SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Iliac stent

Device Trade Name: Omnilink Elite® Vascular Balloon-Expandable Stent System

Device Procode: NIO

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

Dates of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P110043

Date of FDA Notice of Approval: July 31, 2012

Expedited: Not applicable

II. INDICATIONS FOR USE

The Omnilink Elite Vascular Balloon-Expandable Stent System is indicated for the treatment of atherosclerotic lesions in the native common iliac artery and native external iliac artery with reference vessel diameters of ≥ 5.0 mm and ≤ 11.0 mm and lesion lengths up to 50 mm.

III. CONTRAINDICATIONS

There are no known contraindications.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Omnilink Elite Vascular Balloon-Expandable Stent System labeling.

V. DEVICE DESCRIPTION

The Omnilink Elite Vascular Balloon-Expandable Stent System (Omnilink Elite Stent System) consists of a balloon delivery system catheter and a premounted balloon-expandable stent.

The Omnilink Elite stent (**Figure 1**) is made from a cobalt-chromium alloy (L605). The stent delivery system has two radiopaque markers at the proximal and distal end of the

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balloon to aid in the placement of the stent. The stent is delivered to the intended lesion site, expanded by inflation, and remains as a permanent vessel scaffolding implant. An inflatable balloon on the stent delivery system (**Figure 2**) allows for deployment of the stent. Upon deployment, the stent imparts an outward radial force on the arterial lumen to establish patency.

Figure 1: Omnilink Elite Balloon-Expandable Stent

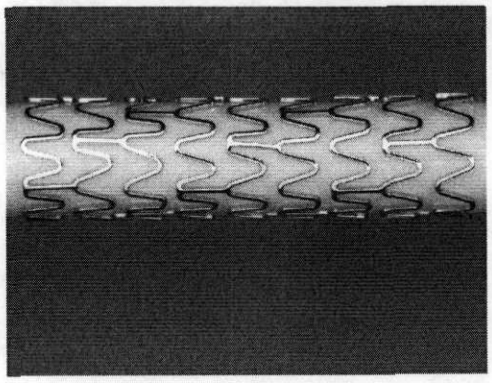
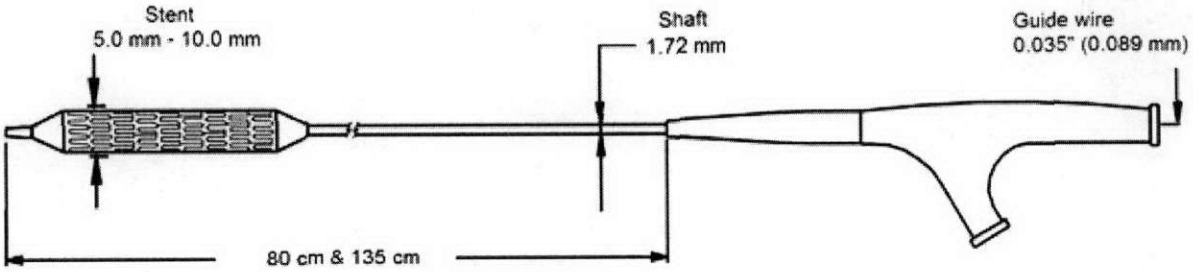


Figure 2: Omnilink Elite Balloon-Expandable Stent Delivery System



The Omnilink Elite Stent System is available in diameters of 6.0-10.0 mm in 1.0 mm increments. The stent comes in lengths of 12, 16, 19, 29, 39, and 59 mm. 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. Product size information is provided in **Table 1**.

Table 1: Omnilink Elite Balloon-Expandable Stent System Product Information

Stent Diameter (mm)	Catheter Lengths (80 cm and 135 cm)					
	Stent Length (mm)					
	12	16	19	29	39	59
6.0	X	X	X	X	X	X
7.0	X	X	X	X	X	X
8.0	Not Offered		X	X	X	X
9.0			X	X	X	X
10.0			X	X	X	X

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of iliac artery disease:

- Percutaneous transluminal angioplasty (PTA)
- Stenting with another stent for which there is an approved indication
- Bypass surgery
- Lifestyle modification (exercise and cessation of tobacco use)
- Medical therapy (antiplatelets, lipid control, and medicine to manage claudication symptoms)

Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The Omnilink Elite Stent System, labeled as the Omnilink Elite 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 since May 2009. The Omnilink Elite Stent System 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) 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 studies, please see Section X below.

IX. SUMMARY OF PRECLINICAL STUDIES

A series of non-clinical laboratory studies related to the Omnilink Elite 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 Omnilink Elite Vascular Balloon-Expandable 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 Omnilink Elite Vascular Balloon-Expandable 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 specify and describe material composition of the device components and to provide documentation to certify that incoming raw materials conform to specifications.	The material composition of all materials and device components of the stent and catheter must be specified and pass incoming inspections. The stent material composition must conform to the requirements of ASTM F90.	Pass
Pitting and Crevice Corrosion: Overlapped Stents after Radial Fatigue	To document the potential for pitting and crevice corrosion of the stent.	Cyclic potentiodynamic polarization testing was performed on overlapped stents after radial fatigue testing to determine the breakdown potential. The breakdown potential (Eb) must not have a value lower than 260 mV with respect to saturated calomel electrode.	Pass
Fretting Corrosion: Overlapped Stents after Radial Fatigue	To document the potential for fretting corrosion for overlapped stents.	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.	N/A
Galvanic Corrosion	To document the potential for galvanic corrosion in overlapped stents of dissimilar materials.	Cyclic potentiodynamic polarization testing was performed on Omnilink Elite stents that had been overlapped with stainless steel stents. This study was conducted for informational purposes only, therefore there were no acceptance criteria. Overlapping stents did not result in increased corrosion.	N/A
Expanded Stent Outer Diameter	To determine the stent outer diameter (OD) at nominal pressure.	Stent OD must be within ± 10% of labeled OD at nominal pressure.	Pass

Test	Test Purpose	Acceptance Criteria	Results
Percent Surface Area	To calculate the stent percent surface area.	For informational purposes only.	N/A
Foreshortening	To determine the stent length change after deployment.	Stents must experience ± 10% foreshortening or change in length of < 2 mm.	Pass
Recoil	To determine the percent recoil of the stent after balloon expansion.	The reduction in stent diameter after balloon expansion must be < 12%.	Pass
Stent Integrity	To provide assurance that the stent has no clinically significant defects or flaws after deployment.	This study was conducted for informational purposes only, therefore there were no acceptance criteria. No stent integrity issues were observed.	N/A
Radial Stiffness	To determine the change in stent diameter as a function of uniformly applied external radial pressure.	Minimum of 0.29N/mm at 1mm circumferential compression.	Pass
Radial Strength	To determine the pressure at which the stent experiences irrecoverable deformation.	Radial strength (collapse pressure) of all single stents must be ≥ 366 mbar under applied radial pressure.	Pass
Mechanical Properties	To characterize the stent material for the purpose of developing parameters for a finite element analysis of the stent.	Ultimate tensile strength, Yield strength, Elongation, True strain at max. load and True stress at max. load were determined.	Pass
Stress/Strain and Fatigue Analysis (FEA)	To determine the state of stress and strain due to loading imposed by crimping, expansion to maximum rated post dilatation and subsequent radial diastolic and systolic arterial pressure loading on the stent.	Static Loading: Maximum equivalent plastic strain does not exceed the failure strain of 0.6 in/in for the Omnilink Elite stent during the simulated loading process. Fatigue Loading (Goodman Stress-life Analysis): Omnilink Elite stent will survive ten years of radial fatigue life, based on a calculated safety factor > 1.	Pass
Accelerated Durability Testing:	To evaluate the long term fatigue resistance (10 year real time	Stents were subjected to 400 million cycles of radial fatigue and then examined for fractures. No stent	Pass

Test	Test Purpose	Acceptance Criteria	Results
Radial Fatigue	equivalent) of the Omnilink Elite stent in a physiologically simulated environment with accelerated dynamic radial loading.	must have higher than a Type II (multiple strut) fracture and there can be no detachment of any part of the stent. Any stent that suffers a Type I (single strut) or Type II strut fracture must still meet the radial force specification.	
Magnetic Resonance Imaging	To evaluate the response of the Omnilink Elite stent to MR scanning conditions.	This test was executed for informational purposes only, therefore, there were no acceptance criteria. RF-induced heating, image distortion, magnetic force and torque for single and overlapped stents in lengths up to 100 mm were measured under MR field strengths of 1.5 and 3.0 Tesla. Test results must show that the stents are rated MR Conditional per ASTM 2503.	N/A
Radiopacity	To assess the radiopacity of the Omnilink Elite stent in a simulated clinical setting.	The stent shall minimally show an equivalent radiopacity compared to commercially available CoCr and stainless steel stents with similar dimensions.	Pass
Kink Resistance	To evaluate the kink resistance of the Omnilink Elite stent when bent in a radius of curvature that is clinically relevant to the intended implant site.	The average diameter of all Omnilink 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 Dimensional Verification	To measure various dimensional characteristics of the Omnilink Elite Delivery Catheter.	The length of the delivery catheters must meet the labeled dimensions ± 2 cm. The outer diameter of the catheter shaft must be 1.72 ± 0.04 mm.	Pass
Crossing Profile	To determine the maximum diameter found between the proximal end of the mounted stent and the distal tip of the delivery system.	Varied depending on stent size.	Pass

Test	Test Purpose	Acceptance Criteria	Results
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.	Omnilink Elite 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" guide wires and the catheter shaft coating must allow for delivery and retraction of the devices.	Pass
Balloon Rated Burst Pressure	To determine the pressure at which 99.9% of balloons can survive with 95% confidence.	The rate burst pressure is ≥ 14 atm for diameters 6 - 10 mm.	Pass
Balloon Fatigue	To demonstrate that the balloons will withstand a minimum of 10 repeated inflations at the rated burst pressure.	The stent must be successfully inflated to RBP for a total of 10 cycles.	Pass
Balloon Compliance	To determine the stent outer diameter at various pressures.	This test was conducted for characterization purposes, to establish the compliance chart provided in the instructions for use.	N/A
Balloon Inflation Time	To determine the balloon inflation time.	All tested sizes must meet the balloon inflation time acceptance criteria for the appropriate stent diameter. Not all stent sizes were tested; only the largest diameter and longest length balloons were tested because they require the largest contrast volume for inflation and deflation. ≤ 4.0 sec for the 7.0mm x 59mm stent ≤ 5.0 sec for the 10.0mm x 59mm stent	Pass

Test	Test Purpose	Acceptance Criteria	Results
Balloon Deflation Time	To determine the balloon deflation time.	All sizes must meet the balloon deflation time acceptance criteria for the appropriate stent diameter. Not all stent sizes were tested; only the largest diameter and longest length balloons were tested because they require the largest contrast volume for inflation and deflation. ≤ 20 sec for the 7.0mm x 59mm stent ≤ 25 sec for the 10.0mm x 59mm stent	Pass
Catheter Bond Strength and Tip Pull Test	To determine the bond strength at all locations on the Omnilink Elite Delivery Catheter where a joint is present.	Each bond was pulled on a tensile tester until failure. Tip bond strength must be ≥ 2.22N (=0.5 lbf). The manifold bond strength and proximal balloon bond strength must be ≥ 18 N.	Pass
Flexibility and Kink Test	To evaluate the ability of the Omnilink Elite Delivery Catheter to withstand flexural forces typical of clinical use.	Omnilink Elite 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 ≤ 13.0 mm.	Pass
Torque Strength	To determine the ability of the Omnilink Elite 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 more than 3 rotations before failure.	Pass
Coating Integrity	To verify that the following performance attributes are met satisfactorily: stent delivery, stent deployment and delivery system pullback post deployment out of the deployment stent.	The functionality of the coating on the stent delivery system was rated after both tracking and retracting the stent system through simulated peripheral vasculature	Pass

Test	Test Purpose	Acceptance Criteria	Results
Stent Securement for Unsheathed Stents	To determine the force needed to remove the stent from the delivery system.	The force needed to remove the stent from the delivery system must be ≥ 2.0 N	Pass

B. Sterilization

The Omnilink Elite 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 Omnilink Elite Stent System will meet a Sterility Assurance Level (SAL) of 10^{-6} when sterilized at a minimum dose of 25 kGy.

C. Packaging and Product Shelf Life

Packaging Validation testing conducted in compliance with ISO 11607-1/-2 demonstrated that the packaging system for the Omnilink Elite Vascular Balloon-Expandable 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 Omnilink Elite Stent System will maintain functional characteristics for the labeled shelf life of 3.5 years.

D. *In Vivo* Animal Studies

In vivo animal testing was conducted to demonstrate the safety of the Omnilink Elite Vascular Balloon-Expandable Stent System. A total of four studies were carried out in a nonatherosclerotic 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 Omnilink Vascular Balloon-Expandable Elite 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
Acute Performance/ Design Validation	2 Swine Iliac, Renal, Brachial and Carotid Arteries 8 stents plus controls	The study evaluated the acute functional performance of the Omnilink Elite Stent System in healthy porcine arteries. Device performance requirements specified in the protocol were met and all test devices were rated as clinically acceptable. PASS
28 day Safety Study	9 Swine Iliac and Carotid Arteries 24 stents	The study assessed the safety of single and overlapped Omnilink Elite stents at 28-days. The study demonstrated overall tolerability of the Omnilink Elite stent. PASS
28 day Safety Repeat Study	9 Swine Iliac and Carotid Arteries 24 stents	The study assessed the safety of single and overlapped Omnilink Elite stents at 28-days. The study demonstrated overall tolerability of the Omnilink Elite stent. PASS
180 day Safety Study	10 Swine Iliac and Carotid Arteries 25 stents	The study assessed the safety of single and overlapped Omnilink Elite stents at 180-days. The study demonstrated overall tolerability of the Omnilink Elite stent. PASS

E. Biocompatibility

Biocompatibility testing according to ISO 10993-1 was conducted on the Omnilink Elite 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 Omnilink Elite Vascular Balloon-Expandable 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

Test Name	Test Purpose	Acceptance Criteria	Results
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 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

Test Name	Test Purpose	Acceptance Criteria	Results
Hemocompatibility / Hemolysis ISO 10993-4: Hemolysis, Indirect	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

Table 5: Biocompatibility Test Summary for the Omnilink Elite 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

Test Name	Test Purpose	Acceptance Criteria	Results
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 72 hour test period.	Pass
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, Indirect	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

The applicant performed a clinical study in the United States IDE G080171 to establish a reasonable assurance of safety and effectiveness of iliac artery stenting using the Omnilink Elite Vascular Balloon-Expandable 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 Omnilink Elite Stent System were the basis for a PMA approval decision. A summary of the clinical study related to the Omnilink Elite Stent System is presented below. The data are from all enrolled subjects in the Omnilink Elite arm of the MOBILITY study.

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 Omnilink Elite 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 Omnilink Elite Stent System.

The objective of the Omnilink Elite arm of the study was to demonstrate that the Omnilink Elite Stent System is safe and effective for treatment of iliac artery disease by comparing the primary endpoint result to pre-specified Performance Goal (PG) of 19.5% major adverse event MAE rate at 9 months.

Subjects were treated between November 9, 2009 and December 17, 2010. There were a total of 44 clinical sites that enrolled subjects. The data monitoring committee last reviewed data on October 13, 2011 when 153 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 to be enrolled 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 ≤ 50 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 ≥ 5.0 mm and ≤ 11.0 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 cobalt chromium; 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 153 subjects were enrolled. One (1) subject withdrew from the study prior to the 30-day follow-up and 1 subject withdrew prior to the 9- month follow-up. One (1) subject expired prior to the 9-month follow-up, and 2 subjects who did not have a 9-month visit expired between 271 and 326 days post-procedure.

Therefore, there were 149 subjects eligible (excludes subjects who expired or withdrew prior to the visit window, or were determined lost-to-follow-up) 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	153	152
Expired [prior to]	0	1
Withdrew [prior to]	1	1
Lost to follow-up	0	1
Eligible for follow-up	152	149
Missed visit	3	4
Completed follow-up within window	149	145

C. Study Population Demographics and Baseline Parameters

The mean age of the study population was 63.9 ± 9.0, with 57.5% (88/153) male gender. Baseline risk factors included: diabetes mellitus 30.7% (47/153), dyslipidemia requiring medication 79.1% (121/153), hypertension requiring medication 83.0% (127/153), and current or former tobacco use 91.5% (140/153). Two (2) other key risk factors included a history of coronary artery disease 58.9% (89/151) and chronic obstructive pulmonary disease 29.4% (45/153). A significant number of subjects had bilateral lower extremity peripheral artery disease 81.0% (124/153) and all had multi-level lower extremity peripheral artery disease (**Table 8**).

Table 8: Baseline Demographics, Risk Factors and Medical History

Subject Characteristics	N=153
Age (in years) Mean ± SD (n) Median (Q1, Q3) Range (min, max)	 63.9 ± 9.0 (153) 63.8 (57.5, 70.8) (44.6, 86.0)
Male Female	57.5% (88/153) 42.5% (65/153)
Diabetes Type I Type II	30.7% (47/153) 4.3% (2/47) 95.7% (45/47)
Tobacco Use Former Current	91.5% (140/153) 43.8% (67/153) 47.7% (73/153)
Dyslipidemia Requiring Medication	79.1% (121/153)
Hypertension Requiring Medication	83.0% (127/153)
Coronary Artery Disease	58.9% (89/151)
Previous Myocardial Infarction	20.7% (31/150)
Congestive Heart Failure	7.9% (12/152)
Cerebrovascular Disease	24.0% (36/150)
Stroke	6.0% (9/151)
Chronic Obstructive Pulmonary Disease	29.4% (45/153)
Bilateral Lower Extremity Artery Disease	81.0% (124/153)
Multi-level Peripheral Lower Extremity Artery Disease	100% (153/153)
Lower Extremity Artery Disease (excluding iliac artery disease)	62.1% (95/153)
Previous Endovascular or Surgical Intervention to the Target Limb	12.4% (19/153)

Note: Denominators are based on available data.

Fifty subjects had bilateral iliac artery treatment (100 lesions) and 103 subjects had unilateral iliac artery treatment, resulting in a total of 153 subjects with 203 target lesions.

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

Table 9: Baseline Anatomic and Lesion Morphology

Characteristics	Lesions = 203
Anatomic	
Unilateral artery treatment	50.7% (103/203)
Bilateral artery treatment	49.3% (100/203)
Target Artery	
Common iliac	84.2% (170/202)
Common & external iliac, or external iliac only	15.8% (32/202)
Preprocedure Morphology	
Eccentric	62.4% (126/202)
Ulceration	17.8% (36/202)
Calcification	
None/mild	9.9% (20/202)
Moderate	27.2% (55/202)
Severe	62.9% (127/202)
Thrombus	0.5% (1/202)
Postprocedure Morphology	
Dissection Grade	
0 (No dissection)	
A	0.0% (0/201)
B	2.0% (4/201)
C	0.0% (0/201)
D	0.0% (0/201)
E	0.0% (0/201)
F	0.0% (0/201)

Table 10: Angiographic Quantitative Analysis

Lesions = 203			
	Mean ±SD (n)	Median	Min, Max
Preprocedure Reference Vessel Diameter (mm)	8.1 ± 1.7 (202)	7.8	4.5, 12.7
Preprocedure Lesion length (mm)	21.8 ± 12.2 (202)	19.2	5.5, 82.6
Preprocedure Lesion Percent Diameter Stenosis (%)	68.3 ± 15.4 (202)	66.8	16.2, 100.0
Preprocedure Minimum Lumen Diameter (mm)	2.6 ± 1.4 (202)	2.6	0.0, 8.1
Postprocedure Lesion Percent Diameter Stenosis (%)	10.6 ± 11.7 (202)	10.3	-27.3, 50.5
Postprocedure Minimum Lumen Diameter (mm)	7.1 ± 1.4 (202)	6.9	4.2, 11.2

Note: Only 202 procedural angiographic images were available for analysis.

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 Omnilink Elite 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 was 1 MAE at 30 days post procedure. At the primary endpoint time point of 9 months, the MAE rate was 5.4% (8/149), consisting of 1 death, 1 instances of MI, 6 instances of clinically driven TLR, and no major amputations. The upper one-sided 95% confidence interval of the 9-month MAE rate was 9.5%, which is below the performance goal for the study and thus the criterion for study success was met. The details of these 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	0.7% (1/151)	5.4% (8/149)
Death	0.0% (0/151)	0.7% (1/149)
Myocardial infarction	0.0% (0/151)	0.7% (1/149)
Major amputation of the treated limb(s)	0.0% (0/151)	0.0% (0/149)
Clinically-driven TLR	0.7% (1/151)	4.0% (6/149)

Note: Denominators are based on available data.

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 = 153
Blood Dyscrasia	
Anemia	0.7% (1/153)
Gastrointestinal	
GI Bleed	0.7% (1/153)
Nausea	0.7% (1/153)
Infection	
Other: Cellulitis	0.7% (1/153)
Pneumonia	1.3% (2/153)
Metabolic	
Other: Hyponatremia	0.7% (1/153)
Miscellaneous	
Edema (non pulmonary)	0.7% (1/153)
Neurologic other than stroke	
Mental Status Change	0.7% (1/153)
Transient Ischemic Attack	0.7% (1/153)
Procedure-related	
Dissection	1.3% (2/153)
Distal Emboli	0.7% (1/153)
Renal	
Renal Failure	0.7% (1/153)
Respiratory	
Other: COPD Exacerbation	0.7% (1/153)
Stroke	
Other: Cerebral Vascular Accident	0.7% (1/153)
Vascular	
Occlusion	0.7% (1/153)
Other: Deep Vein Thrombosis	0.7% (1/153)

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

Adverse Event	N=153
Blood Dyscrasia	
Anemia	2.0% (3/153)
Cancer	
Cancer	3.3% (5/153)
Cardiac	
Congestive Heart Failure	1.3% (2/153)
Other: Coronary Artery Disease	3.9% (6/153)
Cardiac/Hemodynamic	
Bradycardia	1.3% (2/153)
Gastrointestinal	
GI Bleed	1.3% (2/153)
Other: Cholecystitis	1.3% (2/153)
Infection	
Pneumonia	2.0% (3/153)
Miscellaneous	
Musculoskeletal	3.9% (6/153)
Neurologic other than stroke	
Transient Ischemic Attack	1.3% (2/153)
Respiratory	
Respiratory Failure	1.3% (2/153)
Vascular[1]	
Restenosis	3.9% (6/153)
Stenosis	6.5% (10/153)
Surgery/Interventional Procedure	1.3% (2/153)

[1]Includes any lesion within the vasculature

2 Secondary Endpoints

The secondary endpoints for the Omnilink Elite Vascular Balloon-Expandable Stent System are presented below.

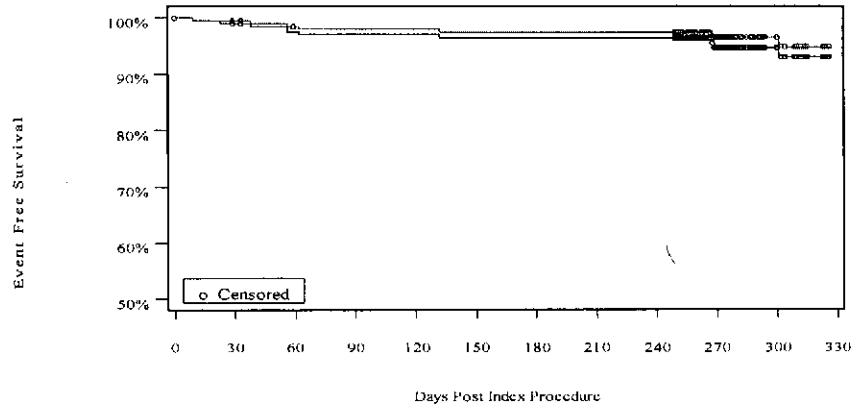
Clinically-Driven TLR

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 96.6% freedom from clinically-driven TLR and 94.8% freedom from all TLR at 270 days. There was 1 revascularization that occurred between 270 and 326 days resulting in 94.9% freedom from clinically-driven TLR and 93.1% freedom from TLR at 326 days **(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=203)

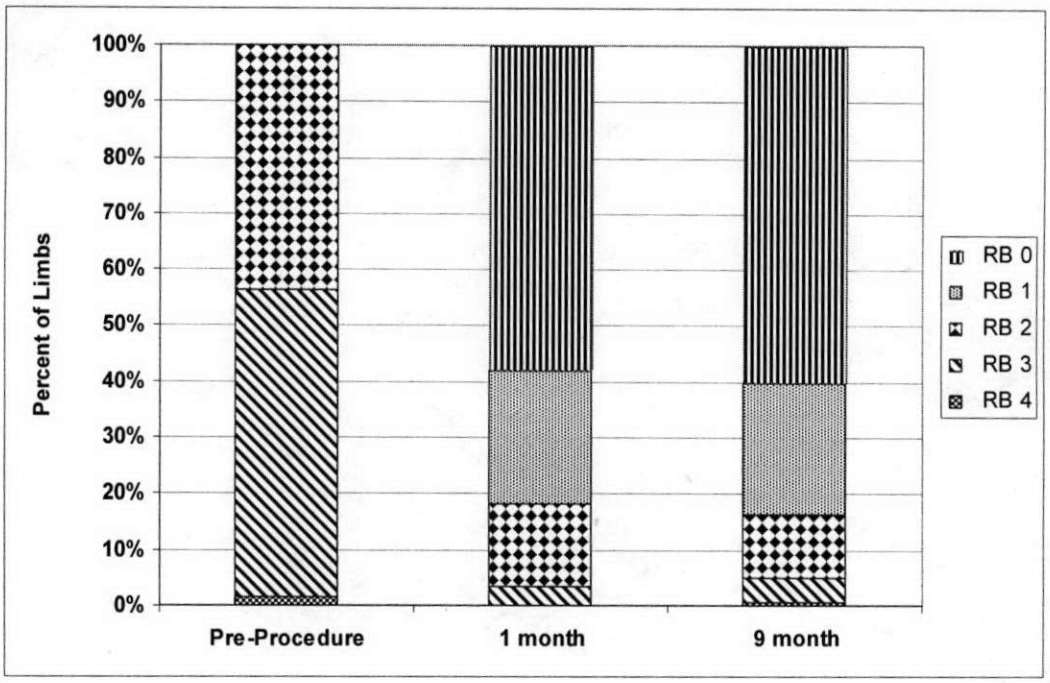
Green line: Clinically Driven Target Lesion Revascularization (n=203)

Days Post Index Procedure	0	(0, 30]	(30, 180]	(180, 270]	(270, 326]
Target Lesion Revascularization					
Number at Risk	203	201	198	191	104
Number Censored	2	1	2	85	103
Number of Events	0	2	5	2	1
Event Free (%)	100%	99.0%	96.5%	94.8%	93.1%
Standard Error (%)	0.0%	0.7%	1.3%	1.8%	2.4%
Clinically Driven Target Lesion Revascularization					
Number at Risk	203	201	199	192	105
Number Censored	2	1	3	86	104
Number of Events	0	1	4	1	1
Event Free (%)	100%	99.5%	97.5%	96.6%	94.9%
Standard Error (%)	0.0%	0.5%	1.1%	1.4%	2.2%

Rutherford Becker (RB) clinical category

At 9 months, 34.6% (63/182) of limbs had improved by ≥ 3 RB clinical categories, 41.2% (75/182) of limbs had improved by 2 RB categories, and 13.2% (24/182) had improved by 1 RB clinical category (**Figure 4**). There were 7.1% (13/182) limbs in which the RB clinical category was unchanged and 3.8% (7/182) with worsened RB category. Six (6) limbs had worsened from RB 2 to RB 3 and 1 limb worsened from RB 3 to RB 4 at 9 months.

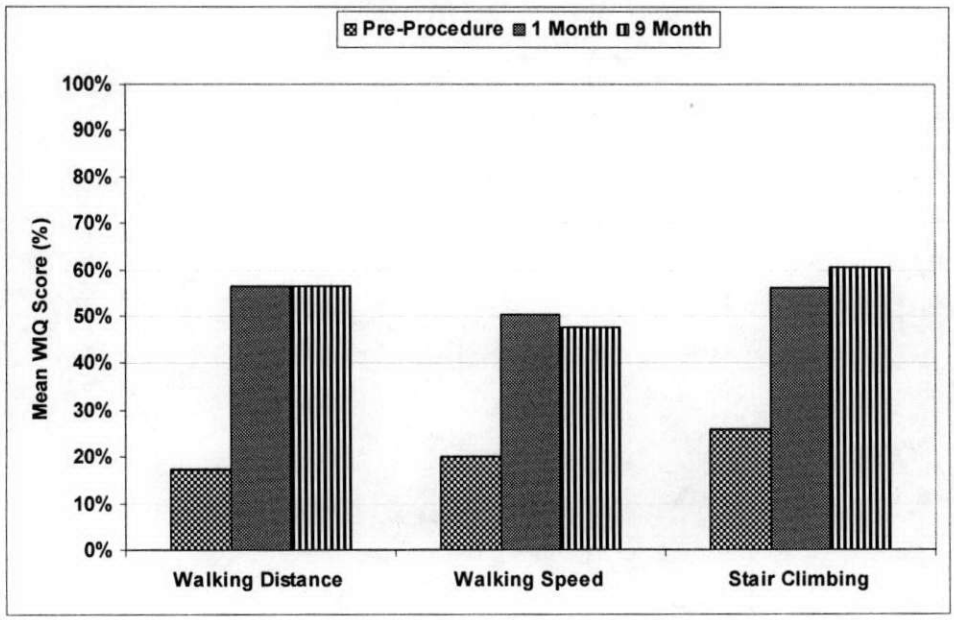
Figure 4: Rutherford-Becker Clinical Category by Follow-up Visit



Walking Impairment Questionnaire

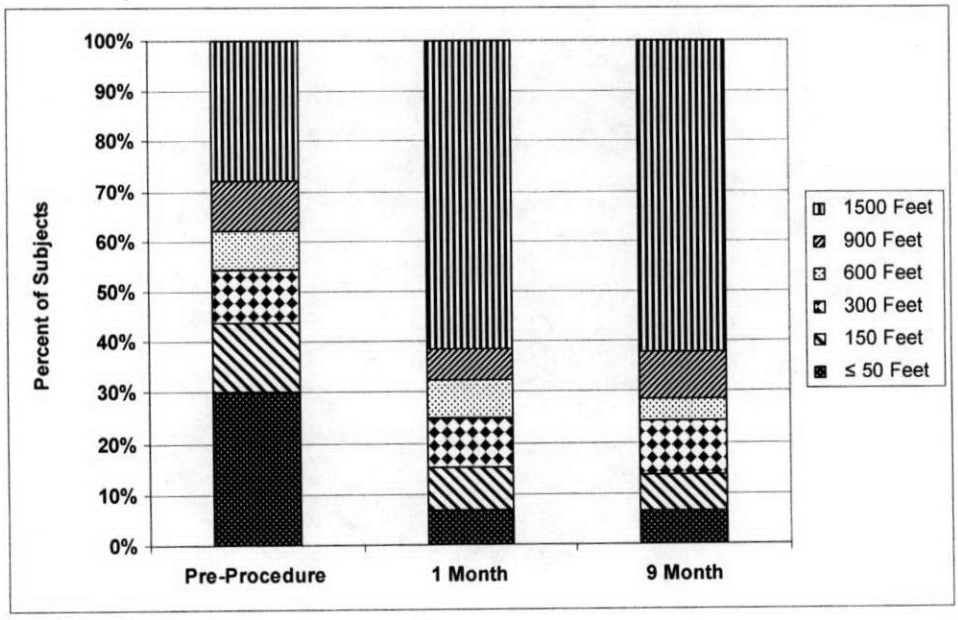
The WIQ was used to assess walking distance, walking speed and stair climbing for study subjects. The walking distance mean score significantly improved from 17.5 ± 22.7% at baseline to 56.6 ± 38.6% at 9 months. The walking speed and stair climbing mean scores also showed significant improvement, increasing from 20.1± 24.0% and 26.0 ± 25.8%, respectively, at baseline, to 47.6 ±33.2% and 60.4 ± 35.9%, respectively, at 9 months (**Figure 5**).

Figure 5: WIQ Score Change



Prior to intervention, 30.1% (46/153) of the subjects could walk ≤ 50 feet, 13.7% (21/153) could walk 150 feet while 28.1% (43/153) could walk 1500 feet. There was an improvement in maximum walking distance; at 9 months, 6.4% (9/140) were limited to walking ≤ 50 feet, 7.1% (10/140) were limited to walking 150 feet and 62.1% (87/140) of subjects could walk 1500 feet (**Figure 6**).

Figure 6: 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	98.6% (208/211)
Lesion based	
Technical success	93.1% (189/203)
Restenosis rate[2] at 9 months[3]	9.0% (16/178)
TLR at 9 months[3] (KM Estimate)	6.9%
Subject based	
Procedure success	91.5% (140/153)
Limb based	
Clinical Success[5]	
30 days	89.4% (161/180))
9 months[3]	89.0% (162/182)
Hemodynamic success[5]	
30 days	94.4% (170/180)
9 months[3]	93.4% (170/182)

[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 Omnilink Elite Vascular Balloon-Expandable 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 Omnilink Elite Vascular Balloon-Expandable Stent System in pediatric populations were not studied in the MOBILITY study.

Mobility Study Results by Gender/Sex

There were 65 female (42.5%) and 88 male (57.5%) subjects enrolled in the Omnilink Elite arm of the MOBILITY study. The demographics and risk factors were generally similar between the two groups. However more female than male subjects were current smokers, 56.9% (37/65) versus 40.9% (36/88), respectively. In female subjects, a medical history of COPD was higher than with male subjects, 43.1% (28/65) versus 19.3% (17/88), respectively. The 9-month MAE rates for men and women were compared using a post-hoc statistical analysis. The rate was 7.9% (5/63) for female subjects versus 3.5% (3/86) for male subjects. This difference in MAE was a result of 1 MI and 5 clinically-driven TLRs in the female subgroup as compared to 1 death, and 2 clinically-driven TLRs in the male subgroup (**Table 15**). The Kaplan-Meier survival analysis yielded 92.1% freedom from MAE for female subjects compared to 95.6% for male subjects at 270 days (Log-Rank, $p = 0.2335$). 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% (0/64)	0.0% (0/87)
Myocardial infarction	0.0% (0/64)	0.0% (0/87)
Major amputation of the treated limb(s)	0.0% (0/64)	0.0% (0/87)
Clinically-driven TLR	1.6% (1/64)	0.0% (0/87)
[0, 270 days]		
Death	0.0% (0/63)	1.2% (1/86)
Device-related[1]	0.0% (0/63)	0.0% (0/86)
Myocardial infarction	1.6% (1/63)	0.0% (0/86)
Device-related[1]	0.0% (0/63)	0.0% (0/86)
Major amputation of the treated limb(s)	0.0% (0/63)	0.0% (0/86)
Clinically-driven TLR	6.3% (4/63)	2.3% (2/86)
Total[2]	7.9% (5/63)	3.5% (3/86)

[1]As reported by site
[2]Hierarchical count

Table 16: Secondary Endpoints and Other Effectiveness Measures by Genders

Effectiveness Measures	Female %[1]	Male %[1]
Device based		
Device success	98.9% (92/93)	98.3% (116/118)
Lesion based		
Technical success	93.4% (85/91)	92.9% (104/112)
Primary patency rate [2]at 9 months[3]	87.2% (68/78)	92.1% (93/101)
Restenosis rate[4] at 9 months[6]	10.4% (8/77)	7.9% (8/101)
Subject based		
Procedure success	92.3% (60/65)	90.9% (80/88)
Limb based		
Clinical Success[5]		
30 days	89.9% (71/79)	89.1% (90/101)
9 months	90.1% (73/81)	88.1% (89/101)
Hemodynamic success[6]		
30 days	93.7% (74/79)	95.0% (96/101)
9 months	88.6% (70/79)	97.1% (100/103)

[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

Both primary and 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.

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 and Effectiveness Conclusions

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

Biocompatibility Testing was performed on the Omnilink Elite Vascular Balloon-Expandable 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 Omnilink Elite Vascular Balloon-Expandable Stent System. The testing demonstrated that the Omnilink Elite Vascular Balloon-Expandable Stent System maintains a Sterility Assurance Level of 10^{-6}. The results of shelf-life testing confirmed that the Omnilink Elite Stent System maintains functionality throughout its 3.5 year shelf life, and the packaging testing demonstrated that the packaging adequately protects the device throughout its 3.5 year shelf life.

A multi-center clinical trial has demonstrated that the Omnilink Elite Vascular Balloon-Expandable 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 5.4%, with the upper one-sided 95% confidence interval of 9.5%, was less than the performance goal of 19.5%. Use of the Omnilink Elite Stent System was associated with a low MAE rate.

B. Benefit-Risk Conclusions

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The probable benefit of the Omnilink Elite Vascular Balloon-Expandable Stent of improving the patient mobility and quality of life outweigh the probable risks associated with use of the device.

Additional factors to be considered in determining probable risks and benefits for the Omnilink Elite Vascular Balloon-Expandable Stent included:

- Patient follow-up was satisfactory and there were few missing data. The study results are similar to the results of similar devices. Follow-up for the PMA was 9 months, but follow-up will continue for 3 years to evaluate the longer term device performance, such as the duration of the benefit and long term adverse event rates.

- The pivotal study was a multi-center study conducted in the United States. There are no reasons to expect that the results of the study will differ from the real-world performance.

- Most patients with the disease have symptoms only, but some patients may have tissue or limb loss. The disease is chronic and affects the mobility of the patient and the quality of life. It is treatable but not curable.

- There are alternative treatments available, but this treatment is perceived as less invasive than open surgery and more effective than percutaneous transluminal angioplasty. This treatment is highly valued by patients and preferred to the alternatives because it improves their quality of life without the need for open surgery.

- Patient risk is minimized by limiting use to operators who have the necessary training to use the device safely and effectively.

In conclusion, given the available information above, the data support that the probable benefits outweigh the probable risks for using the device for the treatment of atherosclerotic *de novo* or restenotic iliac artery disease.

C. 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 July 31, 20112

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.