SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Replacement Heart Valve
Device Trade Name:	TRIFORMIS RESILIA Tricuspid Valve
Device Procode:	LWR
Applicant Name and Address:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614
Date of Panel Recommendation:	None
Premarket Approval Application (PMA) Number:	P150048/S092
Date of FDA Notice of Approval:	October 27, 2025

The original PMA P150048 was for the aortic model of the device (Edwards Pericardial Aortic Bioprosthesis, model 11000A, and Edwards INSPIRIS RESILIA Aortic Valve, model 11500A) and was approved on June 29, 2017, with an indication for the replacement of native or prosthetic aortic heart valves. Subsequently under PMA P150048/S012, the mitral model of the device (Edwards Pericardial Mitral Bioprosthesis, model 11000M) was approved on August 9, 2018, for the indication of replacing native or prosthetic mitral heart valves.

The SSEDs to support the above indications are available on the following FDA websites and are incorporated by reference herein:

- P150048: https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150048B.pdf
- P150048/S012: https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150048S012B.pdf

The current supplement was submitted to introduce the tricuspid model of the device for the indication of replacing native or prosthetic tricuspid heart valves.

II. INDICATIONS FOR USE

The TRIFORMIS RESILIA Tricuspid Valve is indicated for the replacement of native or prosthetic tricuspid heart valves.

III. CONTRAINDICATIONS

The TRIFORMIS RESILIA Tricuspid Valve is contraindicated in patients who have untreatable hypersensitivity to nitinol alloys (nickel and titanium).

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the TRIFORMIS RESILIA Tricuspid Valve labeling.

V. DEVICE DESCRIPTION

The TRIFORMIS RESILIA Tricuspid Valve, model 11300T, as shown in Figure 1, is presently identical to the MITRIS RESILIA mitral valve, model 11400M. It is a low-profile stented prosthetic heart valve with three RESILIA bovine pericardial tissue leaflets attached to a lightweight nickel-titanium alloy (nitinol) wireform.

Figure 1. TRIFORMIS RESILIA Tricuspid Valve, model 11300T.

RESILIA tissue is created with a technology called Edwards Integrity Preservation, which incorporates a stable-capping anti-calcification process that blocks residual aldehyde groups known to bind with calcium. The technology also incorporates tissue preservation with glycerol, which replaces the traditional storage in liquid-based solutions such as glutaraldehyde with dry storage, which eliminates tissue exposure to the residual unbound aldehyde groups commonly found in glutaraldehyde storage solutions and the need for rinsing prior to implantation.

The superelastic nitinol wireform allows it to fold inward during implantation and is covered with a polyester fabric. A cobalt-chromium alloy band and polyester band surround the base of the valve below the wireform frame, providing structural support for the orifice. A compliant silicone-rubber sewing ring that is covered with a porous, seamless polytetrafluoroethylene (PTFE) cloth is attached to the wireform frame and facilitates tissue ingrowth and encapsulation.

The TRIFORMIS RESILIA Tricuspid Valve is available in sizes 25, 27, 29, 31 and 33 mm.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several alternatives for the treatment of diseased and malfunctioning tricuspid valves, including palliative medical therapy, surgical valve repair using an annuloplasty ring, transcatheter tricuspid valve repair or replacement. 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 TRIFORMIS RESILIA Tricuspid Valve has not been marketed in the United States or any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

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

- Death
- Allergic reaction/immunological response
- Angina
- Annulus (damage, dissection, tear)
- Aortic incompetence
- Arterial dissection
- Asystole and/or cardiac arrest
- Bleeding
    - Peri- or post-procedural
    - Anticoagulant related
    - Pericardial tamponade
    - Hematoma
    - Hemorrhage
    - Cerebrovascular
- Blood – Coagulopathy
- Blood – Hemolysis/hemolytic anemia
- Blood – Anemia
- Blood pressure alteration (hypotension, hypertension)
- Cardiac – Arrhythmias/conduction disturbances
- Cardiogenic shock
- Coronary artery (circumflex) injury
- Coronary artery (right) injury
- Deep vein thrombosis (DVT)
- Neurologic events
    - Stroke
    - Transient ischemic attack (TIA)
- Pericardial effusion
- Pleural effusion
- Pulmonary edema
- Pneumonia
- Prosthetic insufficiency – Regurgitation/stenosis
- Reduced exercise tolerance
- Renal failure, acute
- Renal insufficiency
- Respiratory failure
- Right ventricular muscle injury
- Thrombocytopenia, heparin induced (HIT)
- Thrombocytopenia, non-HIT
- Thromboembolism
    - Arterial, venous, peripheral, central
- Transvalvular or valvular leaking
- Valve dislodgement/instability
- Valve - Nonstructural dysfunction
    - Paravalvular leak
    - Leaflet impingement
    - Leaflet tissue damage (instruments /sutures)

- Disseminated intravascular coagulation (DIC)
- Embolism
- Esophageal tear/rupture
- Endocarditis
- Hypoxemia
- Infection – local, wound or systemic
- Myocardial infarction
- Multi-system organ failure (MOF)
    - Pannus
    - Prosthesis-patient mismatch (PPM; due to inappropriate sizing)
    - Distortion at implant
- Valve - Structural dysfunction/deterioration
- Valve - Thrombosis

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

IX. SUMMARY OF PRECLINICAL STUDIES

A summary of previously reported preclinical studies can be found in the SSEDs for the original PMA P150048 and PMA Supplement P150048/S012.

Additional testing performed under the specific conditions applicable to the tricuspid position is presented in Table 1 and Table 2.

Table 1. Summary of Bench Testing Under Tricuspid Conditions.

Test	Purpose	Results
Pulsatile flow testing	To determine the valve hydrodynamic performances (i.e., effective orifice area and regurgitation)	Prespecified minimum hydrodynamic performances met
Flow visualization	To qualitatively assess the flow characteristics of the valve	Acceptable flow patterns throughout the entire cardiac cycle; no retrograde jets or valvular incompetence observed

Table 2. Summary of Animal Study.

Animal model	Ovine
Sample size	7
Test articles	TRIFORMIS RESILIA Tricuspid Valve, model 11300T
Test methodology	Test valves were implanted in the tricuspid position of adult sheep for a duration of 140 to 142 days. Performance and safety of the test valves were assessed at implant and explant based on clinical health of the animals and by gross examination of the valves and animals at explant. An evaluation of ease of surgical handling was performed at implant. Valve and non-valve related pathology was assessed at explant.
Objective	To evaluate the following:

	• Adverse clinically significant consequences, including but not limited to:
	  o Valve thrombosis or valve related thromboembolism
	  o Leaflet calcification/mineralization
	  o Foreign body response (pannus formation, tissue overgrowth, and vegetative growth)
	  o Hemolysis as demonstrated by clinical pathology results
	  o Interference with adjacent anatomical structures
	  o Structural deterioration of the test valve
	  o Valve position and securement
	• Hemodynamic performance (cardiac outputs and tricuspid transvalvular peak pressures) and cardiac conduction (electrocardiogram)

Results	There was no evidence of structural or non-structural dysfunction. There was no interference with adjacent anatomical structures. There were no conduction abnormalities. Hemodynamic performance was within normal limits. Histopathologic and radiographic evaluation demonstrated appropriate healing with no adverse changes.
Conclusion	The study demonstrated the test valves were safe when implanted in sheep in the tricuspid position for the study duration.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a retrospective analysis of real-world off-label use data captured in electronic health records (EHRs) aggregated by a third party to establish a reasonable assurance of the safety and effectiveness of the TRIFORMIS RESILIA Tricuspid Valve in patients receiving surgical tricuspid valve replacement (TVR). The data source contained de-identified EHRs and claims data sourced from 19 U.S. integrated delivery networks, capturing approximately 18% of care delivered in the U.S. This data source was also linked with another third-party partner that provides open claims, social determinants of health data, and mortality data to augment data captured in the EHRs for mortality ascertainment.

The analysis above was the basis of the PMA approval decision. A summary of the clinical data is presented below.

A. Study Design

A data extract from the aggregate EHRs was performed of all patients that underwent surgical tricuspid valve replacement with a Magna Mitral (model 7000TFX), Magna Mitral Ease (model 7300TFX), or MITRIS RESILIA mitral valve (model 11400M) between January 1, 2016, and August 30, 2024, and met the following inclusion and exclusion criteria. Note that Magna Mitral and Magna Mitral Ease valves are earlier design iterations of MITRIS RESILIA valve and share the same core technological characteristics as MITRIS

RESILIA valve. Thus, the clinical performance of Magna Mitral and Magna Mitral Ease valves are considered applicable to MITRIS RESILIA valve.

1. Clinical Inclusion and Exclusion Criteria

   Patients were selected if they met the following inclusion criteria:

   - Age ≥18 years as of the index date
   - Evidence of primary or secondary tricuspid valve disease as of the index date, defined via evidence of TVR surgery within 10 days of the index date
   - An EHR encounter in the 365 days prior to and excluding the index date and in the day following the index date through day 365 (representing observability)

   Patients were not selected if they met the following exclusion criterion:

   - Unable to ascertain whether the device of interest was implanted in the tricuspid position or in the mitral position

2. Follow-up Schedule

   Patients were followed from the index date (device date) until the earliest of:

   - The safety or effectiveness outcome of interest (this was done for each outcome separately)
   - Last EHR encounter date within the year following the index date (for patients with no observed EHR encounters beyond day 365)
   - End of the study time period
   - Day 365 of follow-up (for patients with observed mortality or an EHR encounter beyond day 365)
   - Date of death (for patients with an observed death in the follow-up period with no subsequent EHR encounters)
   - Subsequent TVR or repair at least 11 days following the index date, in order to ensure that when evaluating non-reintervention outcomes, only those outcomes related to the index tricuspid valve replacement (not those related to a reintervention) were captured

3. Clinical Endpoints

   The clinical endpoints evaluated in the analysis included the following:

   - Safety outcomes:
     - Device failure requiring non-surgical (transcatheter) reintervention (e.g., valve-in-valve implantation)
     - Device failure requiring medical intervention (e.g., thrombolytic therapy specifically for valve thrombosis)
     - Valve thrombosis

    - Major paravalvular leak
    - Endocarditis
- Effectiveness outcomes:
    - All-cause mortality
    - Heart failure hospitalization
    - Surgical tricuspid reintervention
- Other outcomes of interest:
    - Pulmonary embolism
    - Major hemorrhage
    - Dialysis
    - Ventricular assist device implantation or heart transplant

The all-cause mortality rate was estimated using the Kaplan-Meier method; all other event rates were estimated using the cumulative incidence function (CIF) method, which treated death as a competing risk. In addition, Kaplan-Meier curves were calculated for all the clinical endpoints where death was handled as a censoring event for all endpoints other than all-cause mortality.

B. Accountability of the PMA Cohort

At the time of database extract, a total of 204 patients were identified to meet the inclusion and exclusion criteria of the study, as shown in Table 3, including 147 patients with a Magna Mitral Ease valve and 57 patients with a MITRIS RESILIA valve. These patients constituted the primary analysis population. The median [interquartile range; IQR] follow-up duration was 303 [82-1042] days (mean: 592). Patient-years follow-up were 131.1 at 1 year and 208.8 at 2 years. The cumulative patient-years accrued over the course of the entire study were 331.1.

Table 3. Patient Screening Attrition.

Screening Criteria	Number of Patients
Patients with TVR procedure (01/01/1980 – 08/30/2024)	1761
Patients with eligible TVR procedure[*]	1525
Patients with eligible TVR and device after 01/01/2016	288
Patients with eligible TVR and device within 10 days of each other	273
Patients with eligible TVR and device within 10 days of each other PLUS device linkable to a TVR (primary analysis population)	**204**
Single device, single TVR	167
Two devices within 10 days, TVR plus MVR within 10 days[†]	33
Two devices within 10 days, only TVR mentioned[‡]	4

TVR: tricuspid valve replacement; MVR: mitral valve replacement
[*]TVR codes: CPT 33465; ICD10PCS 02RJ0KZ, 02RJ0JZ, 02RJ08Z
[†]MVR Codes: CPT: 33430; ICD10PCS 02RG08Z, 02RG0JZ, 02RG0KZ, 02RG07Z
[‡]Double-checked for any mitral procedure; negative

Note: No patients were excluded for age. All patients were ≥18 years old at device (index) date.

C. Study Population Demographics and Baseline Characteristics

The demographics and baseline characteristics of the study population are summarized in Table 4, which are typical for surgical TVR procedures performed in the U.S. Nearly half of the patients (99/204; 48.5%) were undergoing TVR for active infective endocarditis, defined by an endocarditis diagnostic code within 6 weeks prior to the index date.

Table 4. Demographics and Baseline Characteristics of Study Population

Demographics and Baseline Characteristics	Summary Statistic (N=204)
Demographics	
Age (years, mean ± SD)	49.50 ± 18.05
18-64	72.1
65-74	15.2
≥75	12.7
Sex (% female)*	53.9
Race (%)*	
American Indian or Alaska Native	0.5
Asian	1.5
Black or African American	9.3
Native Hawaiian or Other Pacific Islander	2.0
Other Race	4.4
White	65.7
Ethnicity (%)*	
Hispanic or Latino	6.9
Not Hispanic or Latino	77.0
Medical history and comorbidities	
Stroke (%)	5.9
Atrial fibrillation (%)	29.9
Congenital heart disease (%)	20.1
Peripheral artery disease (%)	1.0
Coronary artery disease (%)	29.9
Myocardial infarction (%)	8.3
Ventricular assist device (%)	0.5
Hypertension (%)	51.0
Diabetes (%)	14.7
Chronic kidney disease (%)	19.6
End-stage renal disease (%)	7.4
Liver disease (%)	23.5

Demographics and Baseline Characteristics	Summary Statistic (N=204)
Cirrhosis (%)	8.3
Obesity (%)	13.2
Body Mass Index (median [IQR])[†]	25.30 [21.66, 28.41]
Heart failure (%)	48.0
Heart failure hospitalization within 1 year prior to index (%)	39.7
Tricuspid stenosis (%)	10.8
Pulmonary heart disease (%)	23.0
Infections (e.g., HIV, hepatitis, other bacterial and viral infections) (%)	68.6
Endocarditis (%)	
Current: ≤6 weeks prior to index date	48.5
Remote: >6 weeks prior to index date	4.9
Cancer (%)	12.7
Chronic lung disease/chronic obstructive pulmonary disease (%)	5.9
Home oxygen (%)	3.4
Esophageal varices (%)	0.5
Ascites (%)	7.4
Gastrointestinal bleed (%)	9.8
Smoking within the last year (%)	27.9
Substance use disorder (%)	33.3
Intravenous drug use (%)	33.8
Other mental health disorders (%)	61.8
Remote use of temporary mechanical circulatory support (>10 days prior to index date)	10.3
Prior cardiovascular surgery (>10 days prior to index date)	
Mitral valve replacement (%)	1.0
Other mitral surgery (%)	1.0
Aortic valve replacement (%)	0.0
Non-valvular cardiac surgery with cardiopulmonary bypass (%)	0.5
Heart transplant (%)	0.5

[*]Demographic information was not reported/missing in 9.3%, 16.7%, and 16.2% of eligible patient records for sex, race, and ethnicity, respectively.
[†]Body Mass Index (BMI) was not reported/missing in 10.8% of eligible patient records.

D. Safety and Effectiveness Results

1. Safety Outcomes

The key safety outcomes at 1 year are summarized in Table 5. Endocarditis was the most frequent safety event observed at 1 year, with a cumulative incidence of 37.8% (see sensitivity

analysis for more discussion), which is followed by major paravalvular leak, with a cumulative incidence of 1.2%. There were no device failures requiring medical intervention, transcatheter reintervention, or surgical reintervention (see sensitivity analysis for more discussion) through 1 year. There was also no valve thrombosis observed.

Table 5. Safety Outcomes at 1 Year.

Endpoint	No. of Events	CIF Estimate*
Device failure with transcatheter reintervention	0	0.0% (0.0-0.0%)
Device failure with medical intervention	0	0.0% (0.0-0.0%)
Surgical tricuspid reintervention	0	0.0% (0.0-0.0%)
Valve thrombosis	0	0.0% (0.0-0.0%)
Major paravalvular leak	2	1.2% (0.0-2.9%)
Endocarditis†	66	37.8% (30.3-45.2%)

CIF: cumulative incidence function

*Probability (incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the cumulative incidence function method, which treated death as a competing risk. The CIs were obtained using standard normal approximation.

†Endocarditis events may have been overcaptured due to carryover coding from the index hospitalization.

The Kaplan-Meier curves of the valve thrombosis, major paravalvular leak, and endocarditis outcomes through 2 years are shown in Figure 2 through Figure 4, respectively.

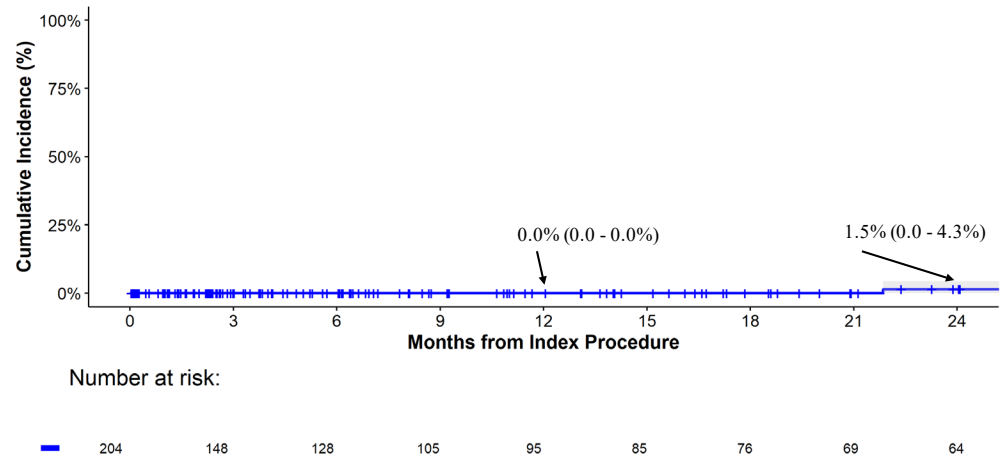

Figure 2. Kaplan-Meier Curve of Valve Thrombosis Through 2 Years.

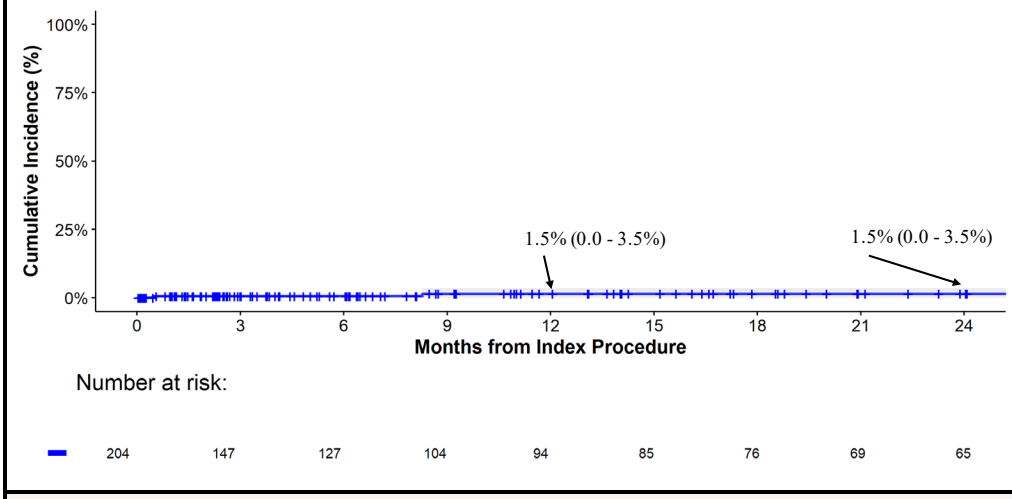

Figure 3. Kaplan-Meier Curve of Major Paravalvular Leak Through 2 Years.

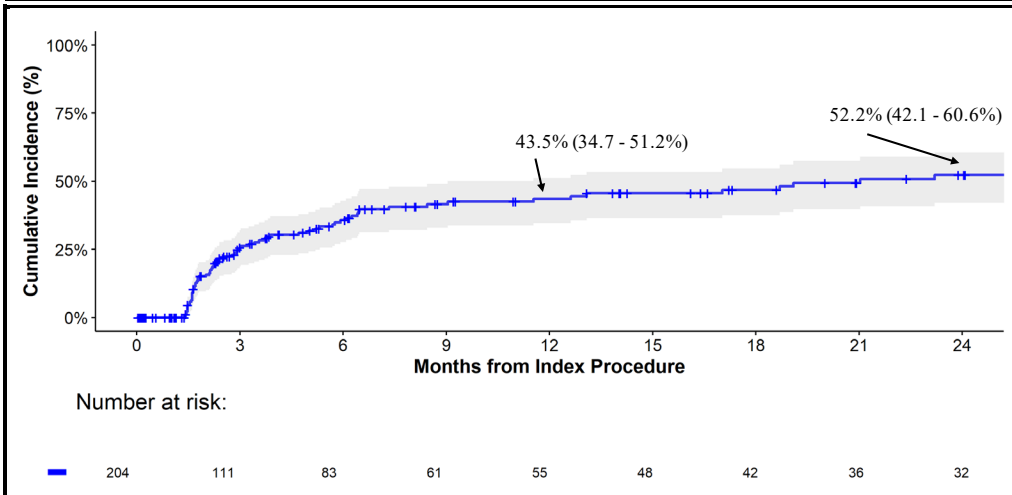

Figure 4. Kaplan-Meier Curve of Endocarditis Through 2 Years.

2. Effectiveness Outcomes

The key effectiveness outcomes at 1 year are summarized in Table 6. The all-cause mortality rate at 1 year was 26.5%. The cumulative incidence of heart failure hospitalization was 21.4% at 1 year.

Table 6. Effectiveness Outcomes at 1 Year.		
Endpoint	**No. of Events**	**CIF Estimate***
All-cause mortality	45	26.5% (19.4-33.0%)
Heart failure hospitalization	32	21.4% (15.5-27.3%)

CIF: cumulative incidence function

*Probability (incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the Kaplan-Meier method for all-cause mortality and using the cumulative incidence function method, which treated death as a competing risk, for heart failure hospitalization. The CI for all-cause mortality was obtained using the log-log transformation method based on Greenwood's formula for variance estimation. The CI for heart failure hospitalization was obtained using standard normal approximation.

The Kaplan-Meier curves of the all-cause mortality and heart failure hospitalization outcomes through 2 years are shown in Figure 5 and Figure 6, respectively.

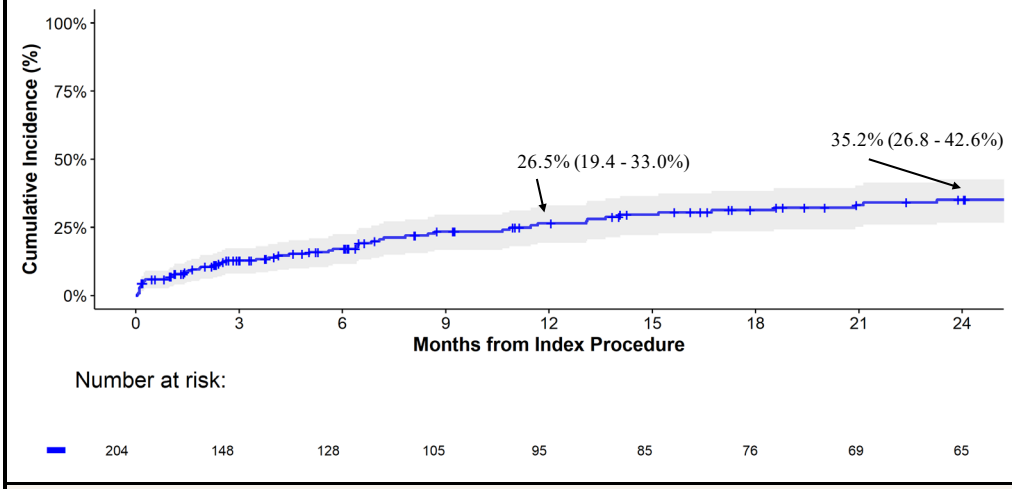

Figure 5. Kaplan-Meier Curve of All-Cause Mortality Through 2 Years.

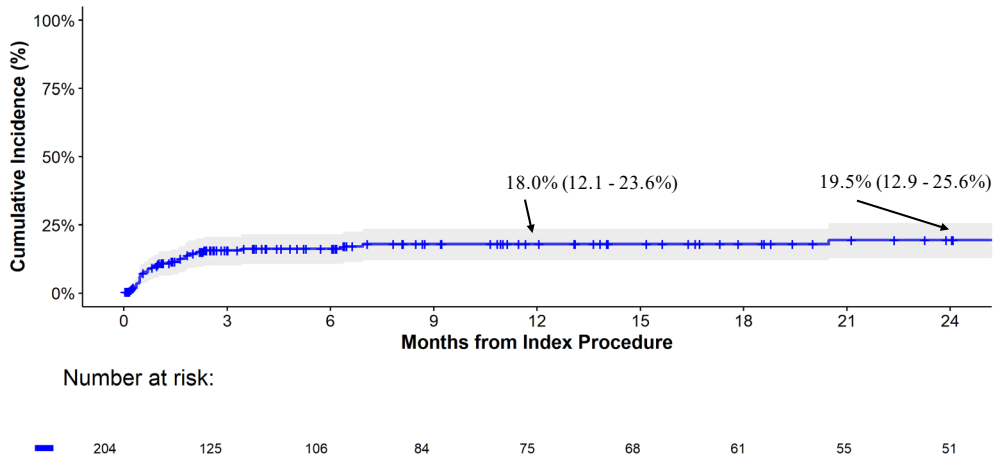

Figure 6. Kaplan-Meier Curve of Heart Failure Hospitalization Through 2 Years.

3. Other Outcomes of Interest

The results of other outcomes of interest at 1 year are summarized in Table 7.

Table 7. Other Outcomes of Interest at 1 Year.

Endpoint	No. of Events	CIF Estimate*
Pulmonary embolism	19	10.1% (5.8-14.5%)
Major hemorrhage	8	4.6% (1.4-7.8%)
Dialysis	15	7.8% (4.0-11.7%)
Ventricular assist device implantation or heart transplant	1	0.5% (0.0-1.5%)

CIF: cumulative incidence function

*Probability (cumulative incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the cumulative incidence function method, which treated death as a competing risk. The CIs were obtained using standard normal approximation.

The Kaplan-Meier curves of other outcomes of interest are presented in Figure 7 through Figure 10.

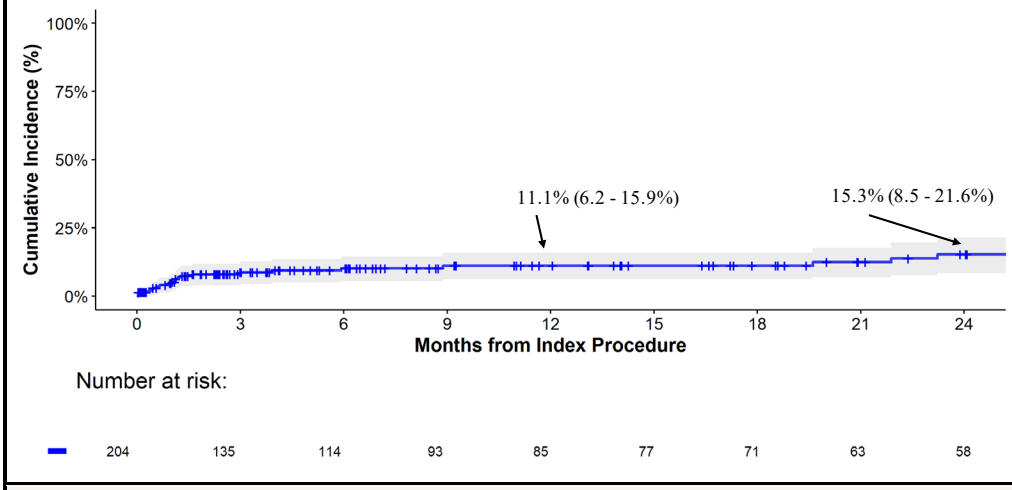

Figure 7. Kaplan-Meier Curve of Pulmonary Embolism Through 2 Years.

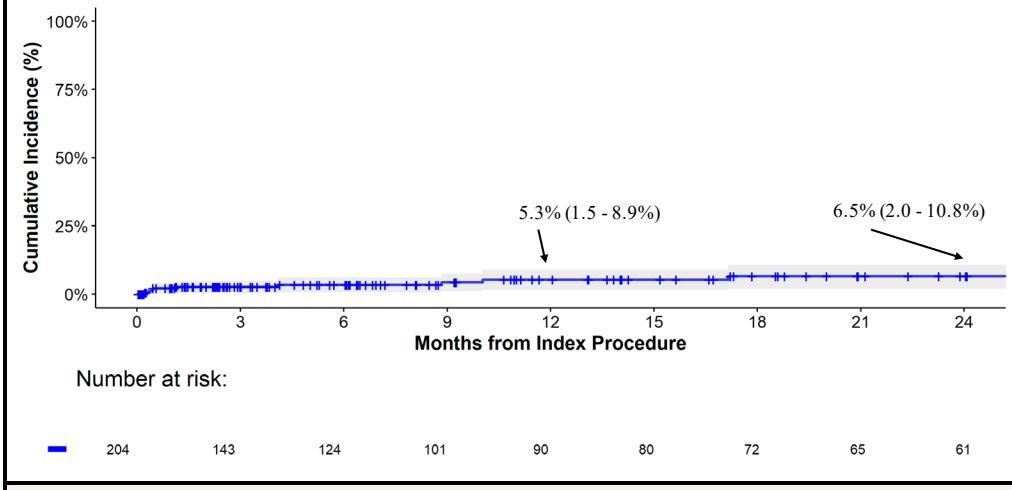

Figure 8. Kaplan-Meier Curve of Major Hemorrhage Through 2 Years.

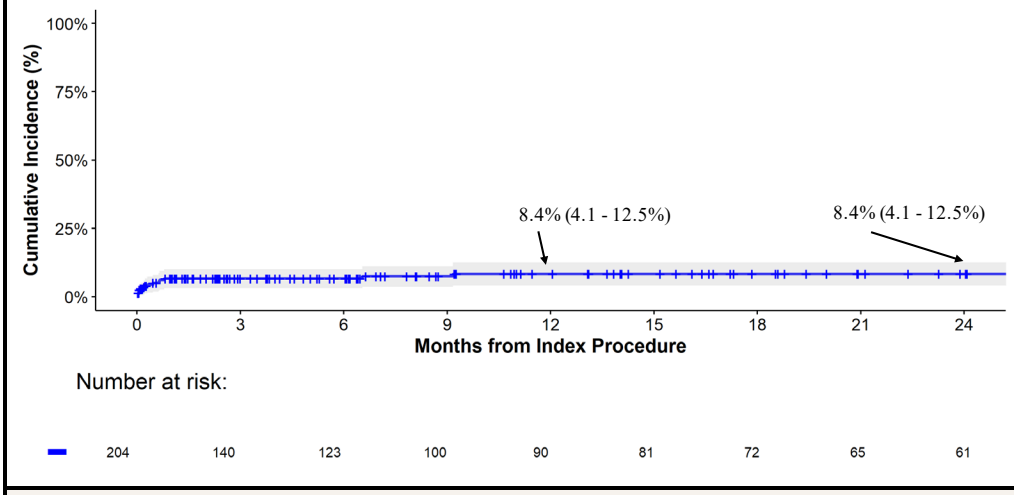

Figure 9. Kaplan-Meier Curve of Dialysis Through 2 Years.

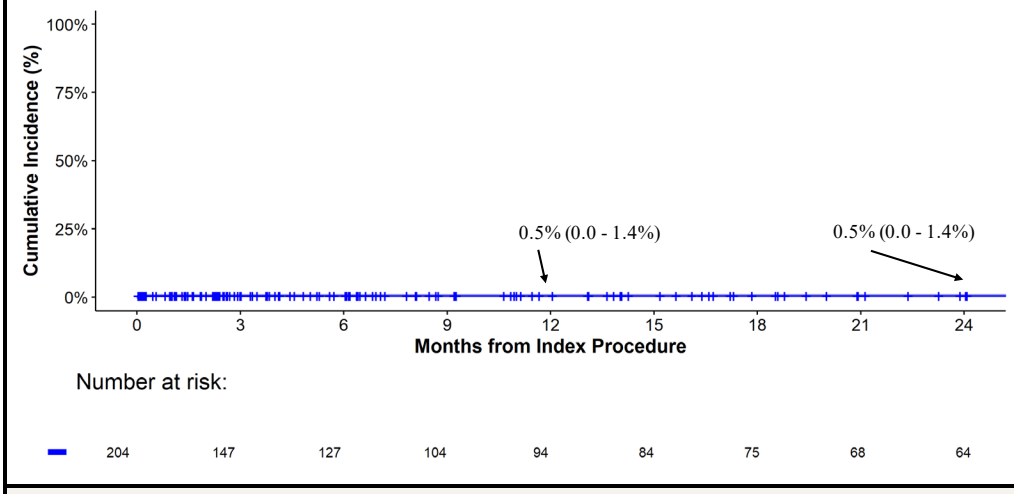

Figure 10. Kaplan-Meier Curve of Ventricular Assist Device Implantation or Heart Transplant Through 2 Years.

4. Sensitivity Analyses

30-Day All-Cause Mortality

The Kaplan-Meier estimate of all-cause mortality at 30 days was 6.9%, as summarized in Table 8.

Table 8. All-Cause Mortality Outcome at 30 Days.		
Endpoint	**No. of Events**	**Kaplan-Meier Estimate***
All-cause mortality at 30 days	14	6.9% (3.3-10.3%)

*Kaplan-Meier estimate (95% confidence interval [CI]). The CIs was obtained using the log-log transformation method based on Greenwood's formula for variance estimation.

Alternative Definition of Surgical Tricuspid Reintervention

To assess the potential undercapture of the surgical tricuspid reintervention outcome, a less specific algorithm was applied, requiring only a code concept from the procedure table indicating tricuspid valve replacement surgery following index procedure, defined via either International Classification of Diseases (ICD)-10 or Current Procedural Terminology (CPT) codes (without requiring a diagnostic code for device failure). Utilizing this less specific definition for surgical tricuspid reintervention revealed 5 events occurring between 4 and 12 months post-procedure, yielding a cumulative incidence for surgical tricuspid reintervention of 3.5% by 1 year, as summarized in Table 9.

Table 9. Surgical Tricuspid Reintervention (Alternative Definition) Outcome at 1 Year.		
Endpoint	**No. of Events**	**CIF Estimate***
Surgical tricuspid reintervention (alternative definition)	5	3.5% (0.5-6.5%)

CIF: cumulative incidence function

*Probability (cumulative incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the cumulative incidence function method, which treated death as a competing risk. The CIs were obtained using standard normal approximation.

Inpatient Endocarditis

The endocarditis events presented in Table 5 may have been overcaptured due to carryover coding from the index hospitalization. Using an alternative definition of endocarditis that required temporal linkage with an inpatient encounter, there were 24 inpatient endocarditis events within 1 year, for a cumulative incidence of 14.8%, as summarized in Table 10.

Table 10. Inpatient Endocarditis Outcome at 1 Year.		
Endpoint	**No. of Events**	**CIF Estimate***
Inpatient endocarditis	24	14.8% (9.2-20.3%)

CIF: cumulative incidence function

*Probability (cumulative incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the cumulative incidence function method, which treated death as a competing risk. The CIs were obtained using standard normal approximation.

5. Subgroup Analyses

Subgroup analyses for key safety and effectiveness outcomes with sufficient events (i.e., endocarditis, heart failure hospitalization, and all-cause mortality) are presented in Table 11 through Table 13. Endocarditis event rates were significantly higher in patients with a history of endocarditis or active endocarditis at baseline, as well as in patients with a history of intravenous (IV) drug use. A large fraction of the study population were IV drug users who underwent TVR because of tricuspid valve endocarditis—a population that is known to have high rates of recurrent endocarditis because of continued drug use. Heart failure hospitalizations were more frequent in older patients and those without a history of endocarditis or IV drug use. Mortality rates were higher in patients with history of endocarditis than in those without.

Table 11. Endocarditis at 1 Year by Subgroup		
Subgroup	**No. of Events**	**CIF Estimate***
No MVR (n=171)	61	42.5% (34.1-50.9%)
MVR (n=33)	5	16.0% (2.8-29.2%)
Female (n=110)	37	39.9% (29.5-50.3%)
Male (n=75)	18	27.3% (16.4-38.3%)
Missing Sex (n=19)	11	57.9% (31.2-84.6-%)
Age 18-64 (n=147)	57	44.3% (35.4-53.3%)
Age 65-74 (n=31)	2	7.5% (0.0-17.7%)
Age ≥75 (n=26)	7	33.8% (11.9-55.7%)
No Endocarditis (n=95)	12	15.6% (7.2-23.9%)
Endocarditis (n=109)	54	56.8% (46.5-67.2%)
No IV Drug Use (n=135)	33	30.1% (21.2-38.9%)
IV Drug Use (n=69)	33	52.0% (39.2-64.9%)
No Prior TVR (n=196)	63	37.4% (29.9-45.0%)
Prior TVR (n=8)	3	37.5% (1.1-73.9%)
MITRIS RESILIA (n=57)	9	20.3% (7.6-33.0%)
Magna Mitral Ease (n=147)	57	42.5% (33.9-51.0%)

Subgroup	No. of Events	CIF Estimate*

CIF: cumulative incidence function; IV: intravenous; MVR: mitral valve replacement; TVR: tricuspid valve replacement

*Probability (cumulative incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the cumulative incidence function method, which treated death as a competing risk. The CIs were obtained using standard normal approximation.

Table 12. Heart Failure Hospitalization at 1 Year by Subgroup

Subgroup	No. of Events	CIF Estimate*
No MVR (n=171)	23	13.1% (7.8-18.4%)
MVR (n=33)	9	28.5% (12.2-44.8%)
Female (n=110)	22	20.2% (12.3-28.0%)
Male (n=75)	8	10.4% (2.9-17.9%)
Missing Sex (n=19)	2	10.5% (0.0-24.9%)
Age 18-64 (n=147)	16	10.7% (5.5-15.8%)
Age 65-74 (n=31)	7	26.7% (8.8-44.5%)
Age ≥75 (n=26)	9	33.1% (13.1-53.1%)
No Endocarditis (n=95)	24	26.0% (16.6-35.5%)
Endocarditis (n=109)	8	6.9% (1.9-11.9%)
No IV Drug Use (n=135)	28	21.0% (13.6-28.3%)
IV Drug Use (n=69)	4	6.0% (0.2-11.7%)
No Prior TVR (n=196)	31	15.8% (10.5-21.2%)
Prior TVR (n=8)	1	12.5% (0.0-37.0%)
MITRIS RESILIA (n=57)	7	12.7% (3.8-21.6%)
Magna Mitral Ease (n=147)	25	16.6% (10.3-22.8%)

CIF: cumulative incidence function; IV: intravenous; MVR: mitral valve replacement; TVR: tricuspid valve replacement

*Probability (cumulative incidence) of an event occurring by 1 year (95% confidence interval [CI]). Probability was estimated using the cumulative incidence function method, which treated death as a competing risk. The CIs were obtained using standard normal approximation.

Table 13. All-Cause Mortality at 1 Year by Subgroup

Subgroup	No. of Events	Kaplan-Meier Estimate*
No MVR (n=171)	35	25.5% (17.6-32.7%)
MVR (n=33)	10	31.9% (13.3-46.5%)
Female (n=110)	19	21.5% (12.2-29.8%)
Male (n=75)	13	20.2% (9.4-29.6%)
Missing Sex (n=19)	13	68.4% (38.8-83.7%)

Subgroup	No. of Events	Kaplan-Meier Estimate*
Age 18-64 (n=147)	32	26.4% (17.9-34.0%)
Age 65-74 (n=31)	6	22.9% (4.5-37.5%)
Age ≥75 (n=26)	7	31.2% (8.0-48.6%)
No Endocarditis (n=95)	17	20.4% (11.1-28.8%)
Endocarditis (n=109)	28	31.0% (20.5-40.1%)
No IV Drug Use (n=135)	28	24.9% (16.2-32.8%)
IV Drug Use (n=69)	17	29.1% (16.3-40.0%)
No Prior TVR (n=196)	43	26.2% (19.0-32.8%)
Prior TVR (n=8)	2	24.4% (0.0-64.8%)
MITRIS RESILIA (n=57)	10	22.1% (8.3-33.8%)
Magna Mitral Ease (n=147)	35	27.0% (18.8-34.4%)

IV: intravenous; MVR: mitral valve replacement; TVR: tricuspid valve replacement

*Kaplan-Meier estimate (95% confidence interval [CI]). The CIs were obtained using the log-log transformation method based on Greenwood's formula for variance estimation.

6. Pediatric Extrapolation

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

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 THE PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The real-world evidence demonstrated that the TRIFORMIS RESILIA Tricuspid Valve is effective in replacing diseased and malfunctioning tricuspid valves in a representative patient population, as evidenced by the reasonable incidence rates of all-cause mortality and heart failure hospitalization.

The Kaplan-Meier estimate of the all-cause mortality rate was 6.9% (95% CI: [3.3%, 10.3%]) and 26.5% [19.4%, 33.0%] at 30 days and 1 year, respectively. Both rates were higher compared to the corresponding rates (3.9% [2.1%, 7.1%] and 13.2% [9.6%, 17.9%]; unpublished data) observed in the test-arm patients in the TRISCEND II trial

(NCT04482062), which compared transcatheter tricuspid valve replacement using the Edwards EVOQUE tricuspid valve replacement system against optimal medical management. The differences could be attributable to the inherent higher risks associated with open-heart surgery and differences in patient baseline characteristics such as a high prevalence of endocarditis in the current study.

The observed rate of heart failure hospitalization was 21.4% [15.5%, 27.3%] at 1 year, which was comparable to 20.9% [16.2%, 26.6%] for the test-arm patients and 24.5% [17.7%, 33.4%] for the control patients in the TRISCEND II trial. The Kaplan-Meier curve of heart failure hospitalization demonstrates that the majority of these events occurred within 30 days of the index hospitalization. Thus, it is likely that many of these events reflected post-operative heart failure, which is common in patients undergoing atrioventricular valve replacement.

B. Safety Conclusions

The risks of the TRIFORMIS RESILIA Tricuspid Valve are based on nonclinical laboratory and animal studies as well as data collected in the real-world evidence study conducted to support PMA approval as described above. The results from the nonclinical laboratory (e.g., biocompatibility, hydrodynamic performance, durability, and structural integrity) and animal studies demonstrated that this device is suitable for long-term implant.

The real-world evidence demonstrated that the use of the TRIFORMIS RESILIA Tricuspid Valve did not raise major safety concerns. The incidence rates of valve thrombosis, major paravalvular leak, and device failure requiring medical intervention, transcatheter reintervention, or surgical reintervention were low at 1 year. Endocarditis was the most frequent safety event observed at 1 year, with a cumulative incidence rate of 14.8% [9.2%, 20.3%] for inpatient endocarditis. This relatively high event rate remains reasonable given the fact that a large fraction of the study population were IV drug users.

C. Benefit-Risk Determination

The probable benefits of surgical TVR using the TRIFORMIS RESILIA Tricuspid Valve include restore of valve hemodynamic function and resulting improvement in patient health and survival status.

The probable risks of the surgical TVR using the TRIFORMIS RESILIA Tricuspid Valve include device- and/or procedure-related severe adverse events, such as death, endocarditis, valve thrombosis, paravalvular leak, and tricuspid valve reintervention.

Additional factors considered in determining probable risks and benefits for the TRIFORMIS RESILIA Tricuspid Valve included the following: Tricuspid valve disease is a debilitating disease. However, due to a relatively small market and challenges in conducting prospective clinical studies of dedicated surgical tricuspid valves, manufacturers have not innovated on these devices and as a result, for decades, surgeons have been using surgical mitral valves for surgical TVR. Although real-world evidence

adopted in the current application has limitations, especially the reliability and accuracy in event ascertainments and lack of direct valve hemodynamic data, comparisons to literature data and examination of outcomes closely associated with valve hemodynamic performance provide certain assurance about device performance.

1. Patient Perspectives

   This submission did not include specific information on patient perspectives.

In conclusion, given the available information above, the data support that for patients with a diseased or malfunctioning tricuspid valve that requires surgical TVR, the probable benefits of using the TRIFORMIS RESILIA Tricuspid Valve outweigh the probable risks.

D. Overall Conclusions

The data in this application support a reasonable assurance of safety and effectiveness of the TRIFORMIS RESILIA Tricuspid Valve in patients with a diseased or malfunctioning tricuspid valve that requires surgical TVR.

XIII. CDRH DECISION

CDRH issued an approval order on October 27, 2025. The final conditions of approval cited in the approval order are described below.

The applicant must conduct two post-approval studies:

1. **EHR-Based New Enrollment Study**: The study will be a single-arm, multi-center, observational cohort study including both prospective and retrospective data of a minimum of 75 evaluable patients enrolled from up to 10 high-volume centers in the U.S. The objective of this study is to assess the real-world performance of the TRIFORMIS RESILIA Tricuspid Valve, with an emphasis on valve hemodynamic performance. The safety and effectiveness endpoints include hemodynamics (discharge, 30 days, and 1 year, at a minimum), all-cause mortality, cardiovascular mortality, all-cause readmission (30 days only), valve-related heart failure hospitalization, freedom from tricuspid valve reintervention, and major valve-related events (including valve thrombosis, endocarditis, thromboembolism, and hemorrhage).

2. **Registry-Based Real-World Use Surveillance**: The surveillance will be carried out to assess the real-world performance of the TRIFORMIS RESILIA Tricuspid Valve. It will involve all consecutive patients implanted with the device up to the first 3 years following commercial launch of the device, who are entered into the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database (ACSD; enrollment period). All patients will be followed through 5 years post-procedure (follow-up duration). The clinical data through 30 days (i.e., tricuspid regurgitation grade, left ventricular ejection fraction, all-cause readmission, and pulmonary embolism) will be collected through the ACSD. The follow-up data (including all-cause mortality, cardiovascular mortality, tricuspid valve

reintervention, and all-cause reoperation) from year 1 through year 5 post-procedure will be obtained through the ACSD (for freedom from tricuspid valve reintervention and all-cause reoperation) and linkage with the National Death Index (for all-cause mortality and cardiovascular mortality).

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 final approved labeling (Instructions for Use).

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the final labeling (Instructions for Use).

Post-approval Requirements and Restrictions: See Approval Order.