

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Transcatheter Septal Occluder (Atrial)

Device Trade Name: Occlutech[®] ASD Occluder and Occlutech[®] Pistol Pusher

Device Product Code: OZG

Applicant's Name and Address: Occlutech Holding AG
Vordergasse 3
8201 Schaffhausen
Switzerland

Date of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P200032

Date of FDA Notice of Approval: December 29, 2023

II. INDICATIONS FOR USE

The **Occlutech[®] ASD Occluder** is indicated for use in the transcatheter closure of *ostium secundum*-type atrial septal defects (ASD). Patients indicated for ASD closure have:

- Echocardiographic evidence of *ostium secundum*-type ASD,
- Clinical evidence of right ventricular (RV) volume overload (hemodynamically significant left-to-right shunt with $Q_p / Q_s \geq 1.5$ or RV enlargement).

The **Occlutech[®] Pistol Pusher** is a percutaneous, transcatheter pusher system designed for the delivery of the Occlutech[®] ASD Occluder to the implantation area. It is used via a minimally invasive catheter delivery system technique.

III. CONTRAINDICATIONS

The Occlutech ASD Occluder is contraindicated for the following:

- Any patient known to have extensive congenital cardiac anomaly which can only be adequately repaired by way of cardiac surgery.
- Any patient known to have sepsis within 1 month prior to implantation, or any systemic infection that cannot be successfully treated prior to device placement.
- Any patient known to have a bleeding disorder, untreated ulcer, or any other contraindications to aspirin therapy, unless another antiplatelet agent can be administered for 6 months.

- Any patient known to have a demonstrated intracardiac thrombi on echocardiography (especially left atrial or left atrial appendage thrombi).
- Any patient whose size (such as, too small for transesophageal echocardiography probe, catheter size) or condition (active infection, etc.) would cause the patient to be a poor candidate for cardiac catheterization.
- Any patient where the margins of the defect are less than 5 mm to the coronary sinus, inferior vena cava rim, AV valves, or right upper lobe pulmonary vein.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Instructions for Use (IFU) for the Occlutech ASD Occluder and the Occlutech Pistol Pusher (OPP).

V. DEVICE DESCRIPTION

The Occlutech ASD Occluder is a permanent implant consisting of two round, pre-shaped Nitinol wire mesh discs connected by a flexible and smaller waist (see Error! Reference source not found.). This middle connecting waist is available in various dimensions so that the ASD implant can accommodate a range of diagnosed *ostium secundum*-type ASD sizes.

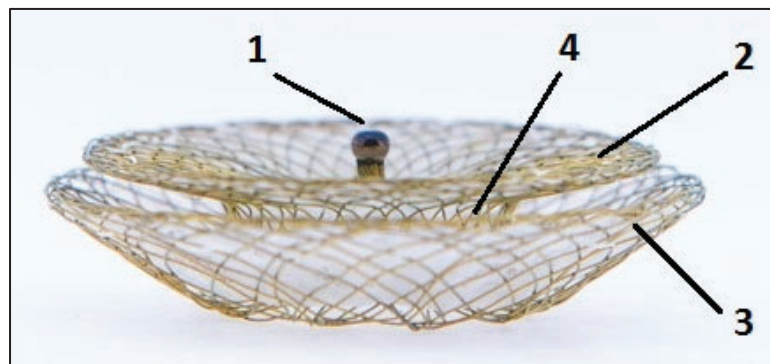
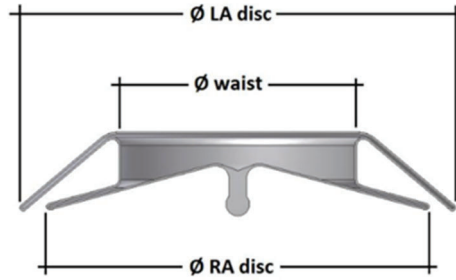


Figure 1: Product picture of Occlutech ASD Occluder with functional components. – (1): Ball-connector for pusher connection; (2) right atrial (RA) Disc with sutured polyester patch; (3) left atrial (LA) disc with sutured polyester patch; (4) waist with sutured polyester patch

The ball-shaped connector on the proximal (RA) disc allows connection with the Occlutech Pistol Pusher (OPP). When connected to the OPP, the Occlutech ASD Occluder and OPP can be loaded into a suitable delivery sheath and advanced to the implant site. The design properties allow the ASD Occluder to collapse and be pulled into a delivery sheath and return to the original shape once it is deployed at the implant site. When properly positioned in the ASD, the device will occlude the defect. Three polyester patches are sewn into both discs and the waist using sutures, to aid in stopping the blood flow through the ASD as well as to optimize tissue in-growth of the implanted occluder.

The ASD Occluder sizes are identified by the three dimensions as shown below in **Figure 2** below. The ASD Occluder is available in a range of sizes as summarized in **Table 1**.



Ø LA Disc: Diameter of distal disc [mm]
 Ø RA Disc: Diameter of proximal disc [mm]
 Ø Waist: Waist Diameter [mm]

Figure 2: Occlutech ASD Occluder dimensions for sizing

The Occlutech Pistol Pusher (OPP, **Figure 32**) is an accessory device used in the delivery of the Occlutech ASD Occluder. Using the OPP, the Occlutech ASD Occluder is loaded into and advanced through the delivery sheath across the atrial septal defect (ASD). Once introduced across the ASD, the physician can deploy the ASD Occluder with the help of this pusher accessory.

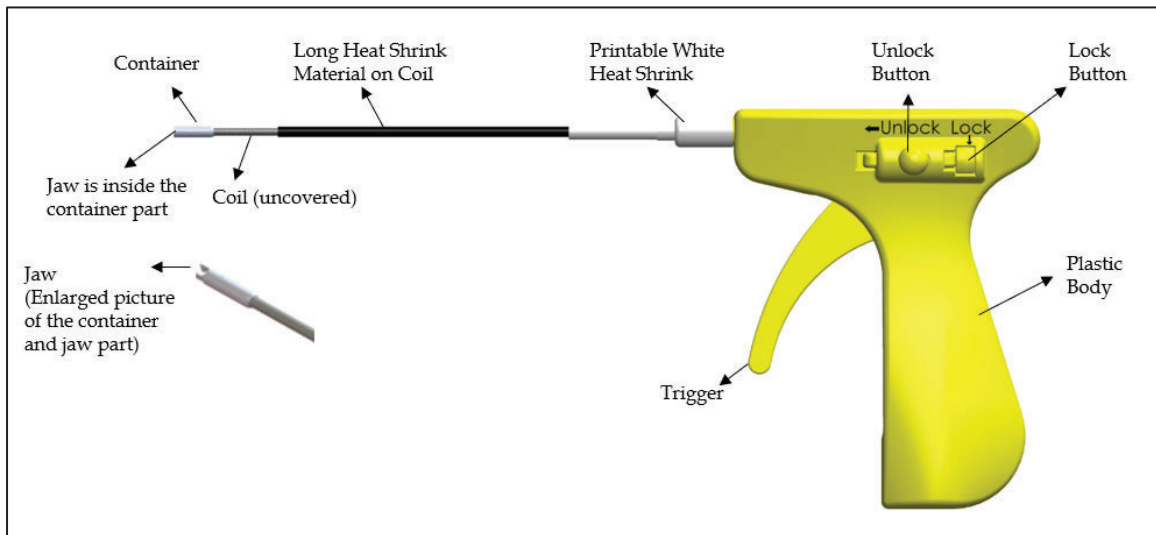


Figure 32: The Occlutech® Pistol Pusher (OPP)

The distal OPP part consists of jaws that can directly grab and fix the ball-connector of the Occlutech ASD Occluder. In the unconnected state, a container encloses these jaws. The proximal OPP section including the colored pistol grip houses the trigger mechanism for moving the pusher jaws. Pulling back the trigger mechanism advances the jaws out of the container and opens them. The trigger release closes the OPP jaws and retracts them into the container. The pistol grip also houses a mechanism for locking the complete system to prevent unintentional release of the Occlutech ASD Occluder (unlock/lock button; see **Figure 32**). The OPP body connects the distal and proximal parts of this accessory and consists of an outer coil with a polymer heat-shrink lamination and an inner wire.

The OPP is available in the length of 120 cm and is manufactured with four different jaw and container sizes for compatibility with the different ball connectors located on the proximal disc of the Occlutech ASD Occluder.

To facilitate size-matching between the implant and its accessory, the color of the OPP handle with locking mechanism is the same as the color-code sticker attached to the primary packing (Tyvek pouch) of the ASD Occluder. The color-code chart is depicted in the background colors in **Table** detailing the size range of the OPP.

Table 1: Occlutech Pistol Pusher Article Numbers and Dimensions

Occlutech Pistol Pusher Article No. (color-code reference)	Outer diameter of the OPP container [mm]
38PP125 (light blue)	2.13
38PP165 (yellow)	2.73
38PP185 (purple)	2.93
38PP210 (blue)	3.23

Table 2 provides the available Occlutech ASD Occluder article numbers and their device sizes, along with their compatible OPP article numbers, and the recommended Occlutech Delivery Set III (ODS III) delivery set article numbers.

Table 2: Occlutech ASD Occluder Device Sizes and Compatible Occlutech Pistol Pushers and Recommended Occlutech Delivery Systems

Occlutech ASD Occluder Article no.	Occlutech Delivery Set III (ODS III) Article no.	Occlutech Pistol Pusher (OPP) Article no.	Ø Waist [mm]	Ø LA Disc [mm]	Ø RA Disc [mm]	Atrial Septal Defect (ASD) Size (D) [mm]
37ASD06P	98DS007	38PP125 (light blue)	6	16.5	12.5	$5 < D \leq 6$
37ASD07P	98DS007	38PP125 (light blue)	7.5	18	14	$6 < D \leq 7.5$
37ASD09P	98DS007	38PP125 (light blue)	9	20,5	16,5	$7.5 < D \leq 9$

Occlutech ASD Occluder Article no.	Occlutech Delivery Set III (ODS III) Article no.	Occlutech Pistol Pusher (OPP) Article no.	Ø Waist [mm]	Ø LA Disc [mm]	Ø RA Disc [mm]	Atrial Septal Defect (ASD) Size (D) [mm]
37ASD10P	98DS007	38PP125 (light blue)	10.5	22	18	$9 < D \leq 10.5$
37ASD12P	98DS009	38PP165 (yellow)	12	27	23	$10.5 < D \leq 12$
37ASD13P	98DS009	38PP165 (yellow)	13.5	28.5	24.5	$12 < D \leq 13.5$
37ASD15P	98DS009	38PP165 (yellow)	15	30	26	$12 < D \leq 15$
37ASD16P	98DS009	38PP165 (yellow)	16.5	31.5	27.5	$15 < D \leq 16.5$
37ASD18P	98DS009	38PP165 (yellow)	18	33	29	$15 < D \leq 18$
37ASD19P	98DS010	38PP165 (yellow)	19.5	34.5	30.5	$16.5 < D \leq 19.5$
37ASD21P	98DS011	38PP185 (purple)	21	36	32	$18 < D \leq 21$
37ASD24P	98DS011	38PP185 (purple)	24	39	35	$21 < D \leq 24$
37ASD27P	98DS012	38PP210 (blue)	27	42	38	$24 < D \leq 27$
37ASD30P	98DS012	38PP210 (blue)	30	45	41	$27 < D \leq 30$
37ASD33P	98DS012	38PP210 (blue)	33	48	43	$30 < D \leq 33$

The Occlutech ASD Occluder is packaged with its compatible OPP, Instructions for Use (IFU) and Patient Card.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of an atrial septal defect including surgical closure and other transcatheter devices indicated for the closure of *ostium secundum*

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

VII. MARKETING HISTORY

The Occlutech ASD Occluder and its accessory the Occlutech Pistol Pusher have been made available in the countries as listed in **Table 1**.

Table 1: List of Countries where the Occlutech ASD Occluder and Occlutech Pistol Pusher have been marketed

Device	Country
Occlutech ASD Occluder	Algeria, Argentina, Australia, Austria, Azerbaijan, Bangladesh, Belarus, Belgium, Brazil, Bulgaria, Canada, Chile, Colombia, Costa Rica, Cuba, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, Egypt, Finland, France, Georgia, Germany, Greece, Hong Kong, Hungary, Iceland, India, Indonesia, Iran, Ireland, Israel, Italy, Japan, Jordan, Kenya, Kingdom of Saudi Arabia, Lebanon, Lithuania, Luxembourg, Malaysia, Mauritius, Mexico, Mongolia, Morocco, Myanmar, Netherlands, New Zealand, Nigeria, Pakistan, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sri Lanka, Sudan, Sultanate of Oman, Sweden, Switzerland, Taiwan R.O.C., Tanzania, Thailand, Tunisia, Turkey, Turkmenistan, Ukraine, United Arab Emirates, United Kingdom, Uruguay, Venezuela, Vietnam.
Occlutech Pistol Pusher	Austria, Belgium, Brazil, Bulgaria, Canada, Colombia, Costa Rica, Denmark, Ecuador, Finland, France, Germany, Georgia, Greece, Hungary, Iceland, Indonesia, Iran, Ireland, Israel, Italy, Latvia, Luxembourg, Myanmar, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Russian Federation, Slovakia, South Africa, Spain, Sweden, Switzerland, Thailand, Ukraine, United Kingdom, Vietnam.

The Occlutech ASD Occluder and its OPP accessory devices have not been withdrawn from marketing for any reason related to its safety or effectiveness.

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 Occlutech ASD Occluder and its OPP accessory.

Occlutech ASD Occluder

- Air embolism
- Allergic reactions
- Anesthesia reactions
- Apnea
- Arrhythmias
- AV-Fistula
- Bleeding (hemorrhage) requiring treatment
- Cardiac / vascular perforation
- Cardiac tamponade
- Death
- Embolization (peri & post procedural)
- Esophageal injury
- Femoral access complication
- Fever
- Hematoma
- Hypertension or Hypotension
- (Immediate) surgical interventions
- Infections, including endocarditis
- Pericardial effusions
- Pericarditis
- Post-pericardiotomy syndrome
- Pseudo aneurysm
- Pulmonary edema
- Seizure
- Stroke
- Tissue erosion
- Thrombus formation on device
- Thrombosis
- Valvular regurgitation

Occlutech Pistol Pusher

The adverse events that may occur during or after a procedure include but are not limited to:

- Cardiac arrhythmia
- Formation of blood clots, vascular injury, and occlusion due to existing vascular calcification and heart disease
- Unintentional injuries to the heart
- Injuries to the blood vessels
- Bleeding or secondary bleeding in the heart or pericardium due to injury of the heart
- Infection via the point of introduction
- Pulmonary embolism
- Arterial embolism
- Cardiac tamponade
- Perforation
- Cardiac arrest
- Damage of heart valves and other structures
- Death

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

IX. SUMMARY OF NONCLINICAL STUDIES

A. Laboratory Studies

Design verification testing, shelf-life evaluation, biocompatibility testing, sterility and packaging evaluation were conducted for both the Occlutech ASD Occluder and the OPP to ensure the design meets all the required inputs per the product specifications. The tests are summarized in **Tables 4** and **5** for the ASD Occluder and the OPP, respectively.

Occlutech ASD Occluder

Table 2: Occlutech ASD Occluder Functional, Shelf Life, Biocompatibility, and Sterility Testing

Test Suite	Test Description	Summary of Results
<i>Bench Tests</i>		
Device Durability	400 million cycles of device durability testing	Passed
Finite Element Analysis	Safety factor >1	Passed
Fatigue strength of Wires	To characterize the fatigue strength of the wires at baseline and after aging.	Characterization only. Results acceptable
Corrosion Resistance and Nickel Leaching Tests	Measurement and evaluation the crevice and pitting corrosion resistance.	Passed
	Evaluation of the nickel release rate.	Passed
Tensile strength test of ball-wire bundle connection joint	Tensile force resistance test on connection joint of ball-mesh.	Passed
Resistance against dislocation test (Retention force)	The largest size occluder was tested under clinically relevant pressures, followed by increasing pressure until the test sample dislocated from the sample holder	Passed
Occluder Functionality (at t=0, Baseline)	Functionality testing of the ASD Occluder with compatible delivery cable and delivery system in a simulated use, at baseline. Testing included visual inspection, dimensional control (pre-deployment and post-deployment), Load Force as well as the following sub-tests in a simulated use model: <ul style="list-style-type: none"> - Handoff Force - Advancement Force - Retraction Force - Deployment and Retrieval - Pull through force - Device Release 	Passed
<i>Shelf life</i>		

Test Suite	Test Description	Summary of Results
Occluder Functionality (After accelerated aging and real-time aging)	Functionality testing of the ASD Occluder with compatible delivery cable and delivery system in a simulated use, after accelerated aging and real time aging. Testing included visual inspection, dimensional control (pre-deployment and post-deployment), Load Force as well as the following sub-tests in a simulated use model: <ul style="list-style-type: none"> - Handoff Force - Advancement Force - Retraction Force - Deployment and Retrieval - Pull through force - Device Release 	Passed
<i>Biocompatibility</i>		
USP Rabbit Pyrogen Study , Material Mediated	Determination of potential pyrogenic response induced by an extract of the test article following intravenous injection in rabbits	Passed
ASTM Hemolysis Study	To evaluate the potential device causing hemolysis	Passed
SC5b-9 Complement Activation Assay	To evaluate the potential to activate the complement system	Passed
Skin Sensitisation Study	Skin Sensitisation Study in Guinea Pigs using the Magnusson and Kligman Method, to determine the sensitizing potential of the test item in guinea pigs by comparison with similarly treated control animals	Passed
In Vitro Cytotoxicity Test	To determine the potential cytotoxic activity on cultured mammalian cells	Passed
Intracutaneous Reactivity Test in Rabbits	To assess the potential of the test item to produce irritation following intradermal injection of extracts of the test item, using one polar and one non-polar extract	Passed
Acute systemic toxicity in the mouse	To evaluate the systemic response to extracts of the test item following injection into mice	Passed

Test Suite	Test Description	Summary of Results
Bacterial Reverse Mutation Assay	To evaluate the mutagenic potential of polar and non-polar test item extracts	Passed
In vitro Mammalian Cell Gene Mutation Test	To determine whether the test item induces genotoxicity (point mutations and/or gross chromosomal changes) at mouse lymphoma cells	Passed
Chemical Characterization	To evaluate the risk of chronic toxicity and carcinogenicity	No chemicals of toxicological concern identified.
<i>Sterilization Evaluation</i>		
Occlutech ASD Occluder Sterilization Validation	Overkill method (3x MPQ, 3x PPQ and EO residual testing) Needs to meet a minimum Sterility Assurance Level (SAL) of 10 ⁻⁶	Passed
<i>Packaging Evaluation</i>		
Shelf-life test of the sterile barrier system	<ul style="list-style-type: none"> • Evaluation of full package integrity • Visual Inspection of the seal • Seal strength in flexible barrier materials • Evaluation of peel characteristics • Verification of no leakage sites 	Passed
Sterile barrier system Shelf-life after real-time aging	<ul style="list-style-type: none"> • Evaluation of full package integrity • Visual Inspection of the seal • Seal strength in flexible barrier materials • Evaluation of peel characteristics • Verification of no leakage sites 	Passed
Transit Performance Test	Environmental conditioning and simulated transportation	Passed
Packaging (Sterile barrier system) Post Transit	Verification of packaging (sterile barrier) strength and integrity post transit performance testing: <ul style="list-style-type: none"> • Visual inspection of seal characteristics • Seal strength testing (peel force) • Seal/pouch integrity testing (bubble leak) 	Passed
Functionality test Flex II ASD Occluder Post Transit	Testing included visual inspection, dimensional control (pre-deployment and post-deployment), Load Force, and the following sub-tests in a simulated use model: <ul style="list-style-type: none"> - Handoff Force - Advancement Force - Retraction Force - Deployment and Retrieval 	Passed

Test Suite	Test Description	Summary of Results
	- Pull through force - Device Release	

Occlutech Pistol Pusher (OPP)

Table 3: OPP Functional, Shelf life, Biocompatibility, Sterility, and Packaging Testing

Test Suite	Test Description	Summary of Results
<i>Bench Tests</i>		
Product Functionality	Verify functionality of - locking/trigger mechanism - Jaw position at 180°, Occluder compatibility & flexibility after attachment - usable length	Passed
Jaw Release Distance Control	Using simulated model to verify jaw release distance of finished OPP, and success of container pointing process step.	Passed
Jaw and Container Analysis	To determine whether surface properties of Jaw & Container are acceptable and manufactured within specified tolerances	Passed
Pointing Depth Analysis	To verify dimensions of OPP container point depth and distance	Passed
Long Heat Shrink Control After Covering	To verify Long Heat Shrink covering dimensions	Passed
Flexibility and Kink Test	To verify ability of OPP to withstand flexural force which may cause kink	Passed
Torque Strength Test	To characterize the torque strength in simulated aortic arch test set-up	Passed
Coil-Container Tensile Test	Evaluate tensile strength of weld bond between coil and container	Passed
Fracture Test	To verify device integrity when OPP wrapped around cylinder with diameter equal to 10x PP heat shrink OD	Passed
Corrosion Resistance	To evaluate the OPP corrosion resistance	Passed
X-ray Visibility	To evaluate the visibility of OPP during the implantation procedure under fluoroscopic and echocardiographic imaging	Passed
<i>Shelf Life</i>		
Shelf-Life Validation Test after accelerated aging	To verify the OPP functionality after accelerated aging	Passed

Test Suite	Test Description	Summary of Results
<i>Biocompatibility</i>		
Cytotoxicity Test	To determine the potential cytotoxic activity on cultured mammalian cells	Passed
Skin Sensitization Study	To determine the sensitizing potential of the test item in guinea pigs by comparison with similarly treated control animals	Passed
Intracutaneous Reactivity Test	To assess the potential of the test item to produce irritation following intradermal injection of extracts of the test item, using one polar and one non-polar extractant	Passed
ASTM Hemolysis Study	To evaluate the potential to cause hemolysis	Passed
SC5b-9 Complement Activation Assay	To evaluate the potential to activate the complement system	Passed
Thrombogenicity Evaluation	To evaluate whether there is a thrombogenic effect due to the usage of Pistol pusher in animal study of the ASD Occluder	Passed
USP Rabbit Pyrogen Study	Determination of potential pyrogenic response induced by an extract of the test article following intravenous injection in rabbits	Passed
Acute Systemic Toxicity Test	To evaluate the systemic response to extracts of the test item following injection into mice	Passed
<i>Sterilization Evaluation</i>		
Sterilization Validation Evaluation	Overkill method (3x MPQ, 3x PPQ and EO residual testing) Needs to meet a minimum Sterility Assurance Level (SAL) of 10 ⁻⁶	Passed
<i>Packaging Evaluation</i>		
OPP Packaging Validation	<ul style="list-style-type: none"> • Drop Test • Visual inspection • Label wipe test • Liquid dye penetration • Seal tensile strength • Tests of Sterility 	Passed
OPP Packaging Validation after real time aging	<ul style="list-style-type: none"> • Visual Inspection • Bubble leak • Seal strength test 	Passed
Transit Performance Test	Environmental conditioning and simulated transportation tests	Passed
Packaging (Sterile barrier) Validation Post Transit	Packaging strength and integrity (peel force and bubble leak) testing post transit performance test	Passed

Test Suite	Test Description	Summary of Results
Functionality Test of OPP Post Transit	Full suite of bench and functionality tests post transit	Passed

Sterility and Shelf-life

The Occlutech ASD Occluder and the Occlutech Pistol Pusher (OPP) are single-use devices which are provided sterile via ethylene oxide (EO) sterilization. The sterilization cycle was validated to ensure successful sterilization to a Sterility Assurance Level (SAL) of 10⁻⁶.

Product and package stability testing of the Occlutech ASD Occluder and OPP were performed. Both devices and their packages were subjected to 2x sterilization, environmental conditioning, distribution cycling, accelerated and real-time aging. Performance testing for both devices and packaging integrity tests for both packages were conducted after all the aging and conditioning/cycling. The test results support a shelf-life of 2 years for the Occlutech ASD Occluder and 3 years for the Occlutech Pistol Pusher.

Magnetic Resonance Imaging (MRI) Compatibility

Non-clinical testing and MRI simulations were performed to evaluate the entire family of the Occlutech ASD Occluders. Non-clinical testing has demonstrated that the entire family of this device is MR Conditional. A patient with a Occlutech ASD Occluder can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined above, the Occlutech ASD Occluder is expected to produce a maximum temperature rise of 3.1°C after 15 minutes of continuous scanning (i.e., per pulse sequence).

Artifact Information: In non-clinical testing, the image artifact caused by the Occlutech ASD Occluder extends approximately 5 mm from this device when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

B. Animal Studies

In vivo GLP animal testing was performed to evaluate the safety and performance of the Occlutech ASD Occluder with the Occlutech Delivery Set (ODS) and the Occlutech Pistol Pusher (OPP). The animal study was performed using a porcine model and included an acute timepoint to assess the usability of the occluder with the delivery system and a chronic timepoint to assess the safety and performance of transcatheter ASD closure. The acute performance (deployment, positioning, and retrieval) of all device and delivery systems performed as expected and met customer requirements. Histopathology collected at the chronic timepoint demonstrated appropriate apposition of the occluder against the septal wall

with appropriate endothelialization. All requirements were met and demonstrated the Occlutech device met customer requirements and intended use.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of transcatheter Atrial Septal Defect (ASD) closure with the Figulla Flex II ASD Occluder for transcatheter closure of *ostium secundum*-type ASD in Germany and France. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

Note that the Occlutech ASD Occluder is identical to the Figulla Flex II ASD Occluder and was clinically evaluated as the Figulla Flex II ASD Occluder in the pre-market clinical trial.

A. Study Design

Patients were treated between October 10, 2012 and July 9, 2015. The database for this PMA reflected data collected through July 9, 2015 and included 176 patients. There were seven investigational sites.

The study was an open-label, prospective, multicenter, randomized, controlled pivotal clinical study to investigate the effectiveness and safety of the Figulla Flex II ASD Occluder transcatheter closure of *ostium secundum*-type atrial septal defects. The control group was the commercially available Amplatzer Septal Occluder (ASO). The study was performed according to ISO14155 (GCP) guidelines and the World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. The study was designed to enroll 300 subjects, aiming to obtain 222 evaluable subjects, with an interim analysis pre-specified once at least 70% of the evaluable cohort (156 subjects) was enrolled. The non-inferiority endpoint was met in the planned interim analysis, and the Data and Safety Monitoring Board (DSMB) recommended the early termination of the study. There were 176 patients randomized to receive the Figulla Flex II (n=116) or the Amplatzer ASO (n=60) in a 2:1 ratio, respectively.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the *Randomised, Controlled, Multi-Centre Trial of the Efficacy and Safety of the Occlutech Septal Occluder (Figulla Flex II) Compared to the AGA Septal Occluder (Amplatzer ASO) for Transcatheter Closure of Secundum Atrial Septal Defects in Patients* Study was limited to patients who met the following inclusion criteria:

- Was able to fluently speak and understand the language in which the study was being conducted
- Had an *ostium secundum* atrial septal defect
- Had a defect with a diameter of <38 mm
- Had a left-to-right shunt with a Qp/Qs ratio of $\geq 1.5:1$ or the presence of right ventricular volume overload as assessed by TTE or clinical symptoms due to the defect

- Had a distance of >5 mm from the margins of the defect(s) to the coronary sinus, atrioventricular (AV) valves and right upper pulmonary vein as measured by echocardiography
- Agreed to participate in the study and comply with the follow-up schedule
- Was willing to freely give (or Legally Authorized Representative was willing to freely give) Informed Consent prior to treatment
- Was willing to return for the post-treatment evaluation.

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

- Had multiple defects that could not adequately be covered by the device
- Had associated congenital cardiac anomalies that required cardiac surgery
- Had a known sensitivity to contrast media that could not be controlled adequately with pre-medication.
- Patient was participating in another clinical device or drug trial that had not completed its primary endpoint or that would clinically confound the current study endpoints or did not permit patients to participate in other studies. Typically, patients that were involved in the long-term surveillance phase of a clinical study were eligible.
- Had ostium primum atrial septal defects
- Had sinus venosus atrial septal defects
- Had partial anomalous pulmonary venous drainage
- Had pulmonary vascular resistance above 7 Woods units or a right-to-left shunt at the atrial level with a peripheral arterial saturation less than 94%
- Had a recent myocardial infarction, unstable angina, and decompensated congestive heart failure (CHF)
- Had right and/or left ventricular decompensation with ejection fraction of <30%
- Had active bacterial and/or viral infection
- Had any type of serious infection <1 month prior to the procedure
- Had malignancy where life expectancy was <2 years
- Had demonstrated intracardiac thrombi on echocardiography
- Weighed < 8 kg
- Had gastritis, gastric ulcer, duodenal ulcer, and other contraindications to aspirin therapy unless other anti-platelet agents could be administered for 6 months
- Had an unstable condition or was otherwise thought to be unreliable or incapable of complying with the requirements of the clinical investigational plan (CIP).
- Had any disorder that, in the opinion of the Investigator, might interfere with the conduct of the study.

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 1 month, 6 months and 12 months postoperatively. Preoperatively, the patients were screened to determine eligibility for the study. At screening, patients were assessed for study eligibility using the inclusion/exclusion criteria through their medical history, demographics, and

transthoracic echocardiography (TTE) and informed consent was obtained. Eligible patients were randomized to have their atrial septal defect closed using either the Figulla Flex II or the Amplatzer ASO device.

Postoperatively, the objective parameters measured during the study included ECG, vital signs, physical examination, and TTE, which were done the day after the procedure (Day 1), at 1 month, and at 6 months after the procedure. Adverse events and complications were recorded at all visits. **Table 6** summarizes the schedule of events and procedures.

Table 6: Schedule of Events and Procedures

	Screening	Pre-procedure	Day 0	Day 1	Follow-up 1	Follow-up 2	Follow-up 3
	Within 45 days of procedure	Randomization	Device implantation	Day after procedure but no later than 36 hrs post-procedure	1 month (\pm 1 week)	6 months (\pm 1 month)	12 months (\pm 1 month)
Written Informed Consent	X						
Inclusion/Exclusion Criteria	X						
IWRS Randomization		X					
Demographics ¹	X						
Medial History	X						
Physical Examination	X			X	X	X	
Vital Signs	X			X	X	X	
Clinical Laboratory Tests ²	X			X ³	X ³	X ³	
12 Lead ECG	X			X	X	X	
Trans Esophageal Echocardiography (TEE) or Intracardiac Echocardiography (ICE)			X ⁶			optional	
Transthoracic Echocardiography (TTE)	X			X	X	X	
Device Implantation			X				
Evaluation of Device Performance ⁴			X				
Concomitant Medications			X	X	X	X	X ⁷
Adverse Events ⁵			X	X	X	X	X

¹ Gender, age (years), height (cm) weight (kg)

²Standard Clinical laboratory tests to include Plt, LDH, PT>

³ At the follow up visit, clinical laboratory tests will be performed at the discretion of the investigator

⁴Device performance will be assessed by delivery performance, implant conditions and implant accuracy

⁵Adverse events and adverse device events

⁶TTE to be performed if TEE or ICE is not performed

⁷In patients below the age of 18 years, the telephone follow up should be performed with the legal representative in the presence of the enrolled subject.

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

3. Clinical Endpoints

Safety Endpoint

With regards to safety, the rates of major complications, minor complications and all other device or procedure related adverse events at 36 hours, 6- and 12-months post procedure were assessed. Major complications were defined as stroke, cardiac perforation with tamponade, endocarditis, repeat surgery, death, pericardial effusion with tamponade, arrhythmia requiring major treatment, and device embolization requiring surgery. Minor complications were defined as device embolization requiring percutaneous treatment, arrhythmia requiring medical therapy, vascular access site complications.

Primary Effectiveness Endpoint

With regards to effectiveness, the primary effectiveness endpoint is early effectiveness success rate, which is defined as the rate of a successful placement of the device, and successful closure of the defect without major complication, surgical reintervention, embolization or moderate or large residual shunt within 36 hours post procedure.

The following hypotheses were tested:

$H_0: R_{OCC} - R_{ASO} \leq -10.0\%$ versus $H_1: R_{OCC} - R_{ASO} > -10.0\%$

where

R_{ASO} = Early effectiveness success rate for the Amplatzer ASO occluder group

R_{OCC} = Early effectiveness success rate for the Occlutech occluder group

The primary analysis was based on the Per-protocol (PP) population. To confirm the results, the analysis was repeated for the Intention-to-treat (ITT) population. The hypotheses were tested using a non-inferiority test according to Farrington-Manning at a one-sided significance level of 0.025. Non-inferiority was concluded if the lower bound of corresponding two-sided 95%-confidence interval for the success rate difference was $> -10.0\%$.

Pre-Specified Interim Analysis

An interim analysis was planned to be performed when 156 patients were evaluable for the primary endpoint. Based on this interim analysis one of the following alternative decisions could be made:

- a. Stop the trial due to proven non-inferiority (reject null hypothesis)
- b. Stop the trial due to futility (accept null hypothesis)
- c. Continue the trial with a re-calculated sample size

The interim analysis was performed by the Data Safety Monitoring Board (DSMB) assisted by an independent statistician.

Secondary Effectiveness Endpoint

The secondary effectiveness endpoint is the rate of closure success (residual shunt is smaller than or equal to 2 mm) within 6 months post procedure, without the need for surgical repair. This endpoint was descriptively analyzed.

Additional Effectiveness Endpoint

The rate of complete closure (no residual shunt) at 6 months post procedure.

B. Accountability of the PMA Cohort

At the time of database lock, of 176 patients enrolled in the PMA study, 62% (109) patients are available for analysis at the completion of the study, the 12 month post-operative visit.

A total of 175 patients were randomized to receive either Figulla Flex II (n=116) or Amplatzer ASO (n=59). A total of 67 patients discontinued from the study; the most common reason for discontinuation was that the sponsor terminated the study prematurely based on the results of the interim analysis. **Table 8** summarizes the patient accountability .

Table 8: Summary of Patient Accountability

Number of Patients	Figulla Flex II	Amplatzer ASO	Total
	Number of Patients, n (%)		
Randomized	116 (100.0)	59 (98.3)	175 (71.7)
Follow-up Completed, total	74 (63.8)	35 (58.3)	109 (44.7)
Day 1	116 (100.0)	59 (98.3)	175 (71.7)
1-month Follow-up	116 (100.0)	54 (90.0)	170 (69.7)
6-month Follow-up	100 (86.2)	46 (76.7)	146 (59.8)
12-month Follow-up	74 (63.8)	35 (58.3)	109 (44.7)
Discontinued	42 (36.2)	25 (41.7)	67 (27.5)

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for an ASD study, and comparable to the expected population in the US. Mean age among the 175 patients in the Safety Population (all randomized patients) was 20.6 years. There were fewer male patients (60, 34.3%) in the Safety Population than female patients (115, 65.7%). Weight ranged from 13 kg to 125 kg overall, with a mean of 46.2 kg. **Table 9** displays the demographic characteristics at baseline for the Safety Population. **Table 10** summarizes the most common medical history for the Safety Population at Baseline.

Table 9: Demographic Summary by Treatment group

Parameter	Figulla Flex II Occluder (N=115)	Amplatzer ASO (N=60)
Age (years) Mean (SD)	20.4 (18.89)	21.1 (20.77)
Gender – n (%) Male Female	39 (33.9) 76 (66.1)	21 (35.0) 39 (65.0)
Weight (kg) Total Mean (SD)	45.8 (27.16)	47.0 (29.48)
Age 2-17 years n Mean	70 27.6	38 28.7

Min, Max	13,70	13,73
Age > 18		
n	45	22
Mean	74.1	78.6
Min, Max	45, 104	54, 125
Height (cm)		
Total		
Mean (SD)	143.0 (27.77)	143.3 (26.87)
BMI (kg/m²)		
Total		
Mean (SD)	19.9 (6.05)	20.3 (6.75)

Abbreviations: ASO =Amplatzer Septal Occluder; BMI=body mass index; Max=maximum; Min=minimum; SD=Standard Deviation

Table 10: Patient Medical History

Most Common Medical History –Body System	Figulla Flex II (N=115) n (%)	Amplatzer ASO (N=60) n (%)
Congenital/Chromosomal Abnormality ¹	115 (100.0)	60 (100.0)
Any Past and/or Concomitant Diseases or Past Surgeries/Interventions	115 (100.0)	60 (100.0)
Circulatory System	69 (60.0)	33 (55.0)
Head, Eyes, Ears, Nose, Throat	25 (21.7)	12 (20.0)
Respiratory System	21 (18.3)	13 (21.7)

¹ ASD was considered a congenital abnormality, all patients have this condition.

Among the 175 patients who underwent the procedure, the total mean defect size (diameter) was 15.69 mm: 16.02 mm for the Figulla Flex II group and 15.07 mm for the Amplatzer ASO group. The aortic rim was similar in size between the groups, but the other rims for the Figulla Flex II group were slightly smaller than those for the Amplatzer ASO group. The mean implant size was 17.84 mm for the Figulla Flex II group and 16.81 mm for the Amplatzer ASO group. **Table 11** summarizes the patients' ASD sizes.

Table 11: Summary of Patient ASD Characteristics

Parameter	Figulla Flex II (N=115)	Amplatzer ASO (N=60)
Defect Size (mm)		
Mean (SD)	16.02 (4.878)	15.07 (5.550)
Median	15.00	14.00
Min, Max	4.0, 31.0	5.3, 29.0
SVC Rim (mm)		
Mean (SD)	11.48 (4.293)	13.22 (4.932)
Median	11.00	13.00
Min, Max	1.4, 24.8	6.0, 28.0

Superior Rim (mm)		
Mean (SD)	11.64 (4.300)	13.40 (4.993)
Median	10.65	13.00
Min, Max	1.4, 24.8	5.0, 28.0
Aortic Rim (mm)		
Mean (SD)	5.88 (2.568)	5.61 (3.041)
Median	5.90	5.10
Min, Max	0.3, 14.0	0.0, 16.1
AV Valve Rim (mm)		
Mean (SD)	11.58 (4.126)	12.55 (5.112)
Median	11.00	12.00
Min, Max	4.4, 30.0	3.0, 25.0
CS Rim (mm)		
Mean (SD)	10.44 (4.077)	11.24 (4.464)
Median	10.00	11.00
Min, Max	0.0, 23.0	3.0, 24.0
Posterior Rim (mm)		
Mean (SD)	11.49 (4.233)	12.49 (4.204)
Median	11.00	12.00
Min, Max	0.6, 24.0	5.0, 27.0
Implant Size (mm)		
Mean (SD)	17.84 (5.692)	16.81 (6.224)
Median	17.00	16.00
Min, Max	6.0, 33.0	5.0, 36.0

Abbreviations: AV=atrioventricular; CS=coronary sinus; Max=maximum; Min=minimum; SD=standard deviation

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the safety cohort of the 175 patients who underwent transcatheter closure with either the Figulla Flex II ASD Occluder or the Amplatzer ASO. The safety information collected included Adverse Events (AEs), Adverse Device Effects (ADEs), Treatment-emergent Adverse Events (TEAEs), Serious Adverse Events (SAEs), Serious Adverse Device Effects (SADEs), deaths, major or minor or both major/minor complications, results of physical examinations, data on vital signs, ECG, and echocardiography, and data from clinical laboratory evaluations. The key safety outcomes and adverse effects are reported in **Tables 11 to 13**.

The rate of major complications was calculated for each group at time points of within 36 hours, within 6 months, and within 12 months, and are summarized in **Table 11**.

Table 11: Rates of Major Complications at Different Timepoints – Safety Population

Timepoint Post Procedure	Rate of Major Complications	
	Figulla Flex II (N= 115)	Amplatzer ASO (N= 60)
Within 36 hours (Day 0 + Day 1)		
No. of patients	115	60
Number of patients with major complications	3	4
Complication Rate	2.61 %	6.67 %
Within 6 months		
No. of patients	99	49
Number of patients with major complications	5	6
Complication Rate	5.05 %	12.25 %
Within 12 months		
No. of patients	76	39
Number of patients with major complications	6	6
Complication Rate	7.90 %	15.39 %

There were no patient deaths during the study. A total of 25 patients (14.3%) experienced serious adverse events (SAEs) during the study: 15 patients (13.0%) in the Figulla Flex II group and 10 patients (16.7%) in the Amplatzer ASO group. Two patients (1.7%) in the Figulla Flex II group and 3 patients (5.0%) in the Amplatzer ASO group experienced Serious Adverse Device Effects (SADEs). Among those SADEs were atrial flutter (1 patient in each group), atrial fibrillation in 1 patient (1.7%) in the Amplatzer ASO group, supraventricular tachycardia in 1 patient (0.9%) in the Figulla Flex II group, and device dislocation in 1 patient (1.7%) in the Amplatzer ASO group.

The most common Treatment-Emergent Adverse Event (TEAEs) (those occurring in \geq 5% of patients in either group) are displayed in **Table 12**. All TEAEs were considered mild or moderate with the exception of one patient with a severe TEAE of bronchitis in the Amplatzer ASO group; the bronchitis was not considered to be related to the study procedure or the study device, and the patient recovered with antibiotic treatment. TEAEs were considered possibly, probably, or definitely related to the study procedure or device in 70 of the 175 patients (40.0%) in the Safety Population: 42 patients (36.5%) in the Figulla Flex II group and 28 patients (35.0%) in the Amplatzer ASO group.

Table 12: Number (%) of Patients with Most Frequent TEAEs (\geq 5% for Any Group)

	Figulla Flex II (N= 115)	Amplatzer ASO (N= 60)	Total (N=175)
	n (%)	n (%)	n (%)
Total Patients with Any TEAE	82 (71.3)	43 (71.7)	125 (71.4)
Adverse Event			
Headache	13 (11.3)	8 (13.3)	21 (12.0)
Hematoma	13 (11.3)	3 (5.0)	16 (9.1)
Chest pain	9 (7.8)	2 (3.3)	11 (6.3)
Vomiting	6 (5.2)	5 (8.3)	11 (6.3)
Palpitations	7 (6.1)	2 (3.3)	9 (5.1)
Epistaxis	7 (6.1)	1 (1.7)	8 (4.6)
Infection	3 (2.6)	4 (6.7)	7 (4.0)

Groin pain	3 (2.6)	3 (5.0)	6 (3.4)
Respiratory tract infection	2 (1.7)	3 (5.0)	5 (2.9)
Device dislocation	1 (0.9)	3 (5.0)	4 (2.3)
Bronchitis	1 (0.9)	3 (5.0)	4 (2.3)

Abbreviations ASO = atrial septal defect; TEAE = treatment-emergent adverse event

Adverse device effects (ADEs), including Serious Adverse Device Effects (SADEs), were reported in 35/175 patients (20.0%): 24 patients (20.9%) in the Figulla Flex II group and 11 patients (18.3%) in the Amplatzer ASO group. The most common ADEs (those occurring in $\geq 1\%$ of patients in either group) are displayed in **Table 13**.

Table 13: Number (%) of Patients with Most Frequent Adverse Device Events ($\geq 1\%$ for any group)

	Figulla Flex II (N=115)	Amplatzer ASO (N=60)	Total (N=175)
	Patients n (%)	Patients n (%)	Patients n (%)
Total patients with any TEADE			
Adverse Device Event	24 (20.9)	11 (18.3)	35 (20.0)
Palpitations	6 (5.2)	2 (3.3)	8 (4.6)
Supraventricular extrasystoles	3 (2.6)	2 (3.3)	5 (2.9)
Tachycardia	3 (2.6)	0	3 (1.7)
Arrythmia	2 (1.7)	0	2 (1.1)
Atrial Fibrillation	1 (0.9)	1 (1.7)	2 (1.1)
Atrial Flutter	1 (0.9)	1 (1.7)	2 (1.1)
Atrioventricular Block	2 (1.7)	0	2 (1.1)
Extrasystoles	2 (1.7)	0	2 (1.1)
Device dislocation	0	2 (3.3)	2 (1.1)
Medical device Complication	1 (0.9)	1 (1.7)	2 (1.1)
Chest Discomfort	0	1 (1.7)	1 (0.6)
Device deployment issue	0	1 (1.7)	1 (0.6)
Epistaxis	1 (0.9)	1 (1.7)	2 (1.1)

Abbreviations: ASO = Amplatzer Septal Occluder; TEADE = treatment emergent adverse device event

2. Effectiveness Results

The analysis of effectiveness was based on the 173 evaluable patients in the Per Protocol (PP) Cohort and the 174 evaluable patients in the Intent-to-Treat Cohort (ITT) at 1-day, 1 month and 6-months post implantation. The ITT cohort consisted of all randomized patients who underwent transcatheter closure with one of the study devices and included 115 Figulla Flex II subjects and 59 Amplatzer ASO subjects. The PP cohort was defined as all patients in the ITT cohort without major protocol deviations and included 114 Figulla Flex II subjects and 59 Amplatzer ASO subjects.

Results were assessed by a Central Echo Core Lab. Device effectiveness was assessed one day after device placement as well as 1- and 6-month(s) post implantation.

Effectiveness outcomes are presented in Tables 14 to 15.

Primary Effectiveness Results

The primary effectiveness endpoint was the early effectiveness success rate, which was defined as the rate of a successful placement of the device, and successful closure of the defects without major complication, surgical re-intervention, device embolization or moderate or large residual shunt the day after procedure but no later than 36 hours after the procedure. The primary analysis was based on the per-protocol cohort (114 Figulla Flex II subjects and 59 Amplatzer ASO subjects). Analysis was also conducted on the intent-to-treat (ITT) cohort (115 Figulla Flex II subjects and 59 Amplatzer ASO subjects) and showed very similar results. Both assessments showed statistically non-inferior early success for the Figulla Flex II compared to the Amplatzer ASO for both the PP population (Table 14) and the ITT population.

Table 14: Primary Effectiveness – Early Effectiveness Success Rate (%)

Cohort	Figulla Flex II	Amplatzer ASO	P-value
Per-Protocol (PP)	94.7% (108/114)	88.1% (52/59)	0.000073

Secondary Effectiveness Results

The secondary effectiveness endpoint was the rate of closure success (residual shunt is smaller than or equal to 2 mm) within 6 months after the procedure, without the need for surgical repair. At 6 months post procedure, the secondary effectiveness endpoint was evaluated based on both the central read and the investigator’s assessment for the PP population, the results are summarized in Table 15. Results were similar for the ITT population.

Table 15: Secondary Effectiveness – Closure Success Rate (%) at 6 months – Per-Protocol (PP) Population

Assessment Source	Assessment	Figulla Flex II (N=114)	Amplatzer ASO (N=59)
Central Read	Closure Success Rate (%)	81.6%	71.2%

Additional Effectiveness Results

An additional effectiveness endpoint was the rate of complete closure (no residual shunt) at 6 months after the procedure. Results of this endpoint based on both Central Lab Read and Investigators’ assessment of the rates of complete closure in the PP Population indicated higher rates of closure with the Figulla Flex II (74.6%) when compared with the Amplatzer ASO (59.3%). Results were similar for the ITT population.

3. Subgroup Analyses

No sub-group analysis was performed.

4. Pediatric Extrapolation

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

E. 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 7 principal investigators and 34 sub-investigators. Of the 41 investigators, none were full-time or part-time employees of the sponsor, and none had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The sponsor has adequately disclosed all its financial arrangements. The information provided does not raise any questions about the reliability of the data.

XI. 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 System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

For the primary effectiveness endpoint, an early effectiveness success rate of 94.8% was achieved in the Occlutech device group. In the per-protocol population, the difference between the treatment and control groups was 6.60%, with a lower boundary of the one-sided 99.18% CI of -3.44%, which was higher than the NI margin of -10% (nominal $p=0.000073$). The primary endpoint was met. In addition, both the secondary and additional effectiveness endpoint results also indicated the closure effect remains durable over time. Therefore, device closure with the Occlutech ASD Occluder was non-inferior to the Amplatzer ASO device. The available clinical evidence provides a reasonable assurance that the Occlutech device is effective for transcatheter closure of *ostium secundum*-type ASD.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory and animal studies as well as data collected in a clinical study conducted to support PMA approval as described above. The results from the nonclinical laboratory and animal studies performed on the Occlutech ASD Occluder demonstrate that this device is suitable for long-term implant. The potential risks associated with the device include device and procedure-related complications such as

hematoma, pericardial effusion, cardiac rhythm disorders, device dislocation, major bleeding, headache, chest pain, epistaxis and vomiting.

There were 21 Serious Adverse Events (SAEs) in 15 patients (13.0%) in the Occlutech group and 15 SAEs in 10 patients (16.7%) in the Amplatzer ASD group. There were no deaths during the study. One of the important safety endpoints of the study is the major complications rate at 6- and 12-months post procedure, where major complications defined as stroke, cardiac perforation with tamponade, endocarditis, repeat surgery, death, pericardial effusion with tamponade, arrhythmia requiring major treatment, and device embolization requiring surgery. The rate of major complications within 6-months was 5.05% for the Occlutech device group and 12.25% for the Amplatzer ASD device group; The rate of major complications within 12-months was 7.9% for the Occlutech device group and 15.39% for the Amplatzer ASD device group. The available clinical evidence provides a reasonable assurance of safety of the Occlutech device for transcatheter closure of *ostium secundum*-type ASD.

C. **Benefit-Risk Determination**

The probable benefits of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The probable benefits include closure of the *ostium secundum*-type ASD and reduction of left to right atrial shunting. Patients may benefit from avoiding open heart surgical repair of the defect and cardiopulmonary bypass which may result in a shorter hospital stay and shorter recovery time. Based on the Occlutech ASD Trial results, a significant portion of patients undergoing ASD closure with the Occlutech ASD Occluder are expected to gain these probable benefits.

The probable risks of the Occlutech ASD Occluder include procedure-related serious adverse events (such as hematoma, pericardial effusion, cardiac rhythm disorders, device dislocation, major bleeding).

Further additional potential risks may occur, such as death, stroke, cardiac tissue erosion, device embolization, air embolism, seizure, thrombus formation on the device, cardiac perforation, esophageal injury, infection and immediate surgical interventions.

Additional factors to be considered in determining probable risks and benefits for the Occlutech ASD Occluder included:

1. Patient Perspective

This submission either did not include specific information on patient perspectives or the information did not serve as part of the basis of the decision to approve or deny the PMA for this device.

In conclusion, given the available information above, the data show that for percutaneous, transcatheter closure of *ostium secundum*-type ASD in patients meeting the criteria described in the indications for use statement, the probable benefits of the Occlutech device outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of the Occlutech ASD Occluder when used in accordance with its indications for use. As discussed in the previous sections, device safety compared to the approved Amplatzer ASO was favorable, and non-inferior rates of closure were observed at all intervals post-procedure. The benefits of transcatheter ASD closure, coupled with the favorable rates of closure success and low rates of postoperative complications, suggest that the probable benefits of using the Occlutech ASD Occluder outweigh the probable risks.

XIII. CDRH DECISION

CDRH issued an approval order on December 29, 2023.

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

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

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

Post-approval Requirements and Restrictions: See approval order.