SUMMARY OF SAFETY AND EFFECTIVENESS (SSED)

I. GENERAL INFORMATION

Device Generic Name: Stent, Iliac

Device Trade Name: Misago™ RX Self-expanding Peripheral Stent

Device Procode: NIO, NIP

Applicant's Name and Address: Terumo Corporation
44-1, 2-Chome
Hatagaya Shibuya-ku
Tokyo
151 0072 Japan

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P140002/S032

Date of FDA Notice of Approval: July 16, 2026

The original PMA (P140002) for the Misago RX Self-expanding Peripheral Stent was approved on May 22, 2015 with the following indication: to improve luminal diameter in symptomatic patients with de novo or restenotic native lesions or occlusions of the Superficial Femoral Artery (SFA) and/or proximal popliteal artery with reference vessel diameters ranging from 4 mm to 7 mm and lesion length up to 150 mm. The SSED to support this indication is available on the CDRH website (https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140002B.pdf) and is incorporated here for reference.

The current supplement was submitted to expand the indications for use for the Misago RX Self-expanding Peripheral Stent to include improvement of the luminal diameter in patients with de novo, restenotic and/or occlusive atherosclerotic lesion(s) in the common and/or external iliac artery. The reference vessel diameters range from 4.0 mm to 9.0 mm and the lesion length is up to 120 mm.

II. INDICATIONS FOR USE

The Misago RX Self-expanding Peripheral Stent is indicated:

- To improve the luminal diameter in symptomatic patients with de novo or restenotic native lesions or occlusions of the superficial femoral artery (SFA) and/or proximal popliteal artery. The reference vessel diameters range from 4.0 mm to 7.0 mm and the lesion length is up to 150 mm.
- to improve the luminal diameter in patients with de novo, restenotic and/or occlusive atherosclerotic lesion(s) in the common and/or external iliac artery. The

reference vessel diameters range from 4.0 mm to 9.0 mm and the lesion length is up to 120 mm.

III. CONTRAINDICATIONS

The Misago RX Self-expanding Peripheral Stent is contraindicated in:

- Patients who exhibit angiographic evidence of severe thrombus in the target vessel or lesion site before/after undergoing Percutaneous Transluminal Angioplasty PTA procedure.
- Patients with contraindication to antiplatelet and/or anticoagulation therapy.
- Patients who are judged to have a lesion that prevents proper placement or deployment of the stent.
- A lesion that is within an aneurysm or an aneurysm with a proximal or distal segment to the lesion.
- A lesion through which a guide wire cannot pass.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Misago RX Self-expanding Peripheral Stent labeling.

V. DEVICE DESCRIPTION

The Misago RX Self-expanding Peripheral Stent System consists of a self-expanding nitinol stent ("stent") pre-mounted on the distal portion of a rapid exchange delivery catheter system ("delivery catheter"), as shown in Figure 1.

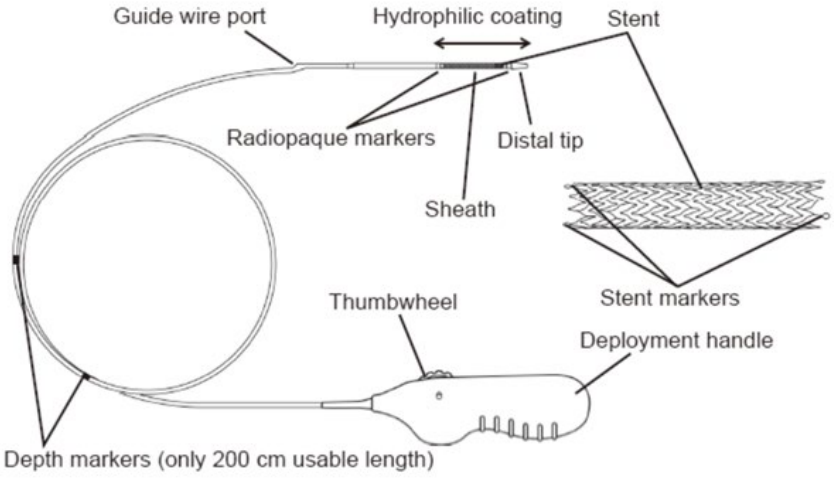


Figure 1: Diagram of Stent System

The stent is made of a nickel-titanium (NiTi) alloy with three (3) radiopaque markers located at each end for a total of six (6) markers. The stent comes in different

configurations of lengths and diameters (**Table 1**).

Table 1: Stent Configurations

Diameter	Length					
	40 mm	**60 mm**	**80 mm**	**100 mm**	**120 mm**	**150 mm**
6.0 mm	X*[1,2]	X*[1,2]	X*[1,2]	X*[1,2]	X*[1,2]	X*[1,2]
7.0 mm	X*[1,2]	X*[1,2]	X*[1,2]	X*[1,2]	X*[1,2]	X*[1,2]
8.0 mm	X*[1,2]	X*[1,2]	X*[1,2]	X*[1,2]		
9.0 mm	X*[2]	X*[2]				
10.0 mm	X*[2]	X*[2]				

[1] available to treat SFA
[2] available to treat iliac artery

The delivery catheter is available in 135 cm and 200 cm usable lengths. The distal part of the delivery catheter has a coaxial construction and is constructed to allow coaxial passage of a guide wire that doesn't exceed 0.89 mm (0.035") in diameter. The distal tip and sheath are coated with hydrophilic polymer which makes them lubricious by wetting. The intermediate shaft is blue to clearly distinguish the non-sliding part from the sliding part. The delivery catheter with 200 cm usable length has two depth markers, approximately 120 cm and 150 cm from the distal end of the catheter, which help to confirm how far the stent system has been advanced. Two inner shaft markers (radiopaque markers) are attached next to each end of the stent and allow confirmation under high-resolution fluoroscopy of the stent's position while in the patient's vessel before deployment. Stent deployment is initiated by pushing down and rolling back a thumbwheel in the deployment handle while holding the handle in place.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the treatment of superficial femoral artery atherosclerotic disease:

- Non-invasive treatment (e.g., exercise, smoking cessation and/or drug therapy)
- Minimally invasive treatment (e.g., balloon angioplasty, endovascular stent or stent-graft placement, directional atherectomy)
- Surgical treatment (e.g., surgical bypass)

Alternatives for treatment of iliac artery atherosclerotic disease include:

- Non-invasive treatment, such as optimal medical therapy including antiplatelet agents, statins, risk factor modification (e.g., smoking cessation), and structured exercise programs.
- Minimally invasive endovascular treatment, including percutaneous transluminal angioplasty (PTA) with or without placement of bare-metal stents or covered stent-grafts.
- Surgical treatment, such as open surgical bypass or endarterectomy, depending on lesion characteristics, disease severity, and patient comorbidities.

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

VII. MARKETING HISTORY

Currently, Currently, the Misago Peripheral Self-expanding Stent System is available in the United States, Puerto Rico, Japan, and Hong Kong. Following the transition to EU-MDR in the European Union, Terumo withdrew Misago from the EU market.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

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

- Allergic reaction
- Amputation of treated limb
- Arrhythmia
- Arterial dissection/perforation/rupture/injury
- Arterial embolism/thrombosis/occlusion
- Arterial spasm
- Arteriovenous fistula
- Bleeding/Hematoma
- Bradycardia/ Palpitation
- Cerebral vascular accident
- Death
- Distal embolization
- Fever
- Hemorrhage
- Hypotension/Hypertension
- Infection and pain at puncture site
- Leg Pain/Claudication
- Myocardial Infarction
- Renal failure
- Restenosis
- Sepsis
- Stent fracture
- Stroke
- Target lesion revascularization

IX. SUMMARY OF PRECLINICAL STUDIES

A. Biocompatibility Testing

Biocompatibility evaluation and testing performed as part of the original PMA, P140002, and subsequent supplements was leveraged to support the expanded indications for use and additional Ø9 and Ø10 stent configurations.

B. In Vitro Bench Testing

The safety and effectiveness of the Misago RX Self-expanding Peripheral Stent was supported by in vitro bench testing. Much of the *in vitro* bench testing performed as part of the original PMA, P140002, and subsequent supplements for the Ø6, Ø7 and Ø8 stent configurations was leveraged to support the expanded Indications for Use and additional stent sizes. Additional *in vitro* bench testing performed for the Ø9 and Ø10 stent configurations is summarized below in **Table 2**.

Table 2: Summary of In Vitro Bench Testing

Test	Purpose	Acceptance Criteria			Results
Delivery Dimensional Verification	To verify the delivery effective length, the position of the depth marker, and the outer diameters of the proximal shaft portion and the stent mounting portion.	**Delivery Effective Length**	1350 [1300 to 1400]; 2000 [1950 to 2050]		All test samples conformed to the specified criteria for delivery effective length, position of the depth marker (200cm only), outer diameter of the proximal shaft, and outer diameter of the stent mounting portion.
		Outer diameter of proximal shaft	1.02 [1.02 to 1.06]		
		Outer diameter of stent mounting portion	2.06 [2.03 to 2.09]		
		Position of depth marker	N/A for 135cm delivery length; 1200mm, 1500mm [1170 – 1210, 1470-1510] for 200 cm delivery length		
Delivery Profile / Diameter	To verify the maximum outer diameters of the distal tip and stent mounting portion.	The maximum outer diameters of each part should be within 2.12mm.			All test samples conformed to the specified criteria for outer diameter of the distal tip and stent mounting portion.
Delivery Flexibility / Kink	To determine kink resistance when the delivery system bends.	Radius of curvature should be less than 15mm when the delivery system kinks or becomes compressed.			All test samples conformed to the specified criteria for radius of curvature when the delivery kinks or becomes compressed.
Simulated Use	To verify operation by conducting a simulation use test.	The release resistance should be less than 14.7 N (1.5 kgf). Utilizing a point system of 0-2, pushability, preparation, trackability, flexibility, efficacy of withdrawal and efficacy of stent should be 1 or more.			All test samples conformed to the specified criteria for release resistance, preparation, pushability, trackability, flexibility, efficacy of withdrawal and stent efficacy.
Stent Integrity Visual Inspection	To verify the presence or absence of abnormal appearance of a stent.	No scratch, kink, crush, or adhesion of foreign matter on a stent is observed.			All test samples conformed to the specified criteria for stent integrity.
Stent Dimensional Verification	To verify stent length and stent expansion diameter.	**Product Type**	**Stent Length**	**Stent Diameter**	All test samples confirmed to the specified criteria for stent length and stent diameter (distal part, center part and proximal part).
		Ø9.0/40	40 ± 4.0 mm	9.0 ± 0.5 mm	
		Ø9.0/60	60 ± 6.0 mm	9.0 ± 0.5 mm	
		Ø10.0/40	40 ± 4.0 mm	10.0 ± 0.5 mm	
		Ø10.0/60	60 ± 6.0 mm	10.0 ± 0.5 mm	
Constrained Foreshortening	To confirm the change in stent length before and after the stent release after delivery.	The rate of change in stent length shall be within 10%.			All test samples confirmed to the specified criteria for foreshortening (constrained).

Test	Purpose	Acceptance Criteria		Results
Unconstrained Foreshortening	To confirm the change in stent length before and after the stent release after delivery.	The rate of change in stent length shall be within 10%.		All test samples confirmed to the specified criteria for foreshortening (unconstrained).
Outward Radial Force	To verify the radial resistive force (RRF) and chronic outward force (COF) of the stent.	**RRF (N/cm)**	**COF (N/cm)**	All test samples confirmed to the specified criteria for radial force. Stent returned to original diameter.
		2.5 ≤ RRF ≤ 12.5	0.7 ≤ COF ≤ 5.1	
Crush Resistance	To verify the resistance of the stent to crushing load and its shape recovery after deformation.	Resistive force should not be less than 0.29 N/cm (30 gf/cm) and not more than 1.27 N/cm (130 gf/cm).		All test samples confirmed to the specified criteria for crush resistance. Stent returned to original diameter.
Stent Kink Resistance	To verify the stent has sufficient kink resistance.	The radius of curvature at which the stent kinks or the tube diameter in the bent state becomes not more than half the tube diameter after release is less than 12.5 mm. The stent recovers to its original shape when the force for bending the tube is released.		All test samples confirmed to the specified criteria for kink resistance.
Austenite Finish Transition Temperature (Af)	To verify the shape memory characteristics of the stent.	Temperature at the Af point is not less than 18°C and not more than 28°C.		All test samples confirmed to the specified criteria for Austenite finish (Af) transition temperature.
Mechanical properties of NiTi-alloy.	To confirm the mechanical properties of NiTi-alloy.	Raw Materials: All items should pass for the criteria of certificate of compliance from the supplier. Post processing material was studied for characterization purposes.		All the test samples conformed to the specified criteria on the supplier's Certificate of Analysis.
Endurance Limit of the NiTi-alloy	To determine the endurance limit of post processing NiTi Alloy stent material	Endurance limit study was for Fatigue analysis.		The strain amplitude at the endurance limit was characterized.
Stent Stress and Strain Fatigue Analysis	To verify the properties of the strain and fatigue (safety factor) applied on the stent using finite element analysis.	The Fatigue Safety Factor > 1 for 10 years simulated pulsatile loading.		The stents were verified to meet the acceptance criteria.
Stent Pulsatile Durability	To determine if the stent will fracture due to the movement of the vessel caused by the cardiac cycle	The fracture rate of the stent after 400 million cycles (simulate 10 years) needs to meet the predetermined criteria (there shall be no Type 3, 4, or 5 fracture).		All test samples conformed to the specified acceptance criteria.
Pitting / Crevice Corrosion Potential	To verify the corrosion resistance of the stent.	The breakdown potential is not less than 300 mV.		In the Pitting Corrosion test, the breakdown potential of all samples was not less than 300 mV, which met the acceptance criteria for the test.
Galvanic Corrosion	To confirm the corrosion resistance between dissimilar metals.	Corrosion rate is 2 μm/year or less.		All test samples confirmed to the specified criteria for galvanic corrosion.

Test	Purpose	Acceptance Criteria	Results
Stent Fretting Corrosion	To verify the corrosion resistance of the stent after the Accelerated Durability Testing.	The breakdown potential shall be not less than 300 mV.	All test samples confirmed to the specified criteria for fretting corrosion.
Percent Surface Area	To confirm the area ratio of outer stent surface to inner surface of blood surface.	In case that stent diameter is Ø9.0 or Ø10.0, percent surface area should be in the range of 9.1% to 12.0%	All test samples confirmed to the specified criteria percent surface area.
MRI Safety (Image Artifacts, Magnetically Induced Forces, Torque, and Heating)	To assess the MRI safety and compatibility of the implantable stent	The presence of the stent must not pose an additional unacceptable risk to patient when subjected to 1.5 T and 3.0 T magnetic fields.	The test results demonstrated that the stent does not pose additional unacceptable risk to the patient. The stent was determined to be MR Conditional.

C. Animal Studies

The Misago RX animal testing performed as part of the original PMA, P140002 was leveraged to support the expanded Indications for Use and additional Ø9 and Ø10 stent configurations.

D. Sterilization

The Misago RX Self-expanding Peripheral Stent is sterilized by ethylene oxide. Validation of the sterilization method to ensure a Sterility Assurance Level (SAL) of 10^{-6} has been conducted in accordance with *ISO 11135:2014 Sterilization of health care products-Ethylene oxide- Requirements for development, validation and routine control of a sterilization process for medical devices.*

The stent component of the device is provided pre-mounted on the delivery catheter which is placed within a holder tube. The holder tube and a flushing syringe (accessory) are attached to a mounting card, the mounting card is inserted into a Tyvek pouch, and the pouch is then heat-sealed, labeled, and placed into a single-unit cardboard box. Multiple single-unit boxes are shipped in corrugated, cardboard shipping boxes.

E. Shelf Life

The devices are provided sterile and labeled with a 3-year shelf life. A shelf life of 3 years has been established for the Misago RX Self-expanding Peripheral Stent based on product and package shelf-life testing.

X. SUMMARY OF PRIMARY CLINICAL STUDIES

The applicant performed a confirmatory pivotal clinical study called the OSPREY ILIAC- **O**cclusive/**S**tenotic **P**eripheral artery **RE**vascularization Stud**Y** for Common and/or External **ILIAC** Artery to establish a reasonable assurance of safety and effectiveness for the Misago RX Self-expanding Peripheral Stent under IDE G160035. This study was conducted to expand the indications for the Misago stent to improve the luminal diameter in patients with de novo, restenotic and/or occlusive atherosclerotic lesion(s) in the common and/or external iliac artery with reference vessel diameters ranging from 4.0 mm to 9.0 mm and a lesion length up to 120 mm. The OSPREY ILIAC trial includes clinical data from procedures accessed via both femoral and radial arteries. A summary of the OSPREY ILIAC clinical study is presented below.

A. OSPREY ILIAC Study Design

The OSPREY ILIAC study was a confirmatory, multi-center, single arm, non-randomized, prospective clinical study to evaluate the clinical effectiveness and safety of the Misago RX Self-expanding Peripheral Stent for the treatment of de novo, restenotic and/or occlusive atherosclerotic lesion(s) of the common and/or external iliac artery.

Patients were enrolled between December 01, 2022 and May 13, 2024. The database for this panel track supplement reflected data collected through May 02, 2025 and included

75 subjects at 9 clinical sites in the United States.

The primary endpoint evaluated stent safety immediately post-procedure, prior to hospital discharge (AEs only) and at 9 months post-procedure. A subject was considered enrolled into the study if the subject signed the informed consent form (ICF), met all eligibility criteria, including intra-procedure criteria, and the study device entered the vasculature.

The Intent-to-Treat (ITT) and Per-Protocol (PP) analysis sets are defined as follows:

ITT: Includes all enrolled subjects who met the protocol-defined enrollment criteria and in whom the study device entered the vasculature, regardless of subsequent protocol deviations or treatment received.

PP: Includes the subset of ITT subjects without major protocol deviations (i.e., protocol eligibility violations). Missed or out-of-window visits were not considered major protocol deviations.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the OSPREY ILIAC study was limited to patients who met the following inclusion criteria:

Baseline:

1. Is ≥ 18 years old and of legal consent.
2. Is willing to comply with all follow-up evaluations at the specified times.
3. Subject or subject's legal representative has been informed of and understands the nature of the study and provides signed informed consent to participate in the study.
4. Has a Rutherford Clinical Category Score of 2, 3 or 4.

Intra-procedure:

5. De novo, restenotic, and/or occlusive target lesion(s) located within the native common and/or external iliac artery.
6. Radiographic evidence of ≥ 50% stenosis or restenosis (from PTA or adjunct therapy, not including stents or stent grafts), or occlusion of target lesion(s) in the common iliac artery and/or external iliac artery.
7. Total combined length of lesion(s) is ≤ 120 mm as determined by the investigator and is amenable to stenting.
8. Reference vessel diameter is ≥ 4.0 mm and ≤ 9.0 mm.
9. At least one patent infrapopliteal artery to the ankle not requiring intervention (i.e., < 50% stenosis).

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

**Criteria marked with an asterisk were reviewed intra-procedurally*

1. Has had previous stent or stent-graft implantation in the target lesion(s).
2. Has a contraindication or known untreatable allergy to antiplatelet therapy, anticoagulants, thrombolytic drugs or any other drug used during the study according to the protocol.
3. Has known hypersensitivity to contrast material that cannot be adequately pretreated.
4. Has known hypersensitivity to nickel-titanium (nitinol).
5. In the opinion of investigator, has bleeding diathesis, coagulopathy, and/or known hypercoagulable condition making the patient unsuitable for study participation.
6. Refuses blood transfusion.
7. Is female currently breastfeeding, pregnant, or of childbearing potential not using adequate contraceptives measures or refuses to use contraception throughout the duration of the study.
8. Has life expectancy of less than 1 year.
9. Has planned use of thrombectomy, atherectomy, brachytherapy, cryotherapy or laser devices to treat the common and/or external iliac arteries during the index procedure.
10. Has any planned surgical intervention (requiring in-patient hospitalization) 14 days before or 30 days after the index procedure.
11. Is currently participating in an investigational drug or other device study that has not yet reached the primary endpoint analysis.
12. Has known aortic disease requiring intervention within 9 months post index procedure.
13. In the opinion of the investigator, has one or more of the following co-morbid conditions that may impact the subject's safety and/or participation in the study:
    - History of severe liver disease (i.e. ascites, esophageal varices, liver transplant).
    - Known or suspected active systemic infection or infection within the target limb.
    - Undergoing immunosuppressant therapy following organ transplant.
    - Chronic Kidney Disease Stage IIIB or worse (i.e., GFR < 45 mL/min).
    - New York Heart Association Classification of III or IV with hospitalization for decompensated heart failure within 30 days of index procedure.
    - Recent (within 30 days of index procedure) myocardial infarction.
    - Recent (within 30 days of index procedure) hemorrhagic or ischemic stroke.
    - Acute thrombophlebitis or deep venous thrombosis in the index limb to be treated.
    - Any other co-morbid condition that in the judgment of the investigator precludes safe percutaneous intervention.

14. Guide wire cannot successfully cross the target lesion(s) and re-enter true vessel lumen beyond the lesion(s), and study device cannot be deployed so that its proximal and distal ends will be within the true vessel lumen. *
15. Aneurysmal target vessel. *
16. Presence of an acute intraluminal thrombus of the proposed lesion site(s). *
17. Perforation, flow-limiting dissection, or other injury requiring additional stenting or surgical intervention prior to the start of target lesion treatment. *

2. Follow-up Schedule

Subjects were evaluated prior to discharge (within 7 days of the index procedure), and at 30 days, 9 months, 12 months, and 24 months post-procedure. The follow-up procedures are documented in **Table 3** below.

Table 3: Study Follow-up Plan

Assessment	Pre-discharge	30-Day Follow-up	9-Month Follow-up	12- and 24-Month Follow-up
Adverse Events (AEs)	**X**	**X**	**X**	**X**
Concomitant antiplatelet and anticoagulant medications only	**X**	**X**	**X**	**X**
Vital Signs	**X**	**X**	**X**	
Rutherford Classification		**X**	**X**	
Ankle-Brachial Index		**X**	**X**	
QoL- WIQ		**X**	**X**	
Radial artery DUS[1]		**X**		
Iliac DUS			**X**	
[1] *Procedural access side only and only for subjects treated via radial artery access.*				

3. Clinical Endpoints

The primary endpoint of the study was defined as freedom from the composite major adverse events (MAE), which includes peri-procedural death (through 30 days), amputation of the target limb and clinically driven target-lesion revascularization (CD-TLR) assessed at 9 months post-procedure. CD-TLR was defined as a re-intervention of the target lesion in the presence of ≥ 50% stenosis accompanied by worsening symptoms, or ≥ 70% stenosis in the absence of symptoms. As this was a confirmatory study, the endpoints were evaluated with descriptive statistics.

Secondary endpoints in this study included the following:

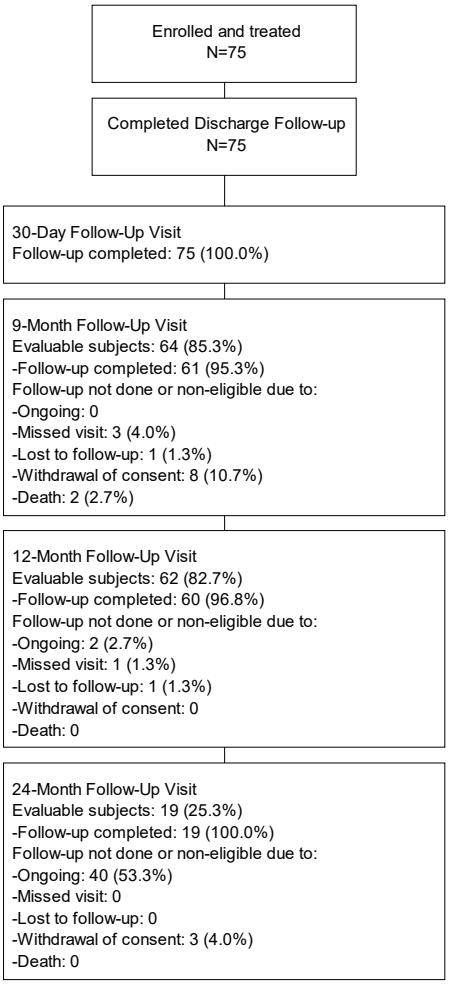
1. Freedom from Major Adverse Events at 30 days, and 12- and 24-months post-procedure. MAE is defined as a composite of peri-procedural related death, amputation of the target limb, and clinically driven TLR.

2. Target lesion primary stent binary patency at 9 months defined by duplex ultrasound peak systolic velocity ratio ≤ 2.4 at the stented target lesion and absence of TLR.
3. Technical Success defined by the following conditions:
    - Successful delivery of the stent at the lesion site.
    - Stent(s) successfully deployed in the lesion with adequate lesion coverage.
4. Procedural Success: Attainment of < 30% residual stenosis of the target lesion and no peri-procedural complications defined as: death, stroke, myocardial infarction (MI), emergent surgical revascularization, significant distal embolization in target limb, and thrombosis of target vessel. Peri-procedural complication is defined as complications after the performance of a medical procedure before hospital discharge.
5. Clinical Success: Relief or improvement (without increase of one or more in the score) from baseline symptoms as measured by the Rutherford score for chronic limb ischemia at 30 days as compared to baseline.
    - Rutherford sustained (without increase of one or more in the score) at 9 months post-procedure from 30 days post-procedure for durability of results.
6. Ankle-Brachial Index (ABI) change from baseline at 30 days post-procedure
    - ABI change from 30 days to 9 months post-procedure for durability of results.
7. Clinically driven Target Vessel Revascularization (TVR) at 30 days and 9-, 12- and 24-months post-procedure defined as any re-intervention or artery bypass surgery involving the target vessel in which the subject has ≥ 50% diameter stenosis with worsening symptoms, or ≥ 70% stenosis without symptoms. The target vessel is defined as the vessel containing the treated lesion (e.g., common and/or external iliac artery).
8. Clinically driven TLR through 30 days and 9-, 12- and 24-months post-procedure.
9. Quality of Life Measurement: Walking Impairment Questionnaire (WIQ) change from baseline (pre-procedure) at 30 days and 9 months post procedure.
10. Evaluation of all AEs at pre-discharge, 30 days, and 9-, 12- and 24-months post-procedure.
11. Evaluation of access site complications including severe bleeding, hematoma, and pseudoaneurysm, occurring prior to hospital discharge.
12. Occurrence of device deficiency.
13. Device Related Complications (DRCs) through 9 months post-procedure. DRCs are defined as any of the following events: amputation of the treated limb, arterial dissection, perforation, rupture, or injury; arterial embolism, thrombosis, or occlusion; arterial spasm; arteriovenous fistula; death; distal embolization; hemorrhage; hypotension; leg pain or claudication; TLR; or thrombosis of the target vessel.

Clinical outcomes were also stratified according to key baseline clinical and anatomical characteristics to assess potential differences in treatment response among subgroups. These stratifications will allow for a detailed evaluation of clinical outcomes across relevant subpopulations.

B. Accountability of PMA Cohort

At the time of database lock, 75 patients were enrolled in the PMA study. Of these, 64/75 [85.3%] patients were available for analysis of the primary endpoint at the 9 months post-operative visit.



Note: Evaluable subjects for the follow-up period were defined as enrolled subjects who either completed their follow-up visit or who remained enrolled in the study during the visit window end date. At the time of database lock, 12- and 24-month follow-up visits were in progress.

Figure 2: Study Subject Disposition

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a study of SFA occlusive disease in the US. The target population included men and women, ≥ 18 years of age, with ≥ 50% stenosis or occlusion of the target lesion(s) located within the native common and/or external iliac artery. Subjects required a Rutherford Clinical Category Score of 2, 3 or 4 and a total combined lesion length of ≤ 120 mm (**Table 4)**.

Table 4: Baseline Demographics

Demographics	Total Mean ± SD or n/N (%)
Age (years)	69.3 ± 6.76
Gender (% Male)	61.3%
Race	
American Indian or Alaska Native	0
Asian	2/75 (2.7%)
Black or African American	14/75 (18.7%)
Native Hawaiian or Pacific Islander	0
White	58/75 (77.3%)
Not reported	1/75 (1.3%)
BMI (kg/m^2)	28.0 ± 5.93
Rutherford Category*	
Category 2: Moderate claudication	6/74 (8.1%)
Category 3: Severe claudication	43/74 (58.1%)
Category 4: Ischemic pain at rest	25/74 (33.8%)

** Rutherford category missing for 1 subject.*

Table 5: Baseline Medical History in ITT Population

Medical History	Total N = 75 Subjects
Risk Factors	
Coronary/Peripheral Disease	71/75 (94.7%)
Diabetes mellitus	31/75 (41.3%)
Type 1	2/31 (6.5%)
Type 2	29/31 (93.5%)
Diabetes Treatment	
Untreated	2/31 (6.5%)
Oral Agents	15/31 (48.4%)
Insulin	7/31 (22.6%)
Insulin and Oral Agents	7/31 (22.6%)
Dyslipidemia	35/75 (46.7%)
Hypertension	68/75 (90.7%)
History of Chronic Kidney Disease	15/75 (20.0%)
Smoking Status[1]	56/75 (74.7%)
Current	22/56 (39.3%)
Former	34/56 (60.7%)
Medical History	
Cardiovascular Disease	59/75 (78.7%)

Medical History	Total N = 75 Subjects
Angina Pectoris	7/75 (9.3%)
Stable	6/7 (85.7%)
Unstable	1/7 (14.3%)
Asymptomatic	0
Coronary Artery Disease	43/75 (57.3%)
Heart Failure	4/75 (5.3%)
NYHA Class I	0
NYHA Class II	2/4 (50.0%)
NYHA Class III	1/4 (25.0%)
NYHA Class IV	0
NYHA Class Missing	1/4 (25.0%)
Myocardial Infraction (MI)	14/75 (18.7%)
Cerebrovascular Disease	4/75 (5.3%)
Hemorrhagic Stroke	1/75 (1.3%)
Transient Ischemic Attack	3/75 (4.0%)
Ischemic Stroke	1/75 (1.3%)
CFA Occlusive Disease/Significant Aortic Occlusive Disease	6/75 (8.0%)
History of Acute Limb Ischemia	3/75 (4.0%)
[1] Smoking Status, 'Former' means the patient has had a history of smoking at any previous timepoint in their life.	

D. Procedural Characteristics

Initial procedural access was to be assessed in the radial artery. If radial access was not feasible or was unable to be established, it was acceptable to choose another point of procedural access. The radial access site was utilized for 88.0% of subjects; the femoral access site was utilized for 12.0% of subjects. The target lesion was to be predilated utilizing standard techniques, if necessary. Subjects underwent iliac stent placement according to the Instructions for Use. Following deployment of the stent, dilation of the target lesion was required. Aspirin intake was recommended to be started within 24 hours of the procedure. During the stenting procedure, use of supplemental anticoagulation was administered according to the investigator's discretion. Post-procedure, subjects were to receive the appropriate anticoagulation at the discretion of the investigator, and it was recommended that all subjects receive aspirin daily to be continued indefinitely.

A total of 83 lesions were treated across 75 subjects: 51.8% of lesions were in the common iliac artery and 39.8% of lesions were in the external iliac artery. Seven subjects (8.4%) had lesions that extended across both arterial segments. All target lesions were de novo with a mean target lesion length was 37.9 mm and a mean initial stenosis of 68.2%. **Table 6** presents target lesion characteristics assessed by the angiographic core laboratory.

Table 6: Target Lesion Characteristics (Core Lab Reported)

Core Lab Angiography	Total N = 83 Lesions Mean ± SD or n/N (%)
Target Lesion Location	
Common Iliac Artery (CIA)	43/83 (51.8%)
External Iliac Artery (EIA)	33/83 (39.8%)
Common Iliac, External Iliac	7/83 (8.4%)
Target Limb by Lesion	
Left	42/83 (50.6%)
Right	41/83 (49.4%)
Pre-Treatment Arteriogram*	
Target Lesion Length (mm)	37.9 ± 29.47
Reference Vessel Diameter (RVD) (mm)	7.3 ± 1.48
Minimal Lumen Diameter (MLD) (mm)	2.4 ± 1.65
Stenosis [%]	68.2 ± 20.12
Post-Treatment Arteriogram*	
Total Treated Lesion Length (mm)	60.2 ± 24.59
Max Stent Diameter (mm)	8.6 ± 1.26
Stent MLD (mm)	6.3 ± 1.31
Stenosis [%]	16.0 ± 9.84
* Pre- and post-treatment arteriograms were conducted on 82 lesions; 1 arteriogram was non-diagnostic.	

E. Safety and Effectiveness Results

1. Primary Composite Safety and Effectiveness Endpoint Analysis

The primary endpoint of the study was defined as freedom from the composite Major Adverse Events (MAE), which included periprocedural death, amputation of the target limb, and clinically driven target lesion revascularizations (TLR), assessed at 9 months post-procedure. CD-TLR was defined as a re-intervention of the target lesion in the presence of ≥50% stenosis accompanied by worsening symptoms, or ≥ 70% stenosis in the absence of symptoms.

Among the evaluable subjects who completed the 9-month follow-up visit or remained enrolled at the end of the 9-month visit window, 64 subjects were analyzed. Eleven of the 75 subjects were not included in the 9-month analysis population due to death (n=2), loss to follow-up (n=1), or withdrawal of consent prior to the 9-month visit (n=8). The 2 deaths were unrelated to the device or procedure (i.e. lung cancer and influenza B). Of these, 63 subjects (98.4%) were free from MAEs at 9 months post-procedure. No peri-procedural related deaths or amputations of the target limb were reported. Clinically driven TLR was observed in 1 subject (1.6%), with 63 subjects (98.4%) remaining free from TLR. **Table 7** summarizes the primary safety endpoint analysis.

Table 7: Primary Endpoints in Evaluable Subjects at 9-months Follow-up

	n/N (%)
Subjects without MAE at 9 Months Post-Procedure	63/64 (98.4%)
Subjects without Peri-Procedural Related Death	64/64 (100.0%)

Subjects without Amputation of the Target Limb	64/64 (100.0%)
Subjects without Clinically Driven Target Lesion Revascularization (TLR)	63/64 (98.4%)

Note: Evaluable subjects for the 9 months follow-up (64) were defined as enrolled subjects who either completed their 9-month follow-up visit or who remained enrolled in the study on their 9-month visit window end date.

2. Secondary Endpoint Analysis

Secondary endpoints in this study included a comprehensive evaluation of clinical, procedural, and device-related outcomes at 30 days and/or 9 months post-procedure. **Table 8** below summarizes the secondary safety endpoints in the ITT population and in the per protocol (PP) population. At each time point, high rates of event-free survival were observed across all assessed endpoints.

Table 8: Secondary Safety Endpoints

	ITT Population		**PP Population**	
	30 Days Follow-up	**9 Month Follow-up**	**30 Days Follow-up**	**9 Month Follow-up**
Subjects without MAE	75/75 (100.0%)	63/64 (98.4%)	75/75 (100.0%)	63/64 (98.4%)
Subjects without Peri-Procedural Related Death	75/75 (100.0%)	64/64 (100.0%)	75/75 (100.0%)	64/64 (100.0%)
Subjects without Amputation of the Target Limb	75/75 (100.0%)	64/64 (100.0%)	75/75 (100.0%)	64/64 (100.0%)
Subjects without Clinically Driven Target Lesion Revascularization (TLR)	75/75 (100.0%)	63/64 (98.4%)	75/75 (100.0%)	63/64 (98.4%)
Subjects without Clinically Driven Target Vessel Revascularization (TVR)	75/75 (100.0%)	63/64 (98.4%)	75/75 (100.0%)	63/64 (98.4%)

Table 9 summarizes the secondary effectiveness endpoints in the ITT population.

Table 9: Secondary Effectiveness Endpoints

Secondary Effectiveness Endpoint(s)	**Total Mean ± SD or % (n/N)**
Primary Stent Patency at 9 months defined as a binary duplex ultrasound PSVR ≤ 2.4 or stenosis category <50% and absence of TLR [1]	94.5% (52/55)
Clinical success, defined as relief or improvement without an increase of one or more in Rutherford score, at 30 days compared to baseline	98.6% (71/72)
Clinical success, defined as relief or improvement without an increase of one or more in Rutherford score, at 9 months compared to baseline [2]	96.6% (56/58)
Site reported technical success, defined by successful delivery of the stent at the lesion site and the stent(s)	100.0% (75/75)

successfully deployed in lesion with adequate lesion coverage.	
Core lab reported technical success, defined by successful delivery of the stent at the lesion site and the stent(s) successfully deployed in lesion with adequate lesion coverage.	97.3% (72/74)
Procedural Success, defined as the attainment of < 30% residual stenosis of the target lesion and no peri-procedural complications	94.6% (70/74)
Ankle-Brachial Index (ABI) change from baseline to 30 days post-procedure	0.20 ± 0.23
Target Limb Ankle-Brachial Index (ABI) change from baseline to 9 months post-procedure	0.19 ± 0.24
Walking Impairment Questionnaire (WIQ) Score Improvement from baseline to 30 days	22.3 ± 30.02
Walking Impairment Questionnaire (WIQ) Score Improvement from baseline to 9 months	22.3 ± 28.51
Subjects without Clinically Driven Target Lesion Revascularization (TLR) at 9 months post-procedure	98.4% (63/64)
Subjects without Clinically Driven Target Vessel Revascularization (TVR) at 9 months post-procedure	98.4% (63/64)

[1]Three subjects did not achieve primary stent patency at 9 months due to either a PSVR >2.4, ≥50% stenosis, or target lesion revascularization (TLR). DUS assessments were evaluable for 55 subjects, meaning that diagnostic-quality iliac artery ultrasound images and the required measurements were available for core laboratory assessment of vessel patency.
[2]Two subjects did not achieve clinical success at 9 months because their Rutherford Classification scores worsened compared with baseline. Fifty-eight subjects were considered evaluable for clinical success since both baseline and 9-month Rutherford Classification assessments were available.

Table 10 summarizes the device-related complications and device deficiencies in the ITT population through 9 months.

Table 10: Device-Related Complications and Device Deficiencies through 9 Months

Secondary Endpoint(s)	Total % (n/N)
Subjects with Device-Related Complications	2.7% (2/75)
Subjects with Device Deficiencies	1.3% (1/75)

3. Adverse Events

Table 11 provides a summary of the non-serious adverse events, as reported by sites, documented in the OSPREY ILIAC study. The data are presented as a percentage of subjects experiencing non-serious adverse events.

Table 11: Non-Serious Adverse Events (Site Reported)

Adverse Event	N (%) subjects with ≥1 condition / number of events		
	Within 30 days (0-30 days)	9 months (31-270 days)	Overall (0-270 days)
Evaluable Subjects	N=75	N=69	N=75

Any Adverse Events	33 (44.0%) / 63	53 (76.8%) / 135	59 (78.7%) / 198
Non- Serious Adverse Events	31 (41.3%) / 52	44 (63.8%) / 81	54 (72.0%) / 133
Incidence of Adverse Event by SOC/PT			
Vascular disorders	19 (25.3%) / 21	14 (20.3%) / 15	29 (38.7%) / 36
General disorders and administration site conditions	7 (9.3%) / 7	11 (15.9%) / 11	16 (21.3%) / 18
Musculoskeletal and connective tissue disorders	5 (6.7%) / 5	9 (13.0%) / 9	13 (17.3%) / 14
Cardiac disorders	-	6 (8.7%) / 9	6 (8.0%) / 9
Respiratory, thoracic and mediastinal disorders	1 (1.3%) / 1	6 (8.7%) / 8	6 (8.0%) / 9
Infections and infestations	3 (4.0%) / 3	6 (8.7%) / 7	8 (10.7%) / 10
Injury, poisoning and procedural complications	7 (9.3%) / 8	1 (1.4%) / 1	8 (10.7%) / 9
Nervous system disorders	1 (1.3%) / 1	4 (5.8%) / 5	5 (6.7%) / 6
Gastrointestinal disorders	1 (1.3%) / 1	4 (5.8%) / 4	5 (6.7%) / 5
Renal and urinary disorders	1 (1.3%) / 1	4 (5.8%) / 4	4 (5.3%) / 5
Blood and lymphatic system disorders	1 (1.3%) / 1	1 (1.4%) / 1	2 (2.7%) / 2
Metabolism and nutrition disorders	2 (2.7%) / 2	2 (2.9%) / 2	3 (4.0%) / 4
Reproductive system and breast disorders	-	1 (1.4%) / 1	1 (1.3%) / 1
Investigations	-	1 (1.4%) / 1	1 (1.3%) / 1
Skin and subcutaneous tissue disorders	-	1 (1.4%) / 1	1 (1.3%) / 1
Ear and labyrinth disorders	-	1 (1.5%) / 1	1 (1.3%) / 1
Hepatobiliary disorders	-	-	-
Psychiatric disorders	1 (1.3%) / 1	-	1 (1.3%) / 1
Surgical and medical procedures	-	1 (1.4%) / 1	1 (1.3%) / 1

Note: Evaluable subjects include those who are enrolled and either completed the follow-up visit within the protocol-defined visit window or were evaluable for adverse event reporting during the corresponding adverse event reporting period.

Table 12 provides a summary of the serious adverse events (SAEs), as reported by sites, documented in the OSPREY ILIAC study. The data are presented as a percentage of subjects experiencing serious adverse events.

Table 12: Serious Adverse Events (SAEs) (Site Reported)

Adverse Event	N (%) subjects with ≥1 condition / number of events		
	Within 30 days (0-30 days)	9 months (31-270 days)	Overall (0-270 days)
Evaluable Subjects	N=75	N=69	N=75
Any Adverse Events	33 (44.0%) / 63	53 (76.8%) / 135	59 (78.7%) / 198
Serious Adverse Events	7 (9.3%) / 11	25 (36.2%) / 54	29 (38.7%) / 65
Incidence of Adverse			

Event by SOC/PT			
Vascular disorders	4 (5.3%) / 5	15 (21.7%) / 23	17 (22.7%) / 28
Infections and infestations	2 (2.7%) / 2	5 (7.2%) / 7	7 (9.3%) / 9
Cardiac disorders	1 (1.3%) / 1	3 (4.3%) / 3	4 (5.3%) / 4
Renal and urinary disorders	1 (1.3%) / 1	4 (5.8%) / 4	5 (6.7%) / 5
Gastrointestinal disorders	-	3 (4.3%) / 3	3 (4.0%) / 3
General disorders and administration site conditions	1 (1.3%) / 1	1 (1.4%) / 1	2 (2.7%) / 2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (1.3%) / 1	2 (2.9%) / 2	3 (4.0%) / 3
Nervous system disorders	-	3 (4.3%) / 3	3 (4.0%) / 3
Respiratory, thoracic and mediastinal disorders	-	1 (1.4%) / 2	1 (1.3%) / 2
Eye disorders	-	2 (2.9%) / 2	2 (2.7%) / 2
Injury, poisoning and procedural complications	-	2 (2.9%) / 2	2 (2.7%) / 2
Hepatobiliary disorders	-	1 (1.4%) / 1	1 (1.3%) / 1
Musculoskeletal and connective tissue disorders	-	1 (1.4%) / 1	1 (1.3%) / 1
Psychiatric disorders	-	-	-

Note: Evaluable subjects include those who are enrolled and either completed the follow-up visit within the protocol-defined visit window or were evaluable for adverse event reporting during the corresponding adverse event reporting period.

Among the 75 subjects in the ITT population, safety outcomes through the 9-month follow-up window (day 0–270), which corresponds to the primary endpoint timepoint, demonstrated a low incidence of serious procedure- and device-related adverse events.

A total of 19 events were adjudicated by the Clinical Events Committee in 15 subjects (20.0%), including procedure- or device-related events, SAEs, and TLRs. Of these, 5 events in 3 subjects (4.0%) were adjudicated as procedure related, and 3 events in 2 subjects (2.7%) were adjudicated as device related.

4. Subgroup Analyses

Clinical outcomes were stratified according to key baseline clinical and anatomical characteristics to assess potential differences in treatment response among subgroups (e.g., diabetic versus non-diabetic status, female versus male gender, lesion location in the common iliac artery versus the external iliac artery).

Subgroup analyses were only performed for the primary endpoint (MAE within 9 months post-procedure). Due to the low Major Adverse Event (MAE) rate within 9 months post-procedure, no meaningful comparisons could be made across subgroups.

5. Pediatric Extrapolation

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

XI. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 50 investigators. Five (5) of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f).

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: N/A
- Significant payment of other sorts: $25,000
- Proprietary interest in the product tested held by the investigator: N/A
- Significant equity interest held by investigator in sponsor of covered study: N/A

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data

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

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory Systems Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Safety and Effectiveness Conclusions

The non-clinical engineering testing conducted on the stent and delivery system demonstrates that the safety and performance characteristics of the device met the product specifications. The test results obtained from sterilization testing demonstrate that the product can be adequately sterilized and is acceptable for clinical use. The shelf-life testing has established acceptable performance for a labeled shelf life up to 3 years.

The OSPREY ILIAC study was a multi-center, single arm, non-randomized, prospective clinical study to evaluate the clinical effectiveness and safety of the Misago RX Self-expanding Peripheral Stent for the treatment of de novo, restenotic and/or occlusive atherosclerotic lesion(s) of the common and/or external iliac artery. The composite primary safety and effectiveness endpoint was evaluated descriptively with 98.4% (63/64) of evaluable subjects free from Major Adverse Events (MAE), which included periprocedural death, amputation of the target limb, and clinically driven target lesion revascularizations (TLR), assessed at 9 months post-procedure.

Secondary endpoints demonstrated clinical success showing relief or improvement without an increase of one or more in Rutherford score, at 30 days and 9 months compared to baseline in 98.6% and 96.6% respectively. Patient quality of life was also shown to improve from baseline to 30 days and 9 months.

B. Benefit-Risk Conclusions

The probable benefits of the device are based on data collected in a clinical study conducted to support PMA approval as described above. The probable benefits of the Misago RX Self-Expanding Peripheral Stent include improving or restoring blood flow in patients with occlusive iliac artery disease by improving patient symptoms and quality of life.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. Overall, the occurrence and adverse event types reported in the OSPREY and OSPREY ILIAC studies align with the adverse events from published clinical literature and are expected in the patient population evaluated. In evaluating the overall benefit-risk profile, FDA substantially leveraged information from the original SFA study (OSPREY) from the original PMA P140002 when evaluating the confirmatory iliac study (OSPREY ILIAC) data.

In conclusion, given the available information above, the data support that the probable benefits outweigh the probable risks for using the Misago RX Self-Expanding Peripheral Stent to improve luminal diameter in patients with occlusive iliac artery disease.

1. Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

C. Overall Conclusions

The clinical and non-clinical data in this application provide a reasonable assurance that the device is safe and effective when used in accordance with the Indications for Use. The results from the prospective, multicenter, single-arm OSPREY and OSPREY ILIAC Studies demonstrate that the Misago RX Self-Expanding Peripheral Stent is safe and effective for improving the luminal diameter in patients with de novo, restenotic and/or occlusive atherosclerotic lesion(s) in the common and/or external iliac artery with reference vessel diameters range from 4.0 mm to 9.0 mm and the lesion length is up to 120 mm.

XIV. CDRH DECISION

CDRH issued an approval order on July 16, 2026. The final clinical conditions of approval cited in the approval order are described below.

Post-Approval Study – OSPREY Iliac Continued Follow-Up Study. This study should be conducted per protocol TIS2015-01 version 5.0 (dated 13 June 2024). This study is a

prospective, multi-center follow-up of the pivotal study (G160035) that treated 75 subjects at 9 clinical sites in the United States. It will evaluate the long-term safety and effectiveness of the Misago RX Self-expanding Peripheral Stent. All 64 remaining subjects, active at the end of the 9-month-timepoint evaluation, will continue to be followed annually through 24 months. Follow-up at the 24-month timepoint will include the following: assessment of adverse events, clinically driven target lesion revascularization (TLR), and clinical-driven target vessel revascularization (TVR).

XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.