Post-Approval Studies (PAS) Database

The FDA has the authority to require sponsors to perform a post-approval study (or studies) at the time of approval of a premarket approval (PMA), humanitarian device exemption (HDE), or product development protocol (PDP) application. Post-approval studies can provide patients, health care professionals, the device industry, the FDA and other stakeholders information on the continued safety and effectiveness (or continued probable benefit, in the case of an HDE) of approved medical devices. This database allows you to search Post-Approval Study information by applicant or device information.

Learn more...

Cont F/u Low Risk Premarket Cohort

Suggest Enhancement / Report Issue | Export to Excel

General	
Study Status	**Ongoing**
Application Number / Requirement Number	P130021 S076/ PAS001
Date Original Protocol Accepted	08/17/2020
Date Current Protocol Accepted	
Study Name	Cont F/u Low Risk Premarket Cohort
Device Name	Medtronic CoreValve Evolut R System, Medtronic CoreValve Evolut PRO System, and Medtronic Evolut PRO+ System
General Study Protocol Parameters	
Study Design	Prospective Cohort Study
Data Source	New Data Collection
Comparison Group	No Control
Analysis Type	Descriptive
Study Population	Adult: >21
Detailed Study Protocol Parameters	
Study Objectives	Continued follow-up of all 148 subjects who were enrolled in the Bicuspid Registry under IDE G160022. The objective of this study is to characterize the clinical outcomes annually through 10 years post-procedure.
Study Population	All living subjects who were enrolled in the Bicuspid Registry.
Sample Size	148
Key Study Endpoints	All-cause mortality, all stroke (disabling and nondisabling), life-threatening bleeding, acute kidney injury at stage 2 or 3, coronary artery obstruction requiring intervention, major vascular complication, valve-related dysfunction requiring repeat procedure, new permanent pacemaker implantation, prosthetic valve endocarditis, prosthetic valve thrombosis, New York Heart Association (NYHA) classification, Kansas City Cardiomyopathy Questionnaire (KCCQ) score, and hemodynamic performance metrics by Doppler echocardiography.
Follow-up Visits and Length of Follow-up	10 years. All subjects are followed annually through 10 years post procedure.

Cont F/u Low Risk Premarket Cohort Reporting Schedule

Reporting Schedule	Report Date Due	FDA Receipt Date	Applicant's Reporting Status
1 year report	03/31/2021	03/30/2021	On Time
2 year report	03/31/2022	03/23/2022	On Time
3 year report	03/31/2023	03/27/2023	On Time
4 year report	03/31/2024		
5 year report	03/31/2025		
6 year report	03/31/2026		
7 year report	03/31/2027		
8 year report	03/31/2028		
9 year report	03/31/2029		
10 year report	03/31/2030		

Contact Us

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Additional Resources

- Guidance Document: "Procedures for Handling Post-Approval Studies Imposed by PMA Order" - June 15, 2009
- PAS Database Background
- PAS FAQs

Page Last Updated: 10/09/2023

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English