SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: System, Endovascular Graft, Aortic Aneurysm Treatment

Device Trade Name: Cordis® INCRAFT® AAA Stent Graft System

Device Product Code: MIH

Applicant's Name and Address: Cordis Corporation
1820 McCarthy Boulevard
Milpitas, CA, 95035
U.S.A.

Premarket Approval Application (PMA) Number: P150002

Date of FDA Notice of Approval Order: [Month] [Day], 2017

II. INDICATIONS FOR USE

The INCRAFT® AAA Stent Graft System (**INCRAFT**) is intended for the endovascular treatment of patients with infrarenal abdominal aortic aneurysms with the following characteristics:

- Adequate iliac or femoral vessel morphology that is compatible with vascular access techniques, devices or accessories;
- Proximal neck length ≥ 10 mm;
- Aortic neck diameters ≥ 17 mm and ≤ 31 mm;
- Aortic neck suitable for suprarenal fixation;
- Infrarenal and suprarenal neck angulation ≤ 60°;
- Iliac fixation length ≥ 15 mm;
- Iliac diameters ≥ 7 mm and ≤ 22 mm;
- Minimum overall AAA treatment length (proximal landing location to distal landing location) ≥ 128 mm;
- Morphology suitable for aneurysm repair;
- One of the following:
  - Aneurysm diameter > 5 cm;
  - Aneurysm diameter of 4 to 5 cm, which has also increased in size by 0.5 cm in the last 6 months;
  - Aneurysm that is at least 1.5 times the diameter of the normal infrarenal aorta.

III. CONTRAINDICATIONS

The contraindications can be found in **INCRAFT** labeling.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in **INCRAFT** labeling.

V. DEVICE DESCRIPTION

INCRAFT is a modular bifurcated endovascular stent graft system that is used for the treatment of infrarenal abdominal aortic aneurysms.

INCRAFT is comprised of two main types of devices: the INCRAFT® Stent Graft implant (Prosthesis) and the INCRAFT® Delivery System. The stent graft is preloaded into the delivery system and advanced to the intended location under fluoroscopy, where it is deployed to create a new blood flow channel that excludes the aneurysm.

A. Stent Graft

INCRAFT is typically assembled from three main components: an aortic bifurcate prosthesis and two iliac limb prostheses. In addition, to extend the implant in a caudal direction, the iliac limb prosthesis can be used as an iliac extension prosthesis. Each prosthesis is constructed of a seamless, low porosity, woven polyester graft supported by a series of short, laser-cut, electro-polished, self-expanding nitinol stent-rings throughout the entire length.

B. Delivery System

Each prosthesis is loaded into a delivery system which facilitates controlled deployment of the prosthesis into the intended locations under fluoroscopic guidance. There are two variations of the delivery system: one for the aortic bifurcate prosthesis, and one for the iliac limb prosthesis.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

An Abdominal Aortic Aneurysm (AAA) is a bulging, weakened area in the wall of the aorta resulting in an abnormal widening or ballooning greater than 50 percent of the vessel's normal diameter. The aorta is under constant pressure as blood is ejected from the heart. With each heartbeat, the walls of the aorta distend and then recoil, exerting continual pressure or stress on the already weakened aneurysm wall. Therefore, there is a potential for rupture or dissection of the aorta, which may cause life-threatening hemorrhage and potentially death. The larger the aneurysm becomes, the greater the risk of rupture. Because an aneurysm may continue to increase in size, along with progressive weakening of the artery wall, surgical or endovascular intervention may be needed. Preventing rupture of an aneurysm is one of the goals of therapy. Abdominal aortic aneurysms can be treated three ways: medical management; open surgical repair; and endovascular aneurysm repair (EVAR).

A. Medical Management

Medical management is typically reserved for small aneurysms that have not reached the recommended threshold for intervention, or those patients whose perioperative risks preclude them from undergoing open surgical repair or EVAR. The current standard of care for these small AAAs is “watchful waiting”. A number of approaches have been proposed to prevent progression of aneurysmal disease through medical management including hemodynamic management, inhibition of inflammation, and protease inhibition. Once an aneurysm is detected, the goal is to try to prevent it from enlarging. Life-long control of risk factors, such as cessation of

smoking, controlling blood pressure, cholesterol and diabetes, is a part of medical management. During medical management an aneurysm may continue to increase in size along with progressive weakening of the artery wall, resulting in potential surgical or endovascular intervention.

B. Open Surgical Repair

Open surgical repair is an acceptable treatment option for younger and healthier patients and has been considered the gold standard for AAA management. Open surgery of AAAs requires general anesthesia, a laparotomy or retroperitoneal dissection and an invasive replacement of the diseased segment of the aorta with a surgical graft. There are a number of complications that may occur following open surgery for AAA repair including: cardiac ischemia, arrhythmia, congestive heart failure, acute renal failure, acute pulmonary insufficiency, bleeding, distal thromboembolism, wound infection, and death. Ischemic colitis, stroke and paraplegia are rare clinical complications. Impotence, though poorly defined, may occur in excess of 10% of male patients who have had an aortic repair. Recovery from open surgical repair can be prolonged and usually is estimated to take 6-8 weeks, requiring some rehabilitation in a substantial segment of the patients. There are also a number of serious late post-operative complications that may occur 3-5 years after open aortic reconstruction, which include intestinal obstruction, aortoenteric fistula, graft infection, graft occlusion, and anastomotic aneurysms. In recent years, EVAR has replaced open surgical repair as the most commonly performed procedure for elective AAA repair.

C. Endovascular Aneurysm Repair (EVAR)

The introduction of catheter-based endovascular technology has led to the development and testing of minimally invasive procedures to treat AAA and prevent rupture with the potential to reduce morbidity and mortality rates, shorten hospital stays and provide a satisfactory treatment outcome. EVAR is a minimally-invasive procedure performed to repair an abdominal aortic aneurysm. EVAR may be performed in an operating room, radiology department, or a catheterization laboratory. The physician may use general anesthesia or regional anesthesia. A small bilateral surgical cut-down is made to visualize the femoral arteries in each leg. With the use of special endovascular instruments, along with X-ray images for guidance, a stent-graft is inserted through the femoral artery and advanced up into the aorta to the site of the aneurysm. A stent-graft is a long cylindrical tube made of a thin metal framework (stent) of nitinol or stainless steel that supports a fabric portion (graft) made from materials such as PET or PTFE. The stents help to hold the graft open and in place. A complete stent-graft system is typically two or three implants that are assembled inside the patient to exclude the aneurysm. To accomplish this, the stent-grafts, restrained inside a delivery system, are inserted into the distal aorta and navigated to the aneurysm site. Once at the appropriate location, the stent-graft is deployed from the delivery system so that the stents expand and attach to the walls of the aorta and iliac arteries above and below the aneurysm to redirect blood flow away from the wall of the aneurysm.

EVAR has emerged as an alternative treatment of AAA for most patients. It is less invasive than open repair and carries lower rates of early mortality and morbidity. It has also extended treatment options to patients who cannot undergo conventional

surgical procedures due to a high operative risk. As EVAR technology evolves, it allows treatment of AAA with increasing complexity of the aortic neck and access vessels.

Initial clinical results of prospective trials with endovascular grafts in subjects with AAA have shown a similar mortality rate and a lower morbidity rate compared to open surgery. By 2006, the number of patients undergoing endovascular aneurysm repair was more than 21,000. And while there is no more recent national figures published, the figure was thought to be 35,000 in 2011 (unpublished from Healthcare Cost and Utilization Project [HCUP] sponsored by the Agency for Healthcare Research and Quality [AHRQ]). According to the Millennium Research Group there were almost 50,000 abdominal stent grafts implanted in the US in 2013 alone.

The trend toward low-profile devices, such as **INCRAFT**, resulted in part to treat patients with smaller access vessels without conduit access or bypass grafting, lower access site complications, and diminished need for surgical arteriotomy for access. The need for open surgical femoral exposure can be reduced as well. The low-profile design prevents vessel access issues, improves deliverability, and enables the shift to percutaneous EVAR.

VII. MARKETING HISTORY

INCRAFT received CE Mark in 2014 and has been commercially available within the European Union (EU). In addition, **INCRAFT** is commercially available in Canada and has received regulatory approvals in Australia, New Zealand, Korea, China and Brazil.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse effects associated with **INCRAFT** include, but are not limited to, those related to the implantation procedure, those related to performance of the implanted stent-graft and those related to long-term patient tolerance of the implant. For specific adverse events which occurred in the clinical studies, please see **Section X** below.

IX. SUMMARY OF PRECLINICAL STUDIES

A. Laboratory Studies

INCRAFT underwent numerous testing for design verification and validation, including long term durability and corrosion testing. Testing was performed in accordance with the requirements specified in ISO 25539 - 1, *"Cardiovascular implants – Endovascular devices, Part 1: Endovascular prostheses"* and ISO 25539-1, *"Cardiovascular implants – Endovascular devices, Part 1: Endovascular prostheses, Amendment 1: Test Methods"*. A summary of this testing is provided in **Table 1**.

Table 1: Summary of Design Verification & Validation Testing

ISO 25539-1 Annex D Section	Annex D Test Name/ Test Purpose	Acceptance Criteria	Summary of Results
5.1.1	Dimensional Verification and Component Dimensions Compatibility	All test samples must meet predefined specification for usable length	Pass All test specimens met the pre-defined acceptance criterion.
		All test samples must accept a typical 0.035" stiff guide wire through the entire length of the delivery system's guide wire lumen.	Pass
		The bifurcate outer member inner diameter must be ≥ 4.0 mm and all test samples must meet a maximum limb distal outer member compatibility force with the bifurcate integrated sheath of ≤ 10.0 lbf	Pass
		All test samples must meet predefined specification for luer dimensions	Pass
5.1.2	Profile/ Diameter Test	All test samples must meet its nominal labeled profile.	Pass
5.1.3	Assessment of Hemostasis	All test samples must meet a maximum leak rate of ≤ 60 ml/min	Pass
5.1.4	Simulated Use Models	All test samples must be able to complete flushing of the guidewire lumen and without incident.	Pass
		All test samples must show acceptable balloon compatibility during tracking activities and post deployment shall be assessed.	Pass
		All test samples must pass a clinical acceptability assessment of the delivery system kink resistance.	Pass
		All test samples must not show visible signs of crazing, cracking, blister/ bubble, haze/ cloudiness, pitting, discoloration, precipitate formation or other conditions.	Pass
		All test samples must pass a clinical acceptability assessment of the deployment accuracy.	Pass
		All test samples must have a deployment initiation torque of ≤ 1.75 rotations of the handle.	Pass
		All test samples must meet a handle rotation angle for response of the delivery system tip of ≤ 90 degrees.	Pass
		All test samples must meet a peak push force of ≤ 10.0 lbf.	Pass
		All samples must pass a clinical acceptability assessment of the prosthesis kink resistance.	Pass
		All samples must pass clinical acceptability assessment of the prosthesis conformability to the vessel.	Pass

ISO 25539-1 Annex D Section	Annex D Test Name/ Test Purpose	Acceptance Criteria	Summary of Results
		All test samples must pass a gasket retention assessment.	Pass
		All test samples must meet a peak initiation torque of ≥ 12.0 in-oz.	Pass
		All test samples must meet a peak primary deployment torque of ≤ 24.0 in-lb.	Pass
		All test samples must meet a primary deployment force of < 26.0 lbf.	Pass
		All test samples must meet a secondary release force (Sheathed) of ≥ 1.6 lbf.	Pass
		All test samples must meet a secondary release force (Unsheathed) of ≤ 10.0 lbf.	Pass
		All test samples (bifurcate) must meet a residual retraction length of ≥ 12.0 mm.	Pass
		All test samples (limb) must meet a residual retraction length of ≥ 37.0 mm.	Pass
5.2.5	Bond Strength	All test samples must meet an inner member tip to hypotube tensile strength of ≥ 10.0 lbf.	Pass
		All test samples must meet an inner member wire guide to hypotube tensile strength of ≥ 25.0 lbf (bifurcate) and ≥ 17.0 lbf (limb).	Pass
		All test samples must meet an eyelet wires to wire holder tensile strength of ≥ 1.3 lbf.	Pass
		All test samples must meet a bifurcate release wire to wire holder tensile strength of ≥ 5.0 lbf.	Pass
		All test samples must meet proximal inner member component joint tensile strength of ≥ 10.0 lbf.	Pass
		All test samples must meet an outer member proximal shaft to handle tensile strength of ≥ 26.0 lbf.	Pass
		All test samples must meet haemostasis valve tensile strength of ≥ 35.0 lbf.	Pass
5.2.6	Torsional Bond Strength	All test samples (bifurcate) must meet an inner member to hypotube torque of ≥ 3.5 in-oz.	Pass
		All test samples (limb) must meet an inner member to hypotube torque of ≥ 0.9 in-oz.	Pass
		All test samples must meet an outer member shaft to handle torque of ≥ 13.0 in-oz.	Pass
		All test samples (bifurcate) must meet a haemostasis valve torque of ≥ 13.0 in-oz.	Pass
		All test samples (bifurcate) must meet a prosthesis retention torque of ≥ 2.6 in-oz.	Pass
5.3.1	Dimensional Verification	All test samples (bifurcate) must meet an outer diameter that is +/-5% of the nominal diameter (after a 24 hour soak at 37°C). All test samples (limb) must meet an outer diameter that is between the maximum labeled treatable vessel diameter (immediately after deployment) and +5% of the	Pass

ISO 25539-1 Annex D Section	Annex D Test Name/ Test Purpose	Acceptance Criteria	Summary of Results
		nominal diameter (for 24 mm limb) or +1.0 mm greater than the nominal diameter for all other limbs (after a 24 hour soak at 37°C).	
5.3.7	Water Permeability	All test samples must have a water permeability of ≤ 700 ml/min/cm^2.	Pass
5.3.8	Burst/ Circumferential Strength	All test samples must meet a circumferential tensile strength of ≥ 2.3 lbf/cm.	Pass
5.3.10	Flex/ Kink	All test samples (bifurcate) must meet a minimum radius of curvature of ≤ 38.1 mm. All test samples (limb) must meet a minimum radius of curvature of ≤ 25.4 mm.	Pass
5.3.12	Longitudinal Tensile Strength	All test samples must meet a maximum graft longitudinal tensile force of ≥ 10.0 lbf.	Pass
5.3.13	Migration Resistance	All test samples must have a displacement of ≤ 10 mm at a protocol defined force.	Pass
5.3.14	Pull Test for Modular Components (Or Overlapping Endoprostheses)	All test samples must meet a peak modular junction force of ≥ 0.6 lbf	Pass
5.3.15	Radial Force	All test samples must meet a maximum COF of ≤ 3.58 lbf for the smallest labeled vessel diameter after 24 hour exposure to 37°C water.	Pass
		All test samples (bifurcate) must meet a minimum COF for the largest label vessel diameter (after 24 hour exposure to 37°C) of ≥ 0.50 lbf.	Pass
		All test samples (limb) must meet a minimum COF for the largest label vessel diameter immediately after deployment of ≥ 0.20 lbf.	Pass
5.3.17	Strength of Graft to Stent/ Attachment System Bond	All samples must meet a peak force to complete separation of an internal stent to graft of ≥ 0.02 lbf.	Pass
		All test samples must meet a peak force to complete separation of a transrenal stent to graft of ≥ 15.0 lbf.	Pass
		All test samples must meet a peak marker band tensile force of ≥ 0.1 lbf.	Pass
5.3.18	Corrosion Assessment	For all test samples the average breakdown potential (Eb) of the INCRAFT samples shall be greater than or equal to that of the comparison AAA device.	Pass
		No preference for pitting near dissimilar material contact points in all test units that have dissimilar material contact points for the stents tested for pitting and crevice corrosion.	Pass
5.3.19	Fatigue and Durability Test	All test samples must meet the following: 1. Stent Fracture: No strut fractures unless	Pass

ISO 25539-1 Annex D Section	Annex D Test Name/ Test Purpose	Acceptance Criteria	Summary of Results
	(Pulsatile)	analysis of final design negates the impact of specific strut fractures on migration, sealing and/ or embolic events. 2. Fabric Holes: No holes or fabric abrasions yielding a hole with a major axis >1.34 mm in length. 3. Graft Attachment Separation: No stent or radiopaque marker separation from the graft that can enter the blood stream. 4. Suture Breaks: Suture breaks that lead to separation of a stent from the graft will constitute failure.	
		All test samples must meet the following: 1. No point on the cranial graft edge should migrate in excess of 7 mm through the test. 2. No separation of any transrenal stent apex from the graft edge. 3. The tensile force to remove the transrenal stent from the graft exceeds 15 lbs.	Pass
		For all test samples, the stabilization of the junction must be demonstrated and there must be no complete modular separation.	Pass
5.3.20	Stress/Strain Analysis	The fatigue safety factor (FSF) for each stent shall be ≥ 1.0 under both radial fatigue and axial fatigue loading.	Pass
N/A	Coating Lubricity	The tip and outer member of all test samples must have a pull force of ≤ 376 g.	Pass

In addition, to demonstrate the durability of the INCRAFT® AAA Stent Graft under physiological conditions, several tests were performed, including both computational analyses and physical testing. Acute potentiodynamic corrosion testing was performed for finished, final INCRAFT® stent graft (prosthesis). This testing was also used to assess galvanic corrosion. Potentiodynamic corrosion testing was performed on stents with evidence of fretting or other surface damage from pulsatile accelerated durability testing after 400 MM cycles.

Magnetic resonance (MR) safety of the INCRAFT® stent-graft (prosthesis) was performed based on the non-clinical in vitro tests, per ASTM standards, as recommended by FDA guidance, "*Establishing Safety and Compatibility of Passive Implants in the MR Environment*".

B. Animal Studies

In vivo animal study testing was conducted on **INCRAFT** to evaluate the safety of the device following implantation in ovine aorta and iliac arteries at 30 days and 180 days. **INCRAFT**, including an aortic extension in a sub-group of the animal cohort, was implanted in six (6) animals in the 30 day group, and seven (7) animals in the

180 day group. The tissue response to **INCRAFT** was evaluated histologically and the sealing capability and integrity of the bifurcate and iliac limb were evaluated angiographically and radiographically, respectively. Migration was evaluated angiographically. The effect of trans-renal implantation of the aortic bifurcate on renal function was also assessed. **INCRAFT**was assessed for eight endpoints within the *In Vivo* animal study. In conclusion, the study results demonstrated the following:

1) acceptable healing characteristics/ tissue response;
2) complete to near complete endothelialization;
3) generally complete coverage of stent graft struts and fabric by neointima;
4) no radiographic evidence of strut fractures;
5) high stent: artery ratio as expected for the animal model;
6) rating by the implanting physician that the devices performed flawlessly and the user requirements were met;
7) no clinical or histological indications of renal impairment; and
8) all animals remained in good general health for the study duration.

In addition, there was no device-related mortality and no evidence of adverse systemic effects.

C. Biocompatibility

The biocompatibility assessment performed for **INCRAFT** was based on the matrix for body contact and contact duration included in AAMI/ISO 10993-1:2009//(R) 2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (FDA recognition number: 2-156). **INCRAFT** is comprised of an implantable stent graft (aortic bifurcated prosthesis and limb prostheses) and a corresponding delivery system. For purposes of biocompatibility testing, the prosthesis (stent graft) was classified as an implant device, permanent contact (> 30 days), while the delivery system was classified as an external communicating device, circulating blood, limited exposure (< 24 hours).

INCRAFT successfully completed all required biocompatibility tests with all pre-specified acceptance criteria met and all tests passing with satisfactory results. These results are summarized in **Table 2**.

Table 2: Summary of Biocompatibility Performed

Biological Effect (Test)	Stent Graft Tested	Delivery System Tested
	Permanent (> 30 days)	**Limited (< 24 hours)**
In vitro Cytotoxicity	Yes	Yes
Sensitization	Yes	Yes
Irritation/ Intracutaneous Reactivity	Yes	Yes
Systemic Toxicity (Acute)	Yes	Yes
Material Mediated Pyrogenicity	Yes	Yes
Genotoxicity/ Mutagenicity		
• Ames Assay	Yes	Yes
• *In vitro* Mouse Lymphoma	Yes	Yes

Biological Effect (Test)	Stent Graft Tested	Delivery System Tested
	Permanent (> 30 days)	**Limited (< 24 hours)**
• *In vivo* Mouse Micronucleus	Yes	Yes
Hemocompatibility		
• Hemolysis	Yes	Yes
• Partial Thromboplastin Time (PTT)	Yes	Yes
• Platelet and Leukocyte Count	Yes	Yes
• Complement Activation	Yes	Yes
USP Physiochemical Tests	Yes	Yes
Rabbit Intramuscular Implant (including Chronic Toxicity)		
• 13 week	Yes	N/A
• 26 week	Yes	N/A
In vivo Thrombogenicity	N/A*	Yes

*****In vivo thrombogenicity of the stent prosthesis was assessed in 30- and 180-day in vivo safety studies.

D. Sterilization, Packaging and Shelf-Life

INCRAFT is sterilized using 100% Ethylene Oxide (EO) gas with heated aeration to allow for residual sterilant dissipation. A complete validation of the EO sterilization process (per ISO 11135: 2014, Second Edition: *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*; [FDA recognition number: 14-452], and 10993-7:2008: *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals;* [FDA recognition number: 14-408]) was successfully performed. In conclusion, the data demonstrated that **INCRAFT** meets all specified acceptance criteria, including sterilant residual limits, after one sterilization cycle.

Packaging validation was executed successfully per AAMI/ ANSI/ ISO 11607-1:2006: *Packaging for terminally sterilized devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*. All packaging and shelf life validation testing was performed on sterilized dummy devices that had been environmentally conditioned and transportation tested as per Cordis procedures. Environmental conditioning and transportation testing was performed per the testing protocol. Samples designated for two years of accelerated aging were also aged by the testing facility. The **INCRAFT** packaging configuration used in these studies reflects the final package configuration. All protocol acceptance criteria were met and the results of the testing provided sufficient evidence and data that the packaging configuration for **INCRAFT** is capable of maintaining package integrity for two (2) year shelf life.

X. SUMMARY OF PRIMARY CLINICAL STUDIES

The sponsor performed First-In-Human study (EU) and a pivotal study under Investigational Device Exemption (IDE) within the US (and Japan).

A. First-In-Human Study (EU)

A First-In-Human study was performed to evaluate preliminary safety and performance and the results were used to inform the design of the pivotal study.

B. Pivotal Study (IDE/ US)

A pivotal study was performed to establish a reasonable assurance of safety and effectiveness of **INCRAFT**. The primary objective of the "INSPIRATION" US pivotal clinical study was to evaluate the safety and effectiveness of **INCRAFT** in subjects requiring abdominal aortic aneurysm (AAA) repair. Data from this clinical study combined with safety and performance data from the First-In-Human study were the basis for the PMA approval decision. Subjects were enrolled in the pivotal study beginning July 2012 and ending August 2013. A summary of the study design is presented below.

C. Study Design

The study was a multicenter, prospective, open label, nonrandomized investigation. The study enrolled 190 subjects across 32 sites in the United States and Japan. Subjects were evaluated at 1 month, 6 months, and 1 year post-procedure. Follow-up continues annually until 5 years post-procedure.

D. Clinical Inclusion and Exclusion Criteria

Enrollment in the study was limited to patients who met the following selection criteria as shown in **Table 3**.

Table 3: INSPIRATION Inclusion and Exclusion Criteria

Inclusion	Exclusion
Male or Female age 20 years or older	Vascular anatomy in which the placement of the stent-graft will cause occlusion of both internal iliac arteries or necessitates surgical occlusion of both internal iliac arteries
Proximal aortic neck is 17 - 31 mm in diameter	Subject has one of the following: • Aneurysm sac rupture or leaking abdominal aortic aneurysm: • Mycotic, dissecting, or inflammatory abdominal aortic aneurysm: • Clinically significant acute vascular injury due to trauma
Supra-renal aorta, at 20 mm above the anticipated landing location, is smaller than the nominal diameter of the aortic bifurcate prosthesis to be used	Significant aortic or iliac mural thrombus, plaque or calcification that would compromise fixation and seal of the device

Inclusion	Exclusion
Infra-renal aortic neck is ≥10 mm in length with supra-renal and infra-renal angulations ≤60°	A conical aortic neck defined as >3 mm distal increase over a 10 mm length in the planned seal zone
Subject has at least one of the following: AAA size > 5.0 cm; Increase of the AAA diameter of >0.5 cm over the last 6 months	Thoracic aortic aneurysm ≥45 mm
Abdominal treatment length (lowest renal artery origin to aortic bifurcation) ≥9.4 cm	Any aortic dissection
Aortic bifurcation >18 mm in diameter	Morbid obesity (BMI >40.0 kg.m^2) or other clinical conditions that limit required imaging studies or visualization of the aorta
Iliac landing zone ≥15 mm in length	Renal insufficiency (Creatinine > 2.0 mg/dL) or subject on renal dialysis
Iliac landing zone 7-22 mm in diameter	Known allergy or intolerance to nickel titanium (nitinol) , Polyethylene terephthalate **(**PET), or polytetrafluoroethylene (PTFE)
Minimum access vessel size of ≥5 mm	Known contraindication to undergoing angiography or anticoagulation (e.g. contrast allergies which cannot be treated)
Minimum overall AAA treatment length (from lowest renal artery to distal landing zone) of 128 mm	Connective tissue disorder (such as Marfan's Syndrome or Ehlers-Danlos Syndrome)
Women of child bearing potential must be non-pregnant, non-lactating, and not planning to become pregnant during the course of the trial; and have a negative urine or serum pregnancy test within 7 days prior to index procedure	Coagulopathy, bleeding disorder, or other hypercoagulable state
Provide written informed consent and as applicable written HIPAA authorization (For US sites only) prior to initiation of study procedures	Organ transplant recipient or subject requiring systemic immunosuppressant therapy
Willing to comply with the specified follow-up evaluation schedule	Cerebral vascular accident (CVA), MI, or intracranial bleeding within 3 months prior to the procedure
	Active infection or chronic systemic illness at the time of index procedure that may interfere with the study objectives
	Major surgical procedure within 1 month prior to the index procedure or pre-planned within 1 month afterwards
	Co-existing condition with a life expectancy of less than 2 years at time of procedure

Inclusion	Exclusion
	Current or planned participation in any other investigational drug or medical device clinical study that has not completed primary endpoint(s) evaluation
	Existing AAA surgical graft and/ or a AAA stent-graft system
	Other medical, social, or psychological issues that in the opinion of the investigator preclude the subjects from receiving this treatment, and the procedures and evaluations pre- and post-treatment

E. Primary Safety Endpoint

The primary safety endpoint for this study was the incidence of MAEs at 30 days post-procedure. MAE is defined as a composite of:

- Death
- Stroke
- Myocardial infarction
- New onset renal failure (requiring dialysis)
- Respiratory failure (requires mechanical ventilation)
- Paralysis/paraparesis
- Bowel ischemia (requiring surgical intervention)
- Procedural blood loss ≥1,000 cc

F. Primary Effectiveness Endpoint

The primary effectiveness endpoint was successful aneurysm treatment, which is a composite endpoint defined as meeting all of the following:

- Technical Success at the conclusion of the index procedure, defined as successful insertion of the delivery system through the vasculature and successful deployment of the device at the intended location. The endovascular graft must be patent, with absence of types I or III endoleaks or aneurysm sac rupture, at the time of procedure completion as confirmed by angiography or other imaging modality.
- Absence of post-operative aneurysm enlargement (growth >5 mm) or stent graft migration (>10 mm), compared to the one month size measurement at any time up to 1 year.
- Absence of post-operative conversion to open surgery, sac rupture, endoleak Type I/ III, or graft occlusion (including unilateral or bilateral limb occlusion) at any time up to 1 year.

G. Secondary Safety Endpoints

Secondary safety endpoints included the following:

- MAEs and the individual components at 180 days and 360 days compared with SVS Controls, wherever the appropriate control data is available. These

endpoints will be reported annually to 5 years.

- Procedure-related complications through 30 days, 180 days, 360 days and annually to 5 years.

H. Secondary Effectiveness Endpoints

Secondary effectiveness endpoints included the following:

- Aneurysm-related mortality at 30 days, 180 days, 360 days, and annually through 5 years.
- Technical Success at 30 days as confirmed by computed tomography (CT) or other imaging modality.
- Clinical utility measures to be compared with SVS Controls include:
  - Length of hospital stay (days) post index procedure;
  - Length of Intensive Care Unit (ICU) stay (hours) post index procedure;
  - Length of the Index procedure (minutes).
- Incidence of secondary interventions, or the need for secondary interventions, to repair vascular events or malfunctions which are related to device and/ or peri-graft complications at 1 month, 6 months, 1 year and annually to 5 years. Secondary intervention is any vascular event which requires intervention to repair the AAA or device. Indications for secondary intervention may include endoleaks, stent graft migration, occlusion, or aneurysm sac rupture.
- The incidence of secondary interventions within 1 year post-procedure, needed to prevent the occurrence of a significant event. Significant event being defined as: aneurysm enlargement (growth >5 mm), stent graft migration (>10 mm) compared to the one month size, endoleak type I/ III, graft occlusion, sac rupture.
- Device-related events at 1 month, 6 months, 1 year and annually to 5 years. The device-related event may include:
  - Aneurysm enlargement - defined as an increase in maximum aneurysm cross sectional diameter >5 mm compared to the 1 month measurement;
  - Endoleak(s);
  - Aneurysm sac rupture;
  - Fracture(s);
  - Delivery system malfunction;
  - Device malfunction;
  - Stent graft migration – evidence of proximal or distal movement of the stent graft >10 mm relative to fixed anatomic landmarks compared with 1 month;
  - Graft occlusion (including unilateral or bilateral limb occlusion);
  - Conversion to open surgery.

I. Accountability of PMA Cohort

Overall, both subject accountability and imaging compliance were excellent. One hundred and ninety subjects were implanted with **INCRAFT** and seen through discharge. Ninety nine percent (99%) of the eligible subjects (189/190) completed 1 month follow-up visit. The visit compliance rate was 97% (182/188) at 6 months, 97% (177/183) at 1 year, 94% (161/172) at 2 years and 92% (148/161) at 3 years.

Three (3) subjects withdrew consent after 6 months but prior to the 1 year visit, 5 subjects withdrew after the 1 year but prior to the 2 years visit, and 4 subjects withdrew after the 2 years but prior to the 3 years visit.

There was at least 90% imaging compliance up to the 1 year visit with suitability for evaluating endoleaks, enlargement, migration, and stent fracture. There were two (2) conversions to open surgery after the 6 month visit but prior to the 1 year visit and the devices were explanted in each case. Beyond the 1 year visit, there was at least 85% imaging compliance at 2 years and at least 79% imaging compliance at 3 years with suitability for evaluating endoleaks, enlargement, migration, and stent fracture.

J. Study Population Demographics and Baseline Parameters

The average age of the overall population was 73.8 years, which is within the expected age average range for EVAR trials. The majority of the subjects were male (90%), which was anticipated given the disease prevalence is more common in males. Sixty-nine percent (69%) were white/Caucasian and 30% were Asian, primarily driven by the enrollment of subjects from Japan. The large majority of the subjects (176/190, 92.6%) were current or former smokers. Given the age of this population, the cardiovascular comorbidities of this subject population were expected, such as hypertension (78%) and hypercholesterolemia (72%).

All 190 subjects had a pre-procedural CT scan with contrast and 115 also had CT scan without contrast. The baseline aneurysm and anatomical measurements are provided in **Table 4**.

Table 4: Baseline Aneurysm Characteristics

	INCRAFT® ITT** - All Subjects	
Measure	**Core Lab N = 188**	**Site Reported N = 190**
Imaging Characteristics		
CT With Contrast	98.9% (188/190)	100.0% (190/190)
CT Without Contrast	N/A	60.5% (115/190)
Aneurysm Measurements from CT Scan		
Supra-renal Aortic Diameter (mm)		
Mean ± SD (N)	23.6 ± 2.50 (188)	23.9 ± 2.56 (189)
Median	23.50	24.00
Range (min, max)	18.00, 31.50	17.00, 30.00
Aortic Neck Diameter at start of cranial Attachment (mm)		
Mean ± SD (N)	21.7 ± 2.68 (188)	22.6 ± 2.70 (190)
Median	22.00	23.00
Range (min, max)	15.50, 30.00	17.00, 31.00
Distance to Lowest RA origin (Cranial) (mm)		
Mean ± SD (N)	N/A	0.0 ± 0.12 (73)
Median		0.00
Range (min, max)		0.00, 1.00
Distance to Lowest RA origin (Caudal) (mm)		
Mean ± SD (N)	N/A	2.0 ± 5.61 (106)

Median		1.00
Range (min, max)		0.00, 45.00
Aortic neck Constant Reference Diameter at 10 mm inferior (mm)		
Mean ± SD (N)	22.2 ± 3.81 (188)	22.6 ± 3.03 (190)
Median	22.00	22.50
Range (min, max)	16.00, 50.00	16.00, 32.00
Maximum aortic aneurysm Sac Diameter (mm)		
Mean ± SD (N)	54.9 ± 6.90 (188)	55.7 ± 6.58 (190)
Median	53.95	54.00
Range (min, max)	43.30, 98.30	45.00, 100.00
Maximum aneurysm Sac Diameter (%)		
< 30 mm	0.0% (0/188)	0.0% (0/190)
30-39 mm	0.0% (0/188)	0.0% (0/190)
40-49 mm	20.2% (38/188)	3.2% (6/190)
50-59 mm	63.8% (120/188)	76.8% (146/190)
60-69 mm	13.3% (25/188)	16.3% (31/190)
70-79 mm	1.6% (3/188)	2.1% (4/190)
80-89 mm	0.5% (1/188)	1.1% (2/190)
≥ 90 mm	0.5% (1/188)	0.5% (1/190)
Aortic Diameter at Bifurcation (mm)		
Mean ± SD (N)	19.3 ± 5.50 (188)	25.2 ± 6.56 (190)
Median	18.00	23.00
Range (min, max)	11.00, 48.50	18.00, 52.00
Right caudal landing zone Diameter (mm)		
Mean ± SD (N)	13.8 ± 3.15 (188)	13.5 ± 3.36 (190)
Median	13.20	13.00
Range (min, max)	7.50, 27.00	7.00, 22.00
Distance to IIA origin (Cranial) (mm)		
Mean ± SD (N)	N/A	3.4 ± 4.92 (150)
Median		1.00
Range (min, max)		0.00, 20.00
Distance to IIA origin (Caudal) (mm)		
Mean ± SD (N)	N/A	4.7 ± 10.40 (26)
Median		0.00
Range (min, max)		0.00, 33.00
Left caudal landing zone Diameter (mm)		
Mean ± SD (N)	13.7 ± 2.91 (188)	13.0 ± 3.01 (190)
Median	13.15	13.00
Range (min, max)	8.00, 24.00	7.00, 21.00
Distance to IIA origin (Cranial) (mm)		
Mean ± SD (N)	N/A	3.0 ± 4.78 (154)
Median		1.00
Range (min, max)		0.00, 21.00
Distance to IIA origin (Caudal) (mm)		
Mean ± SD (N)	N/A	6.4 ± 9.66 (20)
Median		0.00
Range (min, max)		0.00, 30.00

Right minimum vessel diameter (mm)		
Mean ± SD (N)	6.8 ± 1.53 (187)	8.1 ± 1.86 (190)
Median	7.00	8.00
Range (min, max)	2.80, 11.10	5.00, 17.00
Left minimum vessel diameter (mm)		
Mean ± SD (N)	6.9 ± 1.50 (187)	8.1 ± 1.82 (190)
Median	7.10	8.00
Range (min, max)	3.30, 11.70	5.00, 14.00

** Intent-to-treat (ITT) analysis set includes all subjects who had the aortic bifurcate device introduced into the body.

K. Procedural Data

The average procedure time was 102.7 minutes with 47.5 minutes from the time of entry of the delivery system to final angiogram. The average hospital length of stay was 2.7 days with an average of eight (8) hours in the ICU. Ninety four (94%) percent of subjects had an estimated blood loss of <500 mL.

L. Technical Success

The INSPIRATION study evaluated technical success at the conclusion of the index procedure as one of the primary effectiveness endpoints and technical success at 1 month as one of the secondary effectiveness endpoints. The definition of technical success at the conclusion of the index procedure is successful insertion of the delivery system through the vasculature, successful deployment of the device at the intended location, the endovascular graft must be patent, with absence of types I or III endoleaks or aneurysm sac rupture, as confirmed by the completion angiography or other imaging modality. The definition of technical success at 1 month, is the endovascular graft must be patent, with absence of types I or III endoleaks or aneurysm sac rupture, up to 1 month post procedure completion as confirmed by CT or other imaging modality.

At the conclusion of the index procedure the rate of technical success was 94.1%. The reasons for not achieving technical success were related to 2 devices that were deployed at the unintended location and 9 Type I endoleaks present at the conclusion of the procedure. Both a technical and clinical review of the 2 cases related to deployment were performed. It revealed that the user failed to stabilize the white handle component of the INCRAFT® Delivery System during the pulling process of the fixation release wire. The 9 Type I endoleaks all resolved by the 1 month follow-up time point.

By the 1 month post procedure, the rate of technical success was 100%. The grafts were patent. There were no Type I or III endoleaks or aneurysm sac ruptures.

M. Aneurysm-Related Mortality

Aneurysm-related mortality was defined as a death from AAA rupture, or death within 30 days of open aortic surgical or endovascular repair, or death from any subsequent procedure required to treat the same aneurysm. One subject died 2 days after the procedure due to a myocardial infarction. The death met the definition of aneurysm-related mortality because the death occurred within 30 days of the endovascular repair. A comparison of the rates of aneurysm-related mortality is presented in **Table 5.**

Table 5: Aneurysm-Related Mortality

	INCRAFT ITT ** Subjects (N = 190)							
	30 Days		180 Days		1 Year		2 Years	3 Years
	INCRAFT® N = 190	Society of Vascular Surgery Controls N = 323	INCRAFT® N = 187	Society of Vascular Surgery Controls N = 320	INCRAFT® N = 182	Society of Vascular Surgery Controls N = 310	INCRAFT® N = 176	INCRAFT® N = 169
Aneurysm-related mortality	0.5% (1/190)	2.8% (9/323)	0.5% (1/187)	3.4% (11/320)	0.5% (1/183)	3.5% (11/310)	0.6% (1/176)	0.6% (1/169)

** Intent-to-treat (ITT) analysis set includes all subjects who had the aortic bifurcate device introduced into the body.
SVS Controls only through 1 year.

N. Safety Endpoint Results

The primary safety endpoint of the specified analysis for the INCRAFT® subjects was achieved and met the pre-planned performance goal for safety of <20%. The composite 30-day MAE rate was 3.2%. No subject developed renal failure, respiratory failure, paralysis/paraparesis, or bowel ischemia. A summary of the Primary Safety Endpoint is provided in **Table 6.**

Table 6: Primary Safety Endpoint Results

	INCRAFT ITT**
Primary Safety Endpoint	Total Subjects (N = 190) [95% CI]
MAE rate at 30 days*	3.2% (6/190) [- , 6.1%]
Death	0.5% (1/190)
Stroke	0.5% (1/190)
Myocardial Infarction	0.5% (1/190)
New onset renal failure (requiring dialysis)	0.0% (0/190)
Respiratory failure (requires mechanical ventilation)	0.0% (0/190)
Paralysis/ paraparesis	0.0% (0/190)
Bowel ischemia (requiring surgical Ix)	0.0% (0/190)
Procedural blood loss ≥ 1,000 cc	2.1% (4/190)

* The Upper Bound of one-sided exact binomial 95% CI.
** Intent-to-treat (ITT) analysis set includes all subjects who had the aortic bifurcate device introduced into the body.

The **INCRAFT** data were compared to an open surgery control group based on the Society of Vascular Surgery (SVS) Lifeline database. The overall rate of MAEs in the **INCRAFT** group at 30 days post-procedure was 3.2% as compared to 43.7% in the SVS Control group.

The overall rate of MAEs is 7.0% at 6 month, 10.9% at 1 year, 18.8% at 2 years, and 23.1% at 3 years. The overall MAE rates are primarily driven by the incidence of death, stroke, and myocardial infarction, all deemed unrelated to the INCRAFT AAA Stent Graft System by the CEC. The overall rate of major adverse events (MAE) and the components of the composite endpoint at each time point are provided in **Table 7**.

Table 7: MAE Rates through 3 years

Major Adverse Events *	**INCRAFT ITT ** Subjects (N = 190)**			
	6 Month	**1 Year**	**2 Years**	**3 Years**
MAE rate	7.0% (13/187)	10.9% (20/183)	18.8% (33/176)	23.1% (39/169)
Death	1.6% (3/187)	3.3% (6/183)	8.0% (14/176)	13.0% (22/169)
Stroke	1.6% (3/187)	2.2% (4/183)	5.1% (9/176)	7.7% (13/169)
Myocardial infarction	1.6% (3/187)	3.3% (6/183)	4.0% (7/176)	5.3% (9/169)
New onset renal failure (requiring dialysis)	0.0% (0/187)	0.0% (0/183)	0.0% (0/176)	0.0% (0/169)
Respiratory failure (requiring mechanical ventilation)	0.5% (1/187)	1.1% (2/183)	1.1% (2/176)	1.2% (2/169)
Paralysis / paraparesis	0.0% (0/187)	0.0% (0/183)	0.0% (0/176)	0.0% (0/169)
Bowel ischemia (requiring surgical intervention)	0.0% (0/187)	0.0% (0/183)	0.0% (0/176)	0.0% (0/169)
Procedural blood loss (≥ 1,000 cc)	2.1% (4/187)	2.2% (4/183)	2.3% (4/176)	2.4% (4/169)
MAE rate (excluding procedural blood loss)	4.8% (9/187)	9.3% (17/183)	17.6% (31/176)	21.9% (37/169)

* Safety endpoints presented in this table are cumulative.

** Intent-to-treat (ITT) analysis set includes all subjects who had the aortic bifurcate device introduced into the body.

O. Effectiveness Endpoint Results

The primary effectiveness objective for the clinical study required that the proportion of subjects with successful aneurysm treatment to 1 year be greater than 80%. In the **INCRAFT** cohort, 87.9% of subjects were determined to have a successful aneurysm treatment to 1 year. There were no postoperative aneurysm enlargements, migrations, or sac ruptures noted, as is shown **Table 8**.

Table 8: Primary Effectiveness Endpoint Results

	INCRAFT ITT**
Primary Effectiveness Endpoint	**Total Subjects (N = 190) [95% CI]**
Successful Aneurysm Treatment to 1-Year* †	87.9% (152/173) [83.0%, -]
Technical Success (Peri procedure)‡	94.1% (176/187)
Successful insertion of the delivery system	100.0% (190/190)
Successful deployment of device at intended location	98.9% (188/190)
Graft patency	100.0% (190/190)
Absence of type I/ III endoleak	95.2% (178/187)
Absence of sac rupture	100.0% (190/190)
Absence of post-operative aneurysm enlargement	100.0% (173/173)
Absence of post-operative migration	100.0% (172/172)
Absence of post-operative conversion	98.9% (173/175)
Absence of post-operative sac rupture	100.0% (175/175)
Absence of post-operative type I/III endoleak	98.3% (170/173)
Absence of post-operative graft occlusion	96.0% (168/175)

* The Lower Bound of one-sided exact binomial 95% CI.
** Intent-to-treat (ITT) analysis set includes all subjects who had the aortic bifurcate device introduced into the body.
† Successful Aneurysm Treatment is described as the composite endpoint of the following:
• Absence of post-operative aneurysm enlargement (growth > 5 mm) or migration (> 10 mm), compared to the one month size measurement at any time up to 1 year;
• Absence of post-operative conversion to open surgery, sac rupture, endoleak Type I/III, or graft occlusion (including unilateral or bilateral limb occlusion) at any time up to 1 year;
• Considered a Technical Success as defined below.
‡ Technical Success at the conclusion of the index procedure, defined as successful insertion of the delivery system through the vasculature and successful deployment of the device at the intended location. The endovascular graft must be patent, with absence of types I or III endoleaks or aneurysm sac rupture, at the time of procedure completion as confirmed by angiography or other imaging modality.

Secondary effectiveness endpoints were measured during the procedure/hospital stay (clinical utility) and then again at the 30 days, 180 days, 360 days and annually up to 5 years. The secondary effectiveness results are summarized in **Table 9**. The technical success at 1 month was 100% defined as graft patency with the absence of Type I or III endoleaks or sac rupture confirmed by imaging. There was 1 (0.5%) aneurysm-related mortality at 1 month and no more aneurysm-related mortality occurred after the 1 month time point through 3 years.

At 1 month, there were no new Type I/III/IV endoleaks. All Type IV endoleaks observed post index procedure were resolved by 1 month. No incidences of

aneurysm sac rupture, stent fracture, patency-related events, or conversion to open surgery were reported. No device malfunctions were reported by clinical sites. There was 1 secondary intervention performed for vascular injury post index procedure.

At 6 months, there were 3 subjects with stent fractures, 4 graft occlusions, 1 conversion to open surgery and 5 secondary interventions. There were no incidences of aneurysm sac rupture, type I or III endoleaks, aneurysm enlargement, or migration. Subjects with stent fractures and migration identified will continue to be included in the numerator and denominator for later time points.

At 1 year, there were 3 new type I endoleaks, 8 total subjects with stent fractures, 2 device malfunctions, 3 graft occlusions, 1 conversion to open surgery and 8 secondary interventions. There were no incidences of aneurysm enlargement, sac rupture or stent migration.

At 2 years, there were 11 aneurysm enlargement, 4 new type I endoleaks, 10 total subjects with stent fractures, 1 device malfunction, 1 graft occlusions, 1 limb migration and 7 secondary interventions. There was no incidence of sac rupture.

At 3 years, there were 23 total aneurysm enlargement (including 10 persistent aneurysm enlargement from 2 years), 2 new type I endoleaks, 1 new type III endoleak, 13 total subjects with stent fractures, 3 device malfunctions, 1 graft occlusion, 5 total limb migrations and 12 secondary interventions. There was no incidence of sac rupture.

Table 9: Secondary Effectiveness Results

Secondary Effectiveness Endpoints	INCRAFT ITT** Subjects (N = 190)					
	Peri-Procedure	1 Month	6 Months	1 Year	2 Years	3 Years
Technical success at 1-Month ‡	N/A	100.0% (188/188)	N/A	N/A	N/A	N/A
Aneurysm-related mortality§	N/A	0.5% (1/190)	0.5% (1/187)	0.5% (1/183)	0.6% (1/176)	0.6% (1/169)
Device-related events*	N/A	0.0% (0/181)	4.2% (7/167)	10.1% (16/159)	17.0% (24/141)	30.8% (40/130)
Aneurysm enlargement	N/A	N/A	0.0% (0/176)	0.0% (0/173)	7.1% (11/155)	16.9% (23/136)
Endoleaks (Type I)	N/A	0.0% (0/186)	0.0% (0/175)	1.8% (3/167)	2.7% (4/149)	1.6% (2/126)
Endoleaks (Type III)	N/A	0.0% (0/186)	0.0% (0/175)	0.0% (0/167)	0.0% (0/149)	0.8% (1/126)
Endoleaks (Type IV)	N/A	0.0% (0/186)	N/A	N/A	N/A	N/A
Aneurysm sac rupture	N/A	0.0% (0/189)	0.0% (0/183)	0.0% (0/176)	0.0% (0/161)	0% (0/146)
Fractures¤ ¥	N/A	0.0% (0/183)	1.7% (3/172)	4.9% (8/163)	6.8% (10/147)	9.6% (13/136)
Delivery system malfunction	4.2% (8/190)	N/A	N/A	N/A	N/A	N/A
Device malfunction¥	N/A	0.0% (0/189)	0.0% (0/183)	1.1% (2/176)	0.6% (1/161)	2.1% (3/146)
Stent graft migration***	N/A	N/A	0.0% (0/177)	0.0% (0/172)	0.6% (1/154)	3.7% (5/135)

Secondary Effectiveness Endpoints	INCRAFT ITT** Subjects (N = 190)					
	Peri-Procedure	1 Month	6 Months	1 Year	2 Years	3 Years
Graft occlusion¥	N/A	0.0% (0/189)	2.2% (4/183)	1.7% (3/176)	0.6% (1/161)	0.7% (1/146)
Conversion to open surgery¥	N/A	0.0% (0/189)	0.5% (1/183)	0.6% (1/176)	0.0% (0/161)	0.0% (0/146)
Incidence of secondary interventions, or the need for secondary interventions, to repair vascular events or malfunctions	N/A	0.5% (1/189)	2.7% (5/183)	4.5% (8/176)	4.3% (7/162)	8.2% (12/146)
Incidence of secondary interventions, within 1-Year post procedure needed to prevent the occurrence of a significant event	N/A	0.0% (0/189)	0.0% (0/182)	0.0% (0/176)	NA	NA

* - For aneurysm enlargement, endoleaks, fractures, and migrations, denominators are based on evaluable core lab data within the imaging windows: 1 Month (post-procedure - 90 days); 6 Month (91 - 270 days); 12 Month (271 - 540 days) 2 Years (541 - 900 days), 3 Years (901 - 1260 days)

- For aneurysm sac ruptures, malfunctions, graft occlusions, conversions to open surgery, and secondary interventions, denominators are based on evaluable site reported data in follow-up windows: 1 Month (procedure - 30 days); 6 Month (31 - 180 days); 12 Month (181 - 360 days) 2 Years (361 - 720 days), 3 Years (721 - 1080 days)

** Intent-to-treat (ITT) analysis set includes all subjects who had the aortic bifurcate device introduced into the body.

¥ - Subjects with fractures and migration identified will continue to be included in the numerator and denominator for later time points

§ Aneurysm-related mortality was defined as a death from AAA rupture, or death within 30 days of open aortic surgical or endovascular repair or death from any subsequent procedure required to treat the same aneurysm.

‡ Technical success at 1-Month was defined as a patent endovascular graft with absence of types I or III endoleaks or aneurysm sac rupture, up to 1 month post-procedure completion as confirmed by CT.

¥ A summary of conversions to open surgery, graft occlusions, device malfunctions and stent fractures are noted above table.

*** The migrations seen through 3 years only include limb migration, no migration of the bifurcate.

P. Financial Disclosure

Code of Federal Regulations (CFR) Title 21 Part 54 “Financial Disclosure by Clinical Investigators” regulation requires applicants who submit a marketing application to include certain information concerning the financial interests, arrangements, and payments to any clinical investigator conducting clinical studies to minimize bias. One sub-investigator had disclosable financial interests/ arrangements as defined in regulation. This information did not raise any questions about the adequacy of the data.

XI. OVERALL CONCLUSION

Based on the information provided in the PMA submission, Cordis concludes that valid scientific evidence for the purpose of determining the safety and effectiveness of **INCRAFT** is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its intended uses and conditions of use and that the benefits outweigh the risks.

XII. CDRH RECOMMENDATIONS/ DECISION

CDRH issued an approval order for the INCRAFT® AAA Stent Graft System on [month] [day] 2017. The following conditions of approval were cited in the approval order:

[Add any conditions of approval].

[To be determined by OC review of M004: The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR, Part 820)].