FDA 510(k) Premarket Notification

CLEARED

K252592 TELLTALE Electrosurgical Guidewire System

Nov 13, 2025
90 days to decision

K252592 · Product code: **SGO** · Cardiovascular
Source: https://www.510kdatabase.net/k252592/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percutaneous Catheter For Electrosurgical Cutting Heart Valve Leaflets Concomitant To Transcatheter Valve Procedures (SGO)
Date received	Aug 15, 2025
Decision date	Nov 13, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Telltale, LLC**
Location	Andover, MA, US
Contact	Koosha Rafiee
510(k) history	1 submissions · 1 cleared · 2025-2025

CLINICAL EVIDENCE - NCT05666713

NHLBI Transmural Electrosurgery LeafLet Traversal And Laceration Evaluation (TELLTALE) BASILICA-TAVR Trial

Status	Completed
Enrollment	90 patients (actual)
Study sites	10 sites
Condition studied	Valvular Heart Disease; Aortic Valve Failure
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Apr 25, 2025
Sponsor	National Heart, Lung, and Blood Institute (NHLBI) (Nih)

Primary outcome

Number of Participant That Experienced Technical Success With the TELLTALE Guidewire System

Secondary outcome

Freedom From Safety Events

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05666713