CLEARED

K222873 Attain Command + SureValve Delivery System, Attain Select II + SureValve delivery system

Nov 7, 2022
46 days to decision

K222873 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k222873/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 22, 2022
Decision date	Nov 7, 2022
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic**
Location	Minneapolis, MN, US
Contact	Sarah Meyer
Website	http://www.medtronic.com/us-en/index.html
510(k) history	32 submissions · 32 cleared · 2007-2026

Medtronic is an American-Irish medical device company with operational headquarters in Minneapolis, Minnesota. The company operates globally across more than 150 countries and is the largest medical device company in the world by revenue. Medtronic has received FDA 510(k) clearances from total submissions since 2007. The company's regulatory portfolio is dominated by cardiovascular devices, including oxygenation systems, arterial filters, cardioplegia delivery systems, and catheter-based interventions. Medtronic also maintains a significant presence in orthopedic spinal s...

CLINICAL EVIDENCE - NCT04863664

Lead EvaluAtion for Defibrillation and Reliability (LEADR) / Lead Evaluation for Defibrillation and Reliability in Left Bundle Branch Area Pacing (LEADR LBBAP)

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	998 patients (actual)
Study sites	55 sites
Condition studied	Tachyarrhythmia
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Nov 6, 2025
Sponsor	Medtronic Cardiac Rhythm and Heart Failure (Industry)

Primary outcome

LEADR: Estimate the rate of major Lead complication-free rate at 6 months

Secondary outcome

LEADR: Estimate the fracture-free rate of the Next Generation ICD lead

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04863664