November 13, 2025

Telltale LLC
Koosha Rafiee
VP of Structural/Congenital Heart Therapies
4 Dundee Park Drive, Suite 101
Andover, Massachusetts 01810

Re: K252592
Trade/Device Name: TELLTALE Electrosurgical Guidewire System
Regulation Number: 21 CFR 870.1254
Regulation Name: Percutaneous catheter for cutting or splitting heart valve leaflets concomitant to transcatheter valve procedures
Regulatory Class: Class II
Product Code: SGO
Dated: August 15, 2025
Received: August 15, 2025

Dear Koosha Rafiee:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Samuel G. Raben -S

for Jennifer Kevit, Ph.D.
Assistant Director (Acting)
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252592

Device Name
TELLTALE Electrosurgical Guidewire System

Indications for Use *(Describe)*
The TELLTALE Electrosurgical Guidewire System is indicated for transcatheter electrosurgical traversal and laceration of native and bioprosthetic tissue in patients at risk of coronary obstruction during TAVR.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary Submitter

Name: TELLTALE LLC, a subsidiary of Transmural Systems
Address: 4 Dundee Park Drive
Andover, MA 01810, USA
Phone: +1-978-387-0068
Contact Person: Koosha Rafiee, VP Structural Heart Therapies
Date Prepared: August 6, 2025

Device

Name of Device:	TELLTALE Electrosurgical Guidewire System
Common or Usual Name:	Catheter System for Electrosurgery Leaflet Traversal and Laceration
Classification Name:	Percutaneous catheter for cutting or splitting heart valve leaflets concomitant to transcatheter valve procedures
Regulatory Class:	Class II per 21 CFR 870.1254
Product Code:	SGO

Predicate Device

Predicate Name and 510(k) Number: ShortCut, Pi-Cardia Ltd, DEN240017 This predicate has not been subject to a design-related recall.
No reference predicates were used in this submission.

Device Description

The TELLTALE system is comprised of the TELLTALE Guidewire, guide catheters and accessories to aid with the preparation, placement, and use of guidewire.
The TELLTALE system consists of the following elements:

- TELLTALE Guidewire
- TELLTALE Pachyderm Guide catheters (for left coronary cusp and for right coronary cusp)
- TELLTALE System Accessories
    - Spring-loaded cable connector
    - Denuder/Kinker
    - Guidewire grippers
    - Insulation envelope
    - Insulation tube
    - Plastic torquers
    - 6F Peel-away introducer
    - Guidewire introducer

The TELLTALE Guidewire has an outer diameter of 0.014” and a working length of 310cm. It is composed of a stainless-steel guidewire covered with an outer insulative polymer layer. The distal tip and proximal end of the guidewire are uninsulated. The TELLTALE Guidewire mid-shaft is provided to the user fully insulated to protect the operator from RF energy when the uninsulated guidewire tip is used for electrosurgical leaflet traversal inside the patient.
The proximal end of the TELLTALE Guidewire, which has no patient contact, is uninsulated and gold-plated to allow for connection to an electrosurgery generator to facilitate the delivery of monopolar RF energy to the cutting surfaces of the guidewire.

The TELLTALE Guidewire is to be used with RF generators that provide continuous wave, monopolar PURE CUT mode energy with power settings of 10 to 50 W (into a rated load of 300 ohms with maximum voltage of 900 V peak or less). There are two cutting surfaces of the TELLTALE Guidewire.

1. the distal tip for leaflet traversal
2. a mid-shaft cutting location for aortic leaflet laceration.

The mid-shaft of the TELLTALE guidewire is identified by a 10mm gold marker band which is radiopaque. The mid-shaft cutting surface is created by the user by removing the insulative coating after the distal tip is used to traverse through tissue.

There are seven guide catheters specifically shaped to aid in leaflet traversal by allowing physicians to select the traversal location and providing support for TELLTALE Guidewire leaflet traversal. The TELLTALE System is supplied with three boxes; all guide catheters will be in separate shelf cartons, within one box. All seven guide catheters have a usable length of 100cm and an outer diameter of 6.4F.

There are multiple accessories provided to aid with the procedure:

- Guidewire gripper: The guidewire gripper attaches to a standard Y-adaptor and clamps onto the TELLTALE Guidewire to assist with guidewire traction during the procedure.
- Insulation envelope: Insulation envelope is provided for the physician to place the end of the guidewire during the traversal procedure to contain the backend of the guidewire and provide additional insulative protection
- Insulation Tube: An insulation tube is provided for the physician to place on the proximal end of the gooseneck snare during traversal (puncture) of the leaflet to provide insulation. It is also place by the physician on the end of the snared tip of the guidewire during the leaflet laceration procedure to provide insulation to the tip of the guidewire.
- Spring Loaded Connector: A detachable spring-loaded connector cable that plugs into the monopolar receptacle of a compatible RF generator that is used in conjunction with a compatible patient return electrode and allows for a secure insulative connection between the TELLTALE Guidewire and the generator. The detachable connector allows for exchange of catheters over the TELLTALE Guidewire as needed during the procedure.
- Denuder/Kinker: The Denuder/Kinker is provided to (1) create a reproducible denuded or uninsulated, area at the mid-shaft location of the TELLTALE Guidewire for laceration and (2) kink the TELLTALE Guidewire at the lacerating surface to produce the required angle for the leaflet laceration procedure.

Indications for Use

The TELLTALE Electrosurgical Guidewire System is indicated for transcatheter electrosurgical traversal and laceration of native and bioprosthetic tissue in patients at risk of coronary obstruction during TAVR.

Comparison of Technological Characteristics with the Predicate Device

The Proposed Device and Predicate Device are similar in indications for use, intended use, technological characteristics, and principles of operation.

The differences between the Proposed Device and the Predicate Device are minor and raise no different questions of safety and effectiveness, thus it was concluded that the Proposed Device is substantially equivalent to the Predicate Device. In accordance with 21CFR807.92(a)(6) a summary of how the technological characteristic of the Proposed Device compares to the Predicate Device is provided below.

Item	The TELLTALE System (Proposed device)	Primary Predicate ShortCut (DEN240017)	Same / Different between Proposed and Predicate?
Intended Use	intended for percutaneous cutting or splitting heart valve leaflets concomitant to transcatheter valve procedures	intended for percutaneous cutting or splitting heart valve leaflets concomitant to transcatheter valve procedures	Same
Indications for use	The TELLTALE Electrosurgical Guidewire System is indicated for transcatheter electrosurgical traversal and laceration of native and bioprosthetic tissue in patients at risk of coronary obstruction during TAVR	ShortCut is indicated for use as a splitting device of bioprosthetic aortic valve leaflets to facilitate valve-in-valve procedures for patients at risk of coronary obstruction.	Substantially Equivalent
Device Class	Class II	Class II	Same
Product Code	SCZ	SGO	Substantially Equivalent
Prescription device	Yes	Yes	Same
Single-Patient Use	Yes	Yes	Same
Target population	Patients at risk of coronary obstruction requiring ViV TAVR and/or a native TAVR	Patients at risk of coronary obstruction requiring ViV TAVR	Substantially Equivalent
Anatomical site	Native and bioprosthetic aortic valve leaflets	Bioprosthetic aortic valve leaflets	Substantially Equivalent
Environment of use	Hospital	Hospital	Same
Components Provided	TELLTALE Guidewire (Cutting element) Guide Catheters (Delivery System) Accessories for use: • Spring-loaded cable connector • Denuder/Kinker • Guidewire grippers • Insulation envelope • Insulation tube • Plastic torquers • 6F Peel-away introducer • Guidewire introducer	16F Catheter with Handle, delivery system, and distal cutting unit	Substantially equivalent

Item	The TELLTALE System (Proposed device)	Primary Predicate ShortCut (DEN240017)	Same / Different between Proposed and Predicate?
Mechanism to create a cut in the leaflet	Use of a cutting element to puncture and cut the aortic valve leaflet. The TELLTALE System uses an electrified guidewire to create the cut in the leaflet.	Use of a cutting element to puncture and cut the aortic valve leaflet. The ShortCut uses a blade to create the cut in the leaflet.	Substantially equivalent
Mechanical Testing	Tensile testing Torsion testing Corrosion testing Simulated Use testing Particulate evaluation Dimensional verification Leak testing Usability testing Electrical/EMC testing	Tensile testing Torsion testing Corrosion testing Simulated Use testing Particulate evaluation Dimensional verification Leak testing Usability testing	Substantially equivalent
Materials	Standard medical device materials which meet the applicable requirements of ISO 10993-1	Standard medical device materials which meet the applicable requirements of ISO 10993-1	Substantially equivalent
Biocompatibility	The TELLTALE is considered an externally communicating device that is intended to come in direct contact with circulating blood for a limited duration (< 24 hours). The biocompatibility of the TELLTALE was evaluated with respect to cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, and hemocompatibility.	The ShortCut is considered an externally communicating device that is intended to come in direct contact with circulating blood for a limited duration (< 24 hours). The biocompatibility of the ShortCut was evaluated with respect to cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, and hemocompatibility.	Same
Sterility	Sterile single-patient use	Sterile single-patient use	Same
Type of Sterilization	Ethylene Oxide gas	Ethylene Oxide gas	Same

Item	The TELLTALE System (Proposed device)	Primary Predicate ShortCut (DEN240017)	Same / Different between Proposed and Predicate?
Detailed Principles of Operation	A pair of Pachyderm Guide catheters is positioned on either side of the targeted aortic leaflet to direct the TELLTALE guidewire across it, near the leaflet scallop hinge point. The guide catheters are aimed at a snare positioned immediately below the leaflet in the ventricular outflow tract. The TELLTALE Guidewire is used to confine the electrical current to the tip and electrified using a radiofrequency generator to traverse (perforate) the base of the target leaflet. The TELLTALE Guidewire is snared in the left ventricular outflow tract and externalized to form a loop through the leaflet between the two guiding catheters. The TELLTALE guidewire shaft is shaped (kinked) to confine the electrical contact with leaflet tissue, and then further electrified under tension to lacerate the leaflet down the centerline. The split leaflet typically splays in systole and coapts in diastole. The TELLTALE Electrosurgical Guidewire System is disconnected and removed from the body and subsequently TAVR is performed.	The ShortCut is placed through a 16F introducer sheath over a guidewire and advanced to the aortic valve. The distal end of the catheter is aligned at the annular level, and the Positioning Arm is exposed and rotated towards the targeted leaflet. The splitting element is activated to penetrate the valve, and the ShortCut catheter is retracted to split the leaflet. The splitting element is deactivated and re-sheathed. The ShortCut is removed from the body and subsequently TAVR is performed.	Substantially Equivalent.

Special Controls

The table below demonstrates how the TELLTALE Electrosurgical Guidewire System meets the special controls related to the Classification Regulation: 21 CFR 870.1254 - Percutaneous catheter for cutting or splitting heart valve leaflets concomitant to transcatheter valve procedures

21 CFR 870.1254 - Percutaneous catheter for cutting or splitting heart valve leaflets concomitant to transcatheter valve procedures	**Does the TELLTALE Electrosurgical Guidewire System meet the special controls (Yes / No)**	**Compliance with the special controls is demonstrated through:**
(1) Clinical performance testing of the device must demonstrate that the device performs as intended under anticipated conditions of use. Testing must evaluate: • The ability to safely deliver and remove the device. • Performance in cutting or splitting of the target valve leaflets • Compatibility with concomitant transcatheter valve procedures; and • All adverse events observed, including device malfunctions, tissue or vascular injury, hemodynamic abnormalities, embolic events, cerebrovascular adverse events, and unanticipated surgical interventions	Yes	TELLTALE Pivotal Study (NCT05666713)
(2) *In vivo* performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be assessed: • Delivery, use, and retrieval of the device • Cutting or splitting of target leaflet(s); and • Gross pathology and histopathology assessing leaflet splitting, soft tissue damage, and downstream embolization	Yes	GLP Animal Study
(3) Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested: • Simulated use testing in a clinically relevant bench anatomic model to assess feasibility of device operation under worst-case clinical conditions, including device delivery, use, retrieval, and compatibility with accessory devices via transcatheter approach • Consistency and reliability of cutting action • Ability to advance and position the device to reach the target site • Mechanical integrity testing (e.g., bond/joint strength, torsional strength) of the device under anticipated loading conditions • Assessment of material-specific risks, such as corrosion if the device contains metal components, or coating integrity and particulates if the device contains lubricious coatings; and • Characterization and verification of critical dimensions	Yes	Non-clinical performance testing

21 CFR 870.1254 - Percutaneous catheter for cutting or splitting heart valve leaflets concomitant to transcatheter valve procedures	**Does the TELLTALE Electrosurgical Guidewire System meet the special controls (Yes / No)**	**Compliance with the special controls is demonstrated through:**
(4) Compatibility testing for devices that contain electrical components must include: • Electrical safety and electromagnetic compatibility (EMC) testing; and • Software verification, validation, and • hazard analysis for all devices that contain software.	Yes (Electrical Safety & EMC) Software N/A	Electrical safety and electromagnetic compatibility (EMC) Performance Testing
(5) All patient-contacting components of the device must be demonstrated to be biocompatible.	Yes	Biocompatibility Testing
(6) Performance data must demonstrate the sterility of the device components intended to be provided sterile.	Yes	Sterility of the device is met via the Sterilization Validation. The validation for the packaged System was completed in accordance with ISO 11135:2014
(7) Performance data must support the shelf-life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.	Yes	Shelf-life testing was performed to demonstrate the shelf-life of the device and packaging.
(8) Labeling must include the following: • The recommended training for safe use of the device • Information on the patient population for which the device has been demonstrated to be effective • Identification of the maximum number of cutting actions and deployments for each device and for each target site; and • A detailed summary of the clinical testing conducted; and • A shelf life	Yes	The instructions for use details a summary of the recommended training, patient population, maximum number of cutting actions, and a detailed summary of the clinical testing conducted. The product labels include a shelf life for Use.

Performance Data

All necessary performance testing has been conducted on the TELLTALE Electrosurgical Guidewire System to assure substantial equivalence to the predicate devices and to demonstrate the device performs as intended. All testing was performed on test units representative of finished devices.

The device passed the following tests, which were conducted in accordance with noted standards:

- Biocompatibility testing per FDA Final Guidance Document, “Use of International Standard ISO 10993- 1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” (2023)
- Sterilization Validation per ANSI/AAMI/ISO 11135
- Packaging validation per ISO 11607-1
- Electrical Safety and electromagnetic (EMC) Testing per requirements of IEC 50501-1
- Verification testing including simulated use, dimensional verification, tensile testing
- Animal testing per GLP regulations

Clinical Data

Pivotal Study – TELLTALE Electrosurgical Guidewire System

Objective

Transmural Systems developed a purpose-built electrosurgical guidewire system (TELLTALE) to simplify the BASILICA-TAVR procedure. The purpose of this study was to test the efficacy and safety of this purpose-built TELLTALE Guidewire System in the setting of BASILICA-TAVR.

Study Design

This study was a prospective, multicenter, single arm, open-label, evaluation of the Transmural TELLTALE Electrosurgical Guidewire System. There were 90 subjects enrolled at 11 investigational sites in the United States. There was a quota of 30 subjects who had native TELLTALE BASILICA-TAVR and 60 subjects who had bioprosthetic TELLTALE BASILICA-TAVR of the 90 total enrolled subjects.

Eligibility Criteria Summary

To be eligible to participate in the study, candidates were required to meet all of the following criteria:

- Adults age ≥ 21 years
- High or prohibitive risk of surgical aortic valve replacement according to the local multidisciplinary heart team
- Undergoing TAVR for bioprosthetic aortic valve failure or native aortic stenosis (“on-label” TAVR)
- Local multidisciplinary heart team determines subject to be at high risk of TAVR-induced coronary artery obstruction
- Deemed likely to suffer coronary artery obstruction from TAVR based on NHLBI Core lab analysis of CT, any of
    - Risk is narrow Sinus of Valsalva: (a) Leaflet height is greater than coronary artery height, and
    - (b) Virtual transcatheter valve-to-coronary (VTC) distance < 4mm
    - Risk is Sinus sequestration: (a) Threatening leaflet height is greater than sinotubular junction, and (b) Virtual transcatheter valve-to-sinotubular-junction distance (VTS) < 2mm at the affected Sinus
- Concurrence of the Study Eligibility Committee
- Able to understand the protocol, consents in writing to participate, and willing to comply with all study procedures for the duration of the study

Key exclusion criteria included:

- Requires doppio (two-leaflet) BASILICA
- Flail target leaflet at baseline
- Excessive target aortic leaflet calcification (no basal calcium-free window or potentially obstructive calcific masses) on baseline CT
- Planned provisional (pre-position coronary artery) stents despite BASILICA
- Requires non-femoral access
- Requires concomitant procedures during TAVR (such as percutaneous coronary intervention for baseline obstructive coronary artery disease)
- Chronic kidney disease KDIGO stage 4 or 5 (eGFR < 29 ml/min/1.73m2) or renal replacement therapy
- Not expected to survive for 12 months
- Pregnant at the time of intended treatment (day 0)

Primary Effectiveness Endpoints

Primary Efficacy endpoint is device technical success, assessed upon exit from the cardiac catheterization laboratory and was defined as:

1. Successful electrosurgical leaflet traversal using the TELLTALE guidewire; and
2. Successful electrosurgical leaflet laceration using the TELLTALE guidewire; and
3. Successful retrieval of the TELLTALE guidewire system.

Primary Safety Endpoints

The primary safety endpoint is Inpatient safety, which is a composite of all of following assessed upon discharge from the index hospital admission:

- (Freedom from) all-cause mortality
- (Freedom from) stroke, both disabling and non-disabling
- (Freedom from) acute coronary artery obstruction
- (Freedom from) emergency cardiac surgery or reintervention related to the TELLTALE BASILICA procedure or device
- (Freedom from) BASILICA-related complications including coronary artery perforation, coronary artery dissection, aortic dissection, cardiac free wall perforation, or systemic embolization of a native or bioprosthetic leaflet

Secondary Endpoints

The secondary endpoint is 30-day safety, as assessed by freedom from MACE (according to VARC-3) at 30 days, including freedom from all of the following:

- All-cause mortality
- All stroke (disabling and non-disabling)
- Bleeding VARC-3 Type 2 or greater (requiring two or more units of transfused blood or hemoglobin drop >3g/dL)
- Major vascular, access-related, or cardiac structural complication (according to VARC-3, which includes coronary obstruction)
- Acute kidney injury stage 3 or 4
- Moderate or severe aortic regurgitation
- New permanent pacemaker due to procedure-related conduction abnormalities
- Surgery or intervention related to the TELLTALE device

Exploratory Endpoints

- Primary and secondary endpoints among subjects with native versus bioprosthetic disease
- Stroke: disabling and non-disabling
- Coronary stenting: snorkel (heterotopic) and orthotopic (through TAVR stent cells), to prevent or treat leaflet-induced coronary obstruction before (preemptive) and after (bailout or cautionary) TAVR.
- Facilitated BASILICA procedure success, as defined in the primary efficacy endpoint
- Composite safety (secondary endpoint) assessed at 90 days
- Ability to selectively engage threatened coronary ostia after BASILICA-TAVR
- Acute hemodynamic deterioration in the interval between BASILICA and TAVR
- Outcomes of subjects who participate in live case demonstrations compared with those who do not

Statistical Methods

A total sample size of 90 subjects was selected to provide reasonable confidence in detecting rare adverse events, specifically stroke. This decision was informed by a literature review of valve-in-valve (ViV) TAVR studies, which reported an average stroke rate of approximately 1.4%.

To evaluate whether the stroke rate associated with the TELLTALE BASILICA procedure could be at least twice the reported rate, a sample size calculation was performed. Assuming an expected stroke incidence of 2.8% (2 × 1.4%), a sample size of 90 yields greater than 80% probability of observing at least one stroke event.

The key study results (primary and secondary endpoints) were analyzed by subgroups including indication (bioprosthetic versus native), site, census region, age (dichotomized by the sample median), non-white status, and sex. For each of the above baseline characteristics, the subgroup differences in the study outcome were evaluated by the two-sided Fisher's exact test at a significance level of 0.05. For the subgroup analysis of study sites, the sites with the smallest number of patients will be combined to have at least 5 subjects in the pseudo-site group. Statistical analysis was performed or confirmed by the NHLBI study statistician.

Accountability

Between February 2023 and February 2025, a total of 157 participants were screened and after exclusions, 90 participants were enrolled into the trial, of whom 30 were undergoing TAVR for native aortic stenosis and 60 for bioprosthetic valve failure.

The table below shows total enrollment counts at the 11 enrolling centers, including native aortic stenosis vs bioprosthetic aortic valve failure cohorts. Enrollment into the native aortic stenosis cohort was completed before enrollment into the bioprosthetic cohort.

Enrolling Center	Overall, N=90[1]	Native, N=30[1]	Bioprosthetic, N=60[1]
St. Francis	20 (22%)	10 (33%)	10 (17%)
BIDMC	14 (16%)	0 (0%)	14 (23%)
Emory	12 (13%)	1 (3.3%)	11 (18%)
MWHC	11 (12%)	6 (20%)	5 (8.3%)
Montefiore	9 (10%)	5 (17%)	4 (6.7%)
UColorado	6 (6.7%)	2 (6.7%)	4 (6.7%)
York	6 (6.7%)	4 (13%)	2 (3.3%)
RGH	4 (4.4%)	0 (0%)	4 (6.7%)
UW	4 (4.4%)	0 (0%)	4 (6.7%)
Roanoke	2 (2.2%)	1 (3.3%)	1 (1.7%)
CPMC	2 (2.2%)	1 (3.3%)	1 (1.7%)

[1] n (%)

Sixty-seven candidates were excluded (screen failures). The most common reasons for exclusion were CT analysis demonstrating low risk for coronary obstruction (n=16), co-morbidity (e.g., clinical instability, n=12) and need for doppio leaflet modification (n=12) which was excluded per protocol because discordant first and second leaflet results would impact assessment of the primary efficacy endpoint. Relatively few (n=8) were excluded for excessive target leaflet calcification.

Demographics

The table below shows baseline demographics and clinical characteristics for the entire group and for the native and bioprosthetic cohorts. Overall, most participants were female, and every participant in the native aortic stenosis cohort was female. The burden of comorbidities was high, although candidates with severe renal disease were excluded. The most common reason for aortic valve failure was stenosis. The proportion of patients with atrial fibrillation is high, which risks thromboembolic complications.

Characteristic	Overall, N = 90[1]	Native, N = 30[1]	Bioprosthetic, N = 60[1]
Age	79 (75, 82)	80 (76, 83)	78 (75, 82)
Sex, Female	59 (66%)	30 (100%)	29 (48%)
Ethnicity			
Hispanic or Latino	7 (7.9%)	3 (10%)	4 (6.7%)
Not Hispanic or Latino	80 (90%)	25 (86%)	55 (92%)
Not Reported	1 (1.1%)	0 (0%)	1 (1.7%)
Unknown	1 (1.1%)	1 (3.4%)	0 (0%)
Race			
African American	2 (2.2%)	2 (6.7%)	0 (0%)
Asian	1 (1.1%)	0 (0%)	1 (1.7%)
Other	5 (5.6%)	2 (6.7%)	3 (5.0%)
White	82 (91%)	26 (87%)	56 (93%)
Body surface area (m^2)	1.86 (1.67, 2.02)	1.80 (1.64, 1.92)	1.88 (1.71, 2.05)
Body mass index (kg/m^2)	26.6 (23.8, 32.3)	26.1 (23.6, 35.0)	26.6 (24.0, 31.2)
Diabetes mellitus			
None	59 (66%)	19 (63%)	40 (67%)
Diet-controlled	2 (2.2%)	0 (0%)	2 (3.3%)
Oral agent	21 (23%)	8 (27%)	13 (22%)
Insulin-dependent	8 (8.9%)	3 (10%)	5 (8.3%)
Tobacco, ongoing	4 (4.4%)	2 (6.7%)	2 (3.3%)
Tobacco, ever	34 (38%)	9 (30%)	25 (42%)
End-stage renal disease	0 (0%)	0 (0%)	0 (0%)
Severe pulmonary disease	10 (11%)	6 (20%)	4 (6.7%)
Home oxygen use	5 (5.6%)	3 (10%)	2 (3.3%)
Cirrhosis			
None	68 (76%)	20 (67%)	48 (80%)
Child-Pugh A	21 (23%)	10 (33%)	11 (18%)
Child-Pugh B	1 (1.1%)	0 (0%)	1 (1.7%)
Estimated glomerular filtration rate (mL/min/1.73m^2)	66 (55, 77)	62 (53, 77)	67 (58, 76)
Chronic kidney disease (grade 3+)	0 (0%)	0 (0%)	0 (0%)
Hypertension	75 (83%)	24 (80%)	51 (85%)
Coronary artery disease	41 (46%)	8 (27%)	33 (55%)
Prior percutaneous coronary intervention	12 (13%)	3 (10%)	9 (15%)

Characteristic	Overall, N = 90[1]	Native, N = 30[1]	Bioprosthetic, N = 60[1]
Prior coronary artery bypass grafting	25 (28%)	2 (6.7%)	23 (38%)
Prior myocardial infarction	8 (8.9%)	3 (10%)	5 (8.3%)
Peripheral artery disease	17 (19%)	5 (17%)	12 (20%)
Prior stroke	14 (16%)	4 (13%)	10 (17%)
Prior transient ischemic neurological attack	8 (8.9%)	3 (10%)	5 (8.3%)
Prior pulmonary thromboembolism or deep vein thrombosis	3 (3.3%)	2 (6.7%)	1 (1.7%)
Atrial fibrillation			
None	63 (70%)	23 (77%)	40 (67%)
Paroxysmal	20 (22%)	5 (17%)	15 (25%)
Persistent > 1 week	6 (6.7%)	2 (6.7%)	4 (6.7%)
Permanent	1 (1.1%)	0 (0%)	1 (1.7%)
Anticoagulation	21 (23%)	6 (20%)	15 (25%)
Pacemaker therapy			
CRT pacemaker	2 (2.2%)	0 (0%)	2 (3.3%)
None	80 (89%)	29 (97%)	51 (85%)
RV or RA/RV pacemaker	8 (8.9%)	1 (3.3%)	7 (12%)
Implanted defibrillator	1 (1.1%)	0 (0%)	1 (1.7%)
Canadian angina classification			
0	65 (72%)	21 (70%)	44 (73%)
1	13 (14%)	5 (17%)	8 (13%)
2	11 (12%)	3 (10%)	8 (13%)
4	1 (1.1%)	1 (3.3%)	0 (0%)
New York Heart Association heart failure classification			
2	34 (38%)	12 (40%)	22 (37%)
3	54 (60%)	16 (53%)	38 (63%)
4	2 (2.2%)	2 (6.7%)	0 (0%)
Prior TAVR	1 (1.1%)	0 (0%)	1 (1.7%)
Prior transcatheter mitral valve replacement or repair	5 (5.6%)	0 (0%)	5 (8.3%)
Prior transcatheter tricuspid valve replacement or repair	0 (0%)	0 (0%)	0 (0%)
Aortic valve failure mode			
Aortic regurgitation	10 (11%)	0 (0%)	10 (17%)
Aortic stenosis	72 (80%)	29 (97%)	43 (72%)
Mixed aortic stenosis and regurgitation	8 (8.9%)	1 (3.3%)	7 (12%)
Size of prior surgical aortic valve implant (mm)	23 (21, 24)	NA (NA, NA)	23 (21, 24)
Society of thoracic surgery predicted risk of 30-day mortality after aortic valve replacement (%)	4.2 (3.0, 6.6)	3.6 (2.3, 6.3)	4.4 (3.1, 6.7)
Years after surgical aortic valve replacement	10.0 (7.5, 14.0)	NA (NA, NA)	10.0 (7.5, 14.0)

[1] n (%); Median (IQR)

The table below describes the baseline medications of participants in the entire cohort. The high proportion of participants using oral anticoagulants portends bleeding, and the high proportion of patients with underlying atrial fibrillation portends thromboembolic complications.

Medication Class	N = 90[1]
Anticoagulants	
Warfarin	3 (3.3%)
DOAC	17 (19%)
Other	1 (1.1%)
None	69 (77%)
Aspirin	59 (66%)
P2Y12 inhibitors	8 (8.9%)
Digoxin	2 (2.2%)
Beta adrenergic blockers	56 (62%)
Calcium channel blockers	29 (32%)
Antiarrhythmic drugs	6 (6.7%)
ACE inhibitors or ARBs	44 (49%)
ARB/neprilysin inhibitors	6 (6.7%)
Aldosterone inhibitors	13 (14%)
SGLT2 inhibitors	11 (12%)
Diuretics	48 (53%)

[1] n (%)

Results

The table below describes characteristics of the catheters used for the TELLTALE BASILICA TAVR procedure, including stratified by "phenotype." The most commonly used guiding catheter was the Pachyderm PAL1.0 intended for the left coronary cusp. All of the guiding catheter shapes were employed frequently except for the Pachyderm PJR5.0 intended for the right coronary cusp. LVOT loop snares were selected based on CT dimensions or snare "behavior" (ability to align parallel to the aortic annulus) in situ.

Characteristic	Overall, N = 90[1]	Native, N = 30[1]	Bioprosthetic, N = 60[1]
BASILICA vascular access			
Both inside TAVR sheath	2 / 90 (2.2%)	1 / 30 (3.3%)	1 / 60 (1.7%)
Femoral R and L	88 / 90 (98%)	29 / 30 (97%)	59 / 60 (98%)
Guiding catheter shape for traversal			
Other*	2 / 90 (2.2%)	0 / 30 (0%)	2 / 60 (3.3%)
PAL0.75	11 / 90 (12%)	6 / 30 (20%)	5 / 60 (8.3%)
PAL1.0	45 / 90 (50%)	19 / 30 (63%)	26 / 60 (43%)
PAL2.0	17 / 90 (19%)	4 / 30 (13%)	13 / 60 (22%)
PJR4.0	14 / 90 (16%)	1 / 30 (3.3%)	13 / 60 (22%)
PJR5.0	1 / 90 (1.1%)	0 / 30 (0%)	1 / 60 (1.7%)
Guiding catheter shape for ensnarement			
JR4.0	28 / 90 (31%)	5 / 30 (17%)	23 / 60 (38%)
Multipurpose (MP1.0)	60 / 90 (67%)	25 / 30 (83%)	35 / 60 (58%)
Other*	2 / 90 (2.2%)	0 / 30 (0%)	2 / 60 (3.3%)
Size of LVOT loop snare			
20	66 / 90 (73%)	28 / 30 (93%)	38 / 60 (63%)
25	23 / 90 (26%)	2 / 30 (6.7%)	21 / 60 (35%)
30	1 / 90 (1.1%)	0 / 30 (0%)	1 / 60 (1.7%)
None	88 / 90 (98%)	30 / 30 (100%)	58 / 60 (97%)
Other microcatheter	2 / 90 (2.2%)	0 / 30 (0%)	2 / 60 (3.3%)

[1] n (%)

Study Intervention Procedure Characteristics

A median of 1 traversal and 1 laceration attempt was required in each participant. The median power 20W for traversal and 30W for laceration for both native and bioprosthetic valves.

Laceration was successful in all, assessed by echocardiographic confirmation before TAVR or by recovery of the "flying-V" guidewire shaft that had successfully traversed the target leaflet. Traction force required for laceration was acceptable in all but one with a Trifecta bioprosthetic valve in whom subjective traction was heavier-than-expected on the operator-assessed ordinal scale. Importantly, TELLTALE did not cause any leaflet avulsions, which would be evident by echocardiography, by induced hemodynamic collapse, or by leaflet prolapse. The TELLTALE system was removed intact after all procedures.

The table below provides additional details of the TELLTALE BASILICA TAVR procedure.

Characteristic	Overall, N = 90[1]	Native, N = 30[1]	Bioprosthetic, N = 60[1]
Electrosurgery power for traversal (W)	20.0 (20.0,20.0)	20.0 (15.0,20.0)	20.0 (20.0, 20.0)
Number of electrifications for traversal	1 (1, 2)	1 (1, 2)	1 (1, 2)
Evidence of successful traversal			
Angiographic confirmation	83 / 90 (92%)	26 / 30 (87%)	57 / 60 (95%)
Tactile confirmation	7 / 90 (7.8%)	4 / 30 (13%)	3 / 60 (5.0%)
Traversal was successful	90 / 90 (100%)	30 / 30 (100%)	60 / 60 (100%)
Traversal into non-target structures	6 / 90 (6.7%)	6 / 30 (20%)	0 / 60 (0%)
Balloon-assisted BASILICA	1 / 90 (1.1%)	1 / 30 (3.3%))	0 / 60 (0%)
Electrosurgery power for laceration (W)	30.0 (30.0,30.0)	30.0 (30.0,30.0)	30.0 (30.0, 30.0)
Dextrose flooding during laceration	88 / 90 (98%)	30 / 30 (100%)	58 / 60 (97%)
Number of electrifications for laceration	1 (1, 1)	1 (1, 1)	1 (1, 1)
Evidence of successful leaflet laceration			
Echocardiography confirmation before TAVR	52 / 90 (58%)	21 / 30 (70%)	31 / 60 (52%)
Recovery of flying-V without echo confirmation	38 / 90 (42%)	9 / 30 (30%)	29 / 60 (48%)
Laceration was successful	90 / 90 (100%)	30 / 30 (100%)	60 / 60 (100%)
Force required for laceration			
Little force	60 / 90 (67%)	21 / 30 (70%)	39 / 60 (65%)
Just enough force	29 / 90 (32%)	9 / 30 (30%)	20 / 60 (33%)
Significant force	1 / 90 (1.1%)	0 / 30 (0%)	1 / 60 (1.7%)
TELLTALE system devices were removed intact	90 / 90 (100%)	30 / 30 (100%)	60 / 60 (100%)
Target leaflet was avulsed by BASILICA			
No	90 / 90 (100%)	30 / 30 (100%)	60 / 60 (100%)
PCI or other rescue procedure required on threatened coronary artery despite TELLTALE BASILICA	0 / 90 (0%)	0 / 30 (0%)	0 / 60 (0%)
Other complications of BASILICA observed	0 / 90 (0%)	0 / 30 (0%)	0 / 60 (0%)
Bioprosthetic frame fracture or remodeling attempted	29 / 89 (33%)		29 / 59 (49%)
Bioprosthetic frame fracture or remodeling timing			
After TAVR	19 / 29 (66%)		19 / 29 (66%)
Before TAVR	10 / 29 (34%)		10 / 29 (34%)

Characteristic	Overall, N = 90[1]	Native, N = 30[1]	Bioprosthetic, N = 60[1]
Bioprosthetic frame fracture or remodeling was successful			
Expansion/remodeling with improved gradient	13 / 90 (14%)		13 / 60 (22%)
Fracture	16 / 90 (18%)		16 / 60 (27%)
NA	61 / 90 (68%)		31 / 60 (52%)
Cerebral embolic protection			
None	13 / 90 (14%)	4 / 30 (13%)	9 / 60 (15%)
Sentinel both baskets	73 / 90 (81%)	25 / 30 (83%)	48 / 60 (80%)
Sentinel only one basket	4 / 90 (4.4%)	1 / 30 (3.3%)	3 / 60 (5.0%)
Debris recovered from cerebral embolic protection device	29 / 76 (38%)	10 / 25 (40%)	19 / 51 (37%)
TAVI device implanted			
Evolut FX/FX+	43 / 90 (48%)	14 / 30 (47%)	29 / 60 (48%)
Sapien 3	2 / 90 (2.2%)	0 / 30 (0%)	2 / 60 (3.3%)
Sapien 3 Ultra NOT Resilia	11 / 90 (12%)	6 / 30 (20%)	5 / 60 (8.3%)
Sapien 3 Ultra Resilia	31 / 90 (34%)	9 / 30 (30%)	22 / 60 (37%)
Navitor	3 / 90 (3.3%)	1 / 30 (3.3%)	2 / 60 (3.3%)
TAVI device nominal diameter			
20	8 / 90 (8.9%)	1 / 30 (3.3%)	7 / 60 (12%)
23	52 / 90 (58%)	17 / 30 (57%)	35 / 60 (58%)
26	25 / 90 (28%)	10 / 30 (33%)	15 / 60 (25%)
29	5 / 90 (5.6%)	2 / 30 (6.7%)	3 / 60 (5.0%)
TELLTALE electrosurgical generator employed			
Valleylabs FT10	89 / 90 (99%)	29 / 30 (97%)	60 / 60 (100%)
Other	1 / 90 (1.1%)	1 / 30 (3.3%)	0 / 60 (0%)
Fluoroscopy time (min)	37 (30, 47)	31 (24, 38)	41 (34, 51)
Radiocontrast volume (mL)	83 (50, 149)	90 (66, 168)	75 (45, 121)
Protamine used	77 / 90 (86%)	25 / 30 (83%)	52 / 60 (87%)
Anesthesia or sedation strategy			
General & extubated in-lab	63 / 90 (70%)	24 / 30 (80%)	39 / 60 (65%)
General & NOT extubated in-lab	2 / 90 (2.2%)	0 / 30 (0%)	2 / 60 (3.3%)
Moderate sedation	25 / 90 (28%)	6 / 30 (20%)	19 / 60 (32%)

[1] n (%)

Primary Effectiveness Endpoints

The Primary Efficacy Endpoint (technical success upon exit from the cath lab) was met in 100% of participants. These findings support the Telltale device is as effective as the predicate.

	All participants (n=90)
Primary Efficacy Endpoint	90 (100%)
Successful electrosurgical leaflet traversal using the TELLTALE Guidewire, and	90 (100%)
Successful electrosurgical leaflet laceration using the TELLTALE Guidewire, and	90 (100%)
Successful retrieval of the TELLTALE Guidewire System	90 (100%)

Values are reported as n (%).

Primary Safety Endpoints

The primary safety endpoint (of freedom from major safety events upon discharge from the index hospital encounter) was met in 96% of subjects. The Primary Safety Endpoint events include no mortality, 3 strokes (1 disabling, 2 non-disabling) and 1 coronary obstruction from THV commissural suture post malalignment.

These findings support the Telltale device is as safe as the predicate.

The primary safety endpoints shown in the table below were determined by an independent CEAC that had access to participants' medical records.

	All participants (n=90)
Primary Safety Endpoint, defined as freedom from all of the following at hospital discharge	86 (96%)
All-cause mortality	0 (0%)
Stroke	3 (3%)
Disabling	1 (1%)
Non-disabling	2 (2%)
Coronary obstruction [a]	1 (1%)
Emergency cardiac surgery or reintervention related to the TELLTALE BASILICA procedure or device	0 (0%)
BASILICA-related complications including coronary artery perforation, coronary artery dissection, aortic dissection, cardiac free wall perforation, or systemic embolization of a native or bioprosthetic leaflet	0 (0%)

Values are reported as n (%). Some participants suffered multiple events contributing to the safety endpoint.

[a] Coronary obstruction resulted in one participant from randomly-aligned commissural post of the balloon- expandable valve in front of the split leaflet.

Secondary Endpoints

The table below summarizes in-hospital and cumulative 30-day clinical outcomes. The only events that occurred between hospital discharge and 30-day follow up were 1 additional pacemaker implantation, 1 gastrointestinal bleed requiring transfusion and 1 vascular complication (pulmonary embolism). The corresponding Secondary Safety Endpoint was met in 89% of participants at 30 days. These findings support the Telltale device is as safe as the predicate.

	In-hospital (n=90)	30 days cumulative (n=90)
Primary Safety Endpoint [a]	96%	–
Secondary Safety Endpoint [b]	–	89%
Mortality, all-cause	0 (0%)	0 (0%)
Stroke	3 (3%)	3 (3%)
Disabling	1 (1%)	1 (1%)
Non-disabling	2 (2%)	2 (2%)
Transient ischemic attack	0 (0%)	0 (0%)
Myocardial infarction [c]	1 (1%)	1 (1%)
Major or life-threatening vascular complication	3 (3%)	4 (5%)
Major or life-threatening bleeding	4 (4%)	5 (6%)
Acute kidney injury stage 3 or 4	0 (0%)	0 (0%)
Coronary obstruction [c]	1 (1%)	1 (1%)
New permanent pacemaker	4 (4%)	5 (6%)

[a] The Primary Safety endpoint was in-hospital safety, assessed upon discharge from the index hospitalization and was defined as a composite of freedom from all-cause mortality, stroke (both disabling and non- disabling), acute coronary artery obstruction, emergency cardiac surgery or reintervention related to the TELLTALE BASILICA procedure or device, and BASILICA-related complications including coronary artery perforation, coronary artery dissection, aortic dissection, cardiac free wall perforation, or systemic embolization of a native or bioprosthetic leaflet.

[b] The secondary endpoint was freedom from MACE (according to VARC-3) at 30 days, including freedom from all of the following: all-cause mortality, stroke (disabling and non-disabling), bleeding VARC-3 Type 2 or greater (requiring two or more units of transfused blood or hemoglobin drop >3g/dL), major vascular, access- related, or cardiac structural complication (according to VARC-3, which includes coronary obstruction), acute kidney injury stage 3 or 4, moderate or severe aortic regurgitation, new permanent pacemaker due to procedure-related conduction abnormalities, surgery or intervention related to the TELLTALE device.

[c] The myocardial infarction corresponded to the coronary obstruction.

Adverse Events

There were three strokes in the study (1 disabling and 2 non-disabling). All three had cerebral embolic protection in place for at least part of the procedure, and site-reported embolic debris were not identified in any.

Only one stroke was clearly procedure-related and occurred in a participant with bioprosthetic valve failure in whom the cerebral embolic protection device was removed after TELLTALE leaflet modification, but before TAVR and bioprosthetic valve fracture. In this case, the operators removed the cerebral embolic protection device after TELLTALE BASILICA as part of snare-assisted THV delivery in a participant with a horizontal aorta. The CEAC determined this stroke to be unlikely related to TELLTALE BASILICA. This stroke was non-disabling.

Two additional strokes occurred in participants with native aortic stenosis and were diagnosed on post- procedure day 2 and day 5. One was disabling and one was non-disabling. Both participants had underlying atrial fibrillation, and oral anticoagulation was withheld peri-procedurally per standard of care. The CEAC determined these strokes to be unlikely related to TELLTALE BASILICA.

One participant had coronary obstruction which manifested after the procedure with shock and returned to the cath lab. Further imaging demonstrated that the randomly-aligned commissural suture post of the balloon-expandable THV landed in front of the split leaflet. Percutaneous coronary intervention was performed with deployment of an orthotopic stent, not otherwise possible without successful BASILICA, and the participant was discharged from hospital.

Complete 30-day clinical follow-up was available for all 90 participants. The only events that occurred between hospital discharge and 30-day follow up were 1 additional pacemaker implantation, 1 gastrointestinal bleed requiring transfusion and 1 vascular complication (pulmonary embolism). The corresponding Secondary Safety Endpoint was met in 89% of participants at 30days. The table below shows the composite safety at 90days. All participants but one (89/90) had their 90-day visits. One withdrew consent to participate between 30 and 90 days.

There were no deaths in the study.

	In-hospital (n=90)	30 days cumulative (n=90)	90 days cumulative (n=89)
Primary Safety Endpoint [a]	86/90 (95.6%)	-	-
Secondary Safety Endpoint [b]	-	80/90 (89%)	-
Exploratory Endpoint: Composite safety (secondary endpoint) assessed at 90 days	-	-	74/89 (83%)
Withdrew from study (post 30-day FU)	-	-	1
Mortality, all-cause	0	0	0
Stroke	3	3	6
Disabling	1	1	3
Non-disabling	2	2	3
Transient ischemic attack	0	0	0
Myocardial infarction [c]	1	1	1
Major or life-threatening vascular complication	3	4	5
Major or life-threatening bleeding	4	5	5
Acute kidney injury stage 3 or 4	0	0	0
Coronary obstruction [c]	1	1	1
New permanent pacemaker	4	5	5
Serious Adverse Events after 30 days			
Congestive Heart Failure			2
Pulmonary Embolus/Atrial fibrillation			1
Pulmonary syndromes not thromboembolic			4
Sepsis-UTI			1
Cancer			2
Elective Surgery			2
Mitral Valve Endocarditis-surgical repair			1

[a] The Primary Safety endpoint was in-hospital safety, assessed upon discharge from the index hospitalization and was defined as a composite of freedom from all-cause mortality, stroke (both disabling and non- disabling), acute coronary artery obstruction, emergency cardiac surgery or reintervention related to the TELLTALE BASILICA procedure or device, and BASILICA-related complications including coronary artery perforation, coronary artery dissection, aortic dissection, cardiac free wall perforation, or systemic embolization of a native or bioprosthetic leaflet.

[b] The secondary endpoint was freedom from MACE (according to VARC-3) at 30 days, including freedom from all of the following: all-cause mortality, stroke (disabling and non-disabling), bleeding VARC-3 Type 2 or greater (requiring two or more units of transfused blood or hemoglobin drop >3g/dL), major vascular, access- related, or cardiac structural complication (according to VARC-3, which includes coronary obstruction), acute kidney injury stage 3 or 4, moderate or severe aortic regurgitation, new permanent pacemaker due to procedure-related conduction abnormalities, surgery or intervention related to the TELLTALE device.

[c] The myocardial infarction corresponded to the coronary obstruction.

Pivotal Study Conclusions

This pivotal trial examined the safety and efficacy of leaflet modification using the TELLTALE Electrosurgical Guidewire System, a novel dedicated electrosurgical system to prevent coronary obstruction in patients undergoing TAVR for native aortic stenosis or bioprosthetic valve failure.

The key findings were:

I. Leaflet traversal and laceration were achieved in 100% of participants with native aortic stenosis or bioprosthetic valve failure and high-risk anatomy for coronary obstruction
II. Leaflet modification was easy and reliable with median 1 traversal and laceration attempt per participant
III. Freedom from in-hospital major safety event was achieved in 96% of participants
IV. Coronary obstruction occurred in only one participant, attributed to THV commissural malalignment, which was rescued with deployment of an orthotopic stent through THV cells only possible because of successful TELLTALE laceration.

Electrosurgical leaflet modification using the TELLTALE Electrosurgical Guidewire System in patients undergoing TAVR for native aortic stenosis or bioprosthetic valve failure at high risk of coronary obstruction has substantial equivalence to the predicate device.

Conclusions

Upon reviewing the information provided in this submission and comparing the intended use, principle of operation and overall technological characteristics, the TELLTALE Electrosurgical Guidewire System is substantially equivalent to the existing legally marketed device.