesion revascularization (worsening RB clinical category that is clearly referable to the target lesion, and target lesion diameter stenosis ≥ 50%), and limb loss (major amputation only) on the treated side(s).

The key secondary endpoints are listed below. Evaluation of the secondary endpoints did not involve any statistical hypotheses; the results were evaluated descriptively.

- Device success, defined as, on a per device basis, the achievement of successful delivery and deployment of the study device(s) at the intended location(s) and successful withdrawal of the delivery catheter(s);
- Technical success, defined as device success and attainment of a final residual stenosis of < 30% by quantitative arteriography (QA) or as reported by the investigator;
- Procedure success, defined as technical success without complications within two (2) days after the index procedure or at hospital discharge, whichever is sooner;
- TBI at post-procedure, 1 and 9 months and at 2 and 3 years for the treated limb(s);
- Walking capacity at 1 and 9 months and at 2 and 3 years as measured by the WIQ;
- RB clinical category at 1 and 9 months and at 2 and 3 years for the treated limb(s);
- Target lesion revascularization (TLR) at 1, 9 and 18 months and at 2 and 3 years;
- Clinically-driven TLR at 1, 9 and 18 months and at 2 and 3 years;
- Target vessel revascularization (TVR) at 1, 9 and 18 months and at 2 and 3 years for the treated limb(s);

B. Accountability of PMA Cohort

A total of 151 subjects were enrolled. Through the 9 month follow-up, 2 subjects withdrew from the study and 4 subjects expired. Therefore, there were 145 subjects eligible for the 9-month visit (**Table 7**).

Table 7: Subject Disposition (Intention-to-Treat Population)

	1 Month Visit (23-44 days)	**9 Month Visit (249-326 days)**
Eligible	151	149
Expired [prior to]	0	4
Withdrew [prior to]	2	0
Lost to follow-up	0	0
Completed follow-up within window	149	145

C. Study Population Demographics and Baseline Parameters

The mean age of the study population was 62.8 ± 9.3, with 64.9% (98/151) male gender. The prevalence of baseline risk factors included: diabetes mellitus 31.1% (47/151), dyslipidemia requiring medication 78.1% (118/151), hypertension requiring medication 76.8% (116/151), and current or former tobacco use 90.1% (136/151). Two (2) other key risk factors included a history of coronary artery disease 59.6% (90/151) and chronic obstructive pulmonary disease 28.8% (42/146). A significant number of subjects had bilateral lower extremity peripheral artery disease 71.5% (108/151) and multi-level lower extremity peripheral artery disease 98.7% (149/151) **(Table 8).**

Table 8: Baseline Demographics, Risk Factors and Medical History

Subject Characteristics	**N=151**
Age (in years) Mean ± SD (n) Median Range (min, max)	 62.8 ± 9.3 (151) 62.5 40.8, 89.2
Male Female	64.9% (98/151) 35.1% (53/151)
Diabetes Type I Type II	31.1% (47/151) 6.4% (3/47) 93.6% (44/47)
Tobacco Use Former Current	 35.8% (54/151) 54.3% (82/151)
Dyslipidemia Requiring Medication	78.1% (118/151)
Hypertension Requiring Medication	76.8% (116/151)
Coronary Artery Disease	59.6% (90/151)
Previous Myocardial Infarction	22.3% (33/148)
Congestive Heart Failure	12.1% (18/149)
Cerebrovascular Disease	19.6% (29/148)
Stroke	9.4% (14/149)
Chronic Obstructive Pulmonary Disease	28.8% (42/146)
Bilateral Lower Extremity Artery Disease	71.5% (108/151)
Multi-level Peripheral Lower Extremity Artery Disease	98.7% (149/151)
Lower Extremity Artery Disease (excluding iliac artery disease)	52.3% (79/151)
Previous Endovascular or Surgical Intervention to the Target	10.6% (16/151)

Limb	

Note: Denominators are based on available data.

Baseline target lesion characteristics (per angiographic core lab analysis) are detailed in **Table 9** and angiographic data in **Table 10**.

Table 9: Anatomic and Lesion Morphology

Characteristics	Lesions = 181
Anatomic	
Unilateral artery treatment	66.9%% (121/181)
Bilateral artery treatment	33.1% (60/181)
Target Artery	
Common iliac	76.0% (136/179)
Common & external iliac, or external iliac only	24.0% (43/179)
Preprocedure Morphology	
Eccentric	47.2% (85/180)
Ulceration	21.1% (38/180)
Calcification	
None/mild	3.3% (6/180)
Moderate	33.9% (61/180)
Severe	62.8% (113/180)
Thrombus	0.0% (0/180)
Postprocedure Morphology	
Dissection Grade	
0 (No dissection)	96.1% (172/179)
A	0.0% (0/179)
B	3.4% (6/179)
C	0.5% (1/179)
D	0.0% (0/179)
E	0.0% (0/179)
F	0.0% (0/179)

Note: Denominators are based on available data.

Table 10: Angiographic Quantitative Analysis

Lesions = 181			
	Mean ±SD (n)	Median	Min, Max
Preprocedure Reference Vessel Diameter (mm)	7.6 ± 1.8 (180)	7.4	4.0, 12.7
Preprocedure Lesion length (mm)	28.8 ± 18.9 (180)	23.1	4.3, 107.7
Preprocedure Lesion Percent Diameter Stenosis (%)	70.3 ± 15.3 (180)	67.0	23.0, 100.0
Preprocedure Minimum Lumen Diameter (mm)	2.3 ± 1.4 (180)	2.3	0.0, 8.9
Postprocedure Lesion Percent Diameter Stenosis (%)	12.7 ± 13.7 (178)	13.2	-42.8, 48.9
Postprocedure Minimum Lumen Diameter (mm)	6.5 ± 1.6 (178)	6.3	3.6, 12.2

D. Safety and Effectiveness Results

1. Primary Safety and Effectiveness Endpoints

The primary endpoint for the MOBILITY study was the MAE rate at 9 months, consisting of death due to any causes, myocardial infarction, clinically-driven target lesion revascularization (worsening RB clinical category that is clearly referable to the target lesion, and target lesion diameter stenosis ≥ 50%), and limb loss (major amputation only) on the treated side(s).

Mathematical representations of the primary endpoint hypotheses are provided below:

$$H_0: \gamma \geq 19.5\%$$
$$H_a: \gamma < 19.5\%$$

where:

γ = 9-month MAE rate.

The performance goal of 19.5% was derived from literature reports of iliac artery interventions. The primary endpoint was analyzed by calculating the one-sided 95% Clopper-Pearson confidence interval of the MAE rate at 9 months. Study arm success was to be concluded if the upper one-sided 95% confidence limit of the MAE rate at 9 months is less than 19.5%. Using an expected rate of MAE of 10.5% at 9 months for the Absolute Pro device, a one-sided type I error of 0.05, a statistical power of 90%, and an assumed 5%

loss to follow-up at 9 months, the required number of patients to be evaluable at 9 months was calculated to be 140 patients.

There were no MAE at 30 days post procedure in any subject. At the primary endpoint time point of 9 months, the MAE rate was 6.1% (9/147), consisting of 4 deaths, 2 instances of MI, 2 instances of clinically driven TLR, and 1 major amputation. The upper one-sided 95% confidence interval of the 9-month MAE rate was 10.4%, which is below the performance goal for the study and thus the criterion for study success was met. The details of the MAEs are listed in **Table 11.**

Table 11: Primary Study Endpoint Results: Major Adverse Events

Events	0 – 30 Days	0 – 270 Days
Total Major Adverse Event (MAE) Rate	0.0% (0/148)	6.1% (9/147)
Death	0.0% (0/148)	2.7% (4/147)
Myocardial infarction	0.0% (0/148)	1.4% (2/147)
Major amputation of the treated limb(s)	0.0% (0/148)	0.7% (1/147)
Clinically-driven TLR	0.0% (0/148)	1.4% (2/147)

Note: Denominators are based on available data.

At 24 days post-procedure, one subject's DUS revealed an asymptomatic total occlusion of a stent and this meets the study definition of stent thrombosis. This subject did not require revascularization within 270 days.

Summary of Adverse Events that Occurred in the MOBILITY Study

An independent Clinical Events Committee (CEC) adjudicated all cases of death, amputation, MI, TLR, target vessel revascularization (TVR), and stent thrombosis that occurred within 9 months of the index procedure, as well as all instances of TLR that occurred within 3 years. Clinical sites also reported all adverse events that occurred. Serious adverse events that occurred within the first 30 days and between 31 to 326 days post procedure are listed in **Tables 12** and **13**.

Table 12: Serious Adverse Events through 30 Days

Adverse Event	N = 151
Access Site Complication	
Bleeding	0.7% (1/151)
Blood Dyscrasia	
Anemia	0.7% (1/151)
Thrombocytopenia	0.7% (1/151)
Cancer	
Cancer	0.7% (1/151)
Cardiac	
Arrhythmias (other than bradycardia)	1.3% (2/151)
Gastrointestinal	
Other: Gastritis	0.7% (1/151)
Other: Pancreatitis	0.7% (1/151)
Infection	
Wound complication or wound infection	0.7% (1/151)
Neurologic other than stroke	
Confusion	0.7% (1/151)
Procedure-related	
Dissection	2.6% (4/151)
Hypertension	0.7% (1/151)
Pulmonary	
Other: Pleural Effusion	0.7% (1/151)
Respiratory	
Pneumonia	0.7% (1/151)
Vascular	
Other: Peripheral Vascular Disease	0.7% (1/151)
Stenosis	1.3% (2/151)
Thrombosis	0.7% (1/151)

Table 13: Serious Adverse Events between 31 Days and 326 Days (Event Rate >1%)

Adverse Event	N=151
Blood Dyscrasia	
Anemia	1.3% (2/151)
Cardiac	
Angina	3.3% (5/151)
Arrhythmias (other than bradycardia)	2.0% (3/151)
Other: Coronary Artery Disease	2.6% (4/151)
Gastrointestinal	
GI Bleed	2.0% (3/151)
Infection	
Wound complication or wound infection	2.0% (3/151)
Myocardial Infarction	
Myocardial Infarction	1.3% (2/151)
Pulmonary	
Chronic Obstructive Pulmonary Disease	1.3% (2/151)
Respiratory	
Pneumonia	2.6% (4/151)
Respiratory Failure	2.0% (3/151)
Stroke	
Other: CVA	1.3% (2/151)
Vascular	
Occlusion	2.0% (3/151)
Other: Peripheral Vascular Disease	4.0% (6/151)
Stenosis	5.3% (8/151)

2. Secondary Endpoints

The secondary endpoints for the Absolute Pro Vascular Self-Expanding Stent System are presented below.

Clinically-Driven TLR

Determination of clinically-driven TLR through 9 months was based on the following:

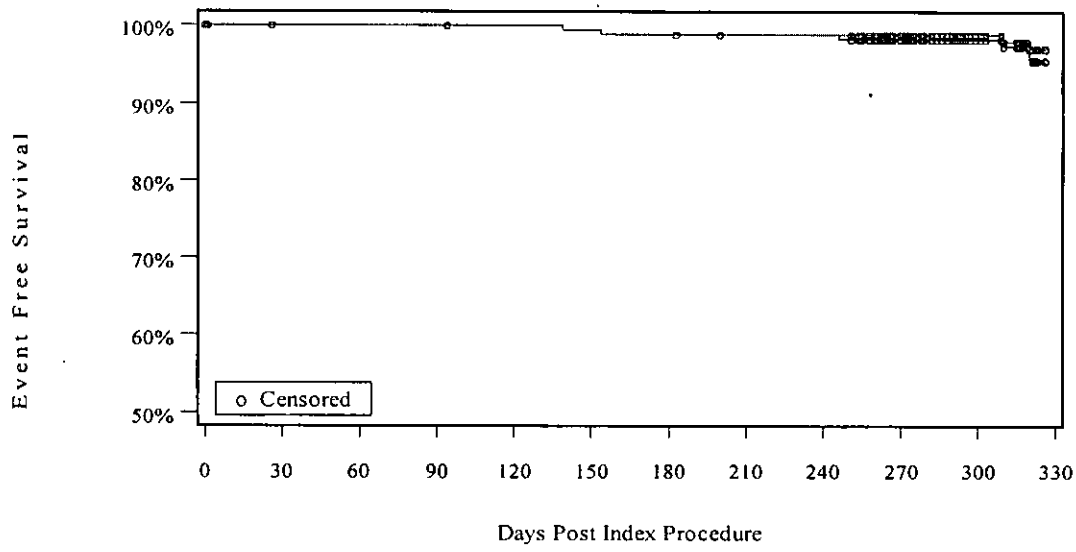
- a percent diameter stenosis (%DS) of ≥ 50% as reported by either angiographic or duplex ultrasound core laboratory; and
- evidence of new distal ischemic signs (worsening RB clinical category

that is clearly referable to the target lesion); and

- CEC adjudication.

Kaplan-Meier (KM) survival analysis of clinically-driven TLR, and all TLR, yields 97.1% freedom from clinically-driven TLR and 95.6% freedom from all TLR at 9 months **(Figure 3)**. The KM survival analysis is based on the time to the first event for each lesion.

Figure 3: Kaplan-Meier Survival Curve: Freedom from Target Lesion Revascularization and Freedom from Clinically-Driven Target Lesion Revascularization Through 9 Months



Black line: Target Lesion Revascularization (n=181)

Green line: Clinically Driven Target Lesion Revascularization (n=181)

Days Post Index Procedure	0	(0, 30]	(30, 180]	(180, 270]	(270, 326]
Target Lesion Revascularization					
Number at Risk	181	179	176	173	151
Number Censored	2	3	1	21	148
Number of Events	0	0	2	1	3
Event Free (%)	100%	100%	98.9%	98.3%	95.6%
Standard Error (%)	0.0%	0.0%	0.8%	1.0%	1.8%
Clinically Driven Target Lesion Revascularization					
Number at Risk	181	179	176	173	152
Number Censored	2	3	1	21	150
Number of Events	0	0	2	0	2
Event Free (%)	100%	100%	98.9%	98.9%	97.1%
Standard Error (%)	0.0%	0.0%	0.8%	0.8%	1.5%

Note: Number at risk gives the number at risk of an event at the start of the interval. Number censored and number of events are the incremental counts during the interval. The intervals are denoted as half-open bracket expression, where the start of interval '(' is exclusive and the end of the interval ']' is inclusive.

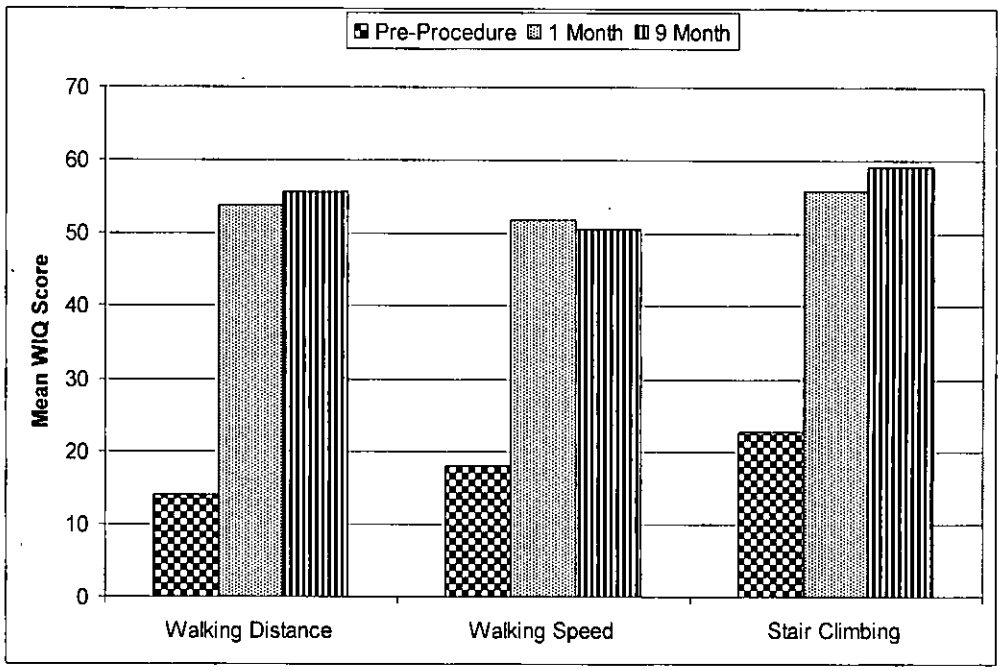
Rutherford Becker (RB) Clinical Category

At 9 months, 93.9% (139/148) of limbs had improved by ≥ 1 RB clinical category.

Walking Impairment Questionnaire

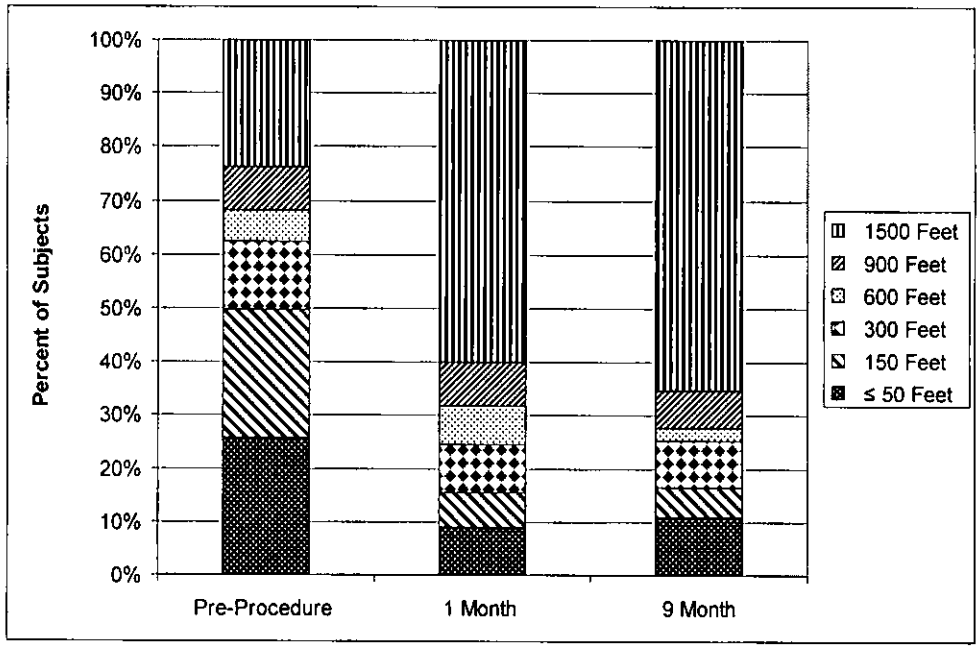
The WIQ was used to assess walking distance, walking speed and stair climbing for study subjects. The walking distance mean score increased from 14.0 ± 19.9% at baseline to 55.7 ± 39.6% at 9 months. The walking speed and stair climbing mean scores also increased from 17.9± 20.8% and 22.7 ± 23.9%, respectively, at baseline, to 50.6 ±33.9% and 59.2 ± 37.5%, respectively, at 9 months **(Figure 4)**.

Figure 4: WIQ Score Change



Prior to intervention, 25.8% (39/151) of the subjects could walk ≤ 50 feet, 49.7% (75/151) could walk ≤ 150 feet while 23.8% (36/151) could walk 1500 feet. There was an improvement in maximum walking distance; at 9 months, 65.4% (83/127) of subjects could walk 1500 feet, 11.0% (14/127) were limited to walking ≤ 50 feet, 16.5% (21/127) were limited to ≤ 150 feet **(Figure 5).**

Figure 5: Summary of Maximum Walking Distance



Additional Secondary Endpoints

Other secondary endpoints and effectiveness measures were also analyzed and their results are listed in **Table 14**.

Table 14: Secondary Endpoints and Other Effectiveness Measures

Effectiveness Measures	%[1]
Device based	
Device success	96.4% (186/193)
Lesion based	
Technical success	87.3% (158/181)
Restenosis rate[2] at 9 months[3]	8.4% (13/154)
TLR at 9 months (KM Estimate)	4.4%
Subject based	
Procedure success	85.4% (129/151)
Limb based	
Clinical success[4]	
30 days	91.3% (147/161)
9 months	93.9% (139/148)
Hemodynamic success[5]	
30 days	95.6% (151/158)

9 months	95.9% (141/147)

[1] Denominators are based on available data.
[2] Restenosis, defined as ≥ 50% stenosis by duplex ultrasound or arteriography
[3] 9-month follow-up is to 326 days
[4]Clinical success is defined as RB clinical category improvement by ≥ 1 category
[5]Hemodynamic success is defined as TBI or ABI improvement > 0.1 from baseline or deterioration ≤ 0.15 from the first post procedure measurement

When considered collectively, the data presented above support the effectiveness of the Absolute Pro Vascular Self-Expanding Stent System in the treatment of subjects with iliac artery disease.

3. Subgroup Analysis

Applicability to Pediatric Population

Peripheral artery disease is not typically found in pediatric populations excepting rare lipid disorders. Accordingly, the safety and effectiveness of the Absolute Pro stent in pediatric populations were not studied in the MOBILITY study.

Mobility Study Results by Gender/Sex

There were 53 female (35.1%) and 98 male (64.9%) subjects enrolled in the Absolute Pro arm of the MOBILITY study. The demographics and risk factors were similar between the two groups. The 9-month MAE rates for men and women were compared using a post-hoc statistical analysis. The rate was 13.7% (7/51) for female subjects versus 2.1% (2/96) for male subjects. This difference in MAE was a result of 2 deaths, 2 MIs, 1 major amputation, and 2 clinically-driven TLRs in the female subgroup as compared to 2 deaths in the male subgroup (**Table 15**). The Kaplan-Meier survival analysis yielded 86.1% freedom from MAE for female subjects compared to 97.9% for male subjects at 270 days (Log-Rank, $p = 0.0048$). Despite the difference in MAE rates at 9 months, study data also showed that the rates of most of the key secondary endpoints, including device success rates, primary stent patency rates at 9 months, clinical success rates at 9 months, hemodynamic success rates at 9 months, and restenosis rates at 9 months, were similar for female and male subjects (**Table 16**):

Table 15: Major Adverse Events by Genders

Events	Female	Male
[0, 30 days]		
Death	0.0% (0/51)	0.0% (0/96)
Myocardial infarction	0.0% (0/51)	0.0% (0/96)
Major amputation of the treated limb(s)	0.0% (0/51)	0.0% (0/96)
Clinically-driven TLR	0.0% (0/51)	0.0% (0/96)
[0, 270 days]		
Death	3.9% (2/51)	2.1% (2/96)
Device-related[1]	0.0% (0/51)	0.0% (0/96)
Myocardial infarction	3.9% (2/51)	0.0% (0/96)
Device-related[1]	0.0% (0/51)	0.0% (0/96)
Major amputation of the treated limb(s)	2.0% (1/51)	0.0% (0/96)
Clinically-driven TLR	3.9% (2/51)	0.0% (0/96)
Total	13.7% (7/51)	2.1% (2/96)

[1]As reported by site

Table 16: Secondary Endpoints and Other Effectiveness Measures by Genders

Effectiveness Measures	Female %[1]	Male %[1]
Device based		
Device success	98.6% (71/72)	95.0% (115/121)
Lesion based		
Technical success	91.3% (63/69)	84.8% (95/112)
Primary patency rate [2]at 9 months[3]	90.7% (49/54)	91.0% (91/100)
Restenosis rate[4] at 9 months[6]	9.3% (5/54)	8.0% (8/100)
Subject based		
Procedure success	88.7% (47/53)	83.7% (82/98)
Limb based		
Clinical Success[5]		

30 days	93.4% (57/61)	90.0% (90/100)
9 months	98.0%(50/51)	91.8% (89/97)
Hemodynamic success[6]		
30 days	96.6% (57/59)	94.9% (94/99)
9 months	94.1% (48/51)	96.9% (93/96)

[1] Denominators are based on available data.
[2] Primary patency was defined as < 50% stenosis and without interval reintervention
[3] 9-month follow-up is to 326 days
[4] Restenosis, defined as ≥ 50% stenosis by duplex ultrasound or arteriography
[5] Clinical success is defined as RB clinical category improvement by ≥ 1 category
[6] Hemodynamic success is defined as TBI or ABI improvement > 0.1 from baseline or deterioration ≤ 0.15 from the first post procedure measurement

While the primary endpoint event rate differed for male and female subjects, the clinical implications of these differences are not clear, particularly for the myocardial infarctions that occurred after 30 days post-procedure; these events are unlikely to be device- or procedure-related. Despite this difference, critical secondary outcomes were similar for the two genders. Given these findings, the information provided in the PMA was found adequate to support approval of the device for treatment of iliac artery disease in both men and women.

E. Additional Clinical Data

The **B**elgian-Italian-Dutch t**R**ial investigating **A**bbott **V**ascular **I**liac **S**tent**S** **I**n the treat**M**ent of TASC A, B, C & D iliac lesi**O**ns **(BRAVISSIMO)** is an Investigator Sponsored, multicenter clinical trial evaluating the long-term (up to 24 months) outcome of the self-expanding nitinol Absolute Pro (Abbott Vascular) stent in TASC A & B and TASC C & D iliac lesions.

The total sample size of the BRAVISSIMO study was 325 patients. Patients were enrolled at 23 centers in Belgium and Italy between July 2009 and September 2010. There were a total of 7 patients that received Absolute Pro 6.0 mm stents.

Study Endpoints: The primary endpoint of the study was primary patency at 12 months, defined as a target lesion without a hemodynamically significant stenosis on duplex ultrasound (>50%, systolic velocity ratio no greater than 2.0) and without Target Lesion Revascularization (TLR) within 12 months.

Conclusion:

The data from the 7 patients from BRAVISSIMO who were treated with 6.0 mm Absolute Pro stents support the safety and effectiveness of the Absolute Pro in treatment of iliac artery lesions. Lesions in BRAVISSIMO were more complex than what was seen in the MOBILITY trial. All lesions were treated successfully, with no lesions losing primary patency within the 9-month window (249 to 326 days) and all 6 patients for

whom data was available at 6 months experienced clinical success (improvement of RB classification of 1 class or more compared to pre-procedure).

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 PRECLINCAL AND CLINICAL STUDIES

A. Safety and Effectivess Conclusions

Comprehensive preclinical bench and *in vivo* animal testing was performed on the Absolute Pro Stent System (both the stent and the delivery system) in accordance with national and international standards and guidance documents. The testing demonstrated that the Absolute Pro Stent System met its performance and design specifications.

Biocompatibility Testing was performed on the Absolute Pro Stent System in accordance with applicable standards. All testing met the requirements as specified in the applicable standard, ensuring the finished device is biocompatible.

Sterilization, packaging, and shelf life testing were performed on the Absolute Pro Stent System. The testing demonstrated that the Absolute Pro Stent System maintains a Sterility Assurance Level of 10^{-6}. The results of shelf-life testing confirmed that the Absolute Pro Stent System maintains functionality throughout its 1 year shelf life, and the packaging testing demonstrated that the packaging adequately protects the device throughout its 1 year shelf life.

A multi-center clinical trial has demonstrated that the Absolute Pro Stent System is safe and effective for its intended use as a treatment option for iliac artery disease in the indicated population. The primary response variable of the study was based on the rate of major adverse events (MAE) at 9 months follow-up. Specifically, the MAE rate of 6.1%, with the upper one-sided 95% confidence interval of 10.4%, exceeded the performance goal of 19.5%. Use of the Absolute Pro Stent System was associated with a low MAE rate.

B. Overall Conclusions

The results from non-clinical and clinical evaluations provide valid scientific evidence and reasonable assurance that the device is safe and effective; therefore,

it is reasonable to conclude that the benefits of use of the device for the target population outweigh the risk of illness or injury when used as indicated in accordance with the labeling and Instructions for Use (IFU).

XIII. CDRH DECISION

CDRH issued an approval order on February 22, 2012.

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.