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.

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Low Risk Real World Use Surveillance

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General	
Study Status	**Ongoing**
Application Number / Requirement Number	P130021 S076/ PAS002
Date Original Protocol Accepted	08/17/2020
Date Current Protocol Accepted	
Study Name	Low Risk Real World Use Surveillance
Device Name	Medtronic CoreValve Evolut R System, Medtronic CoreValve Evolut PRO System, and Medtronic Evolut PRO+ System
General Study Protocol Parameters	
Study Design	Comprehensive/Linked/RegistryBased Surveillance
Data Source	External Registry
Comparison Group	No Control
Analysis Type	Descriptive
Study Population	Adult: >21
Detailed Study Protocol Parameters	
Study Objectives	Comprehensive/linked/registry-based surveillance. The objective of the surveillance is to assess the real-world use of the CoreValve Evolut R System, CoreValve Evolut PRO System, and Evolut PRO+ System to ensure that the devices are used in appropriate patient population.
Study Population	The surveillance of the real-world use will involve all consecutive patients treated within the first 2 years that are entered into the TVT Registry (enrollment period).
Sample Size	All consecutive patients treated within the first 2 years in the commercial setting that are entered into the TVT Registry.
Key Study Endpoints	The clinical data through one (1) year will be collected through the TVT Registry; and the follow-up data from year 2 through year 10 post procedure will be obtained through linking the TVT data with the Centers for Medicare and Medicaid Services (CMS) claims database. The surveillance will monitor the following: (1) device success (intra-procedure); (2) all-cause mortality, all stroke, life-threatening/major bleeding, new requirement for dialysis, peri-procedural myocardial infarction, and repeat procedure for valve-related dysfunction (surgical or interventional therapy) at 30 days and 12 months; (3) neurological (non-stroke), vascular complications, and quality of life (KCCQ) outcomes at 30 days and 12 months; and (4) all-cause mortality, all stroke, and repeat procedure for valve-related dysfunction (surgical or interventional therapy) at 2-10 year post implantation.
Follow-up Visits and Length of Follow-up	10 years. All subjects are followed annually through 10 years post procedure.
Interim or Final Data Summary	
Actual Number of Patients Enrolled	Real World Surveillance Low Risk Bicuspid Cohort: 721
Actual Number of Sites Enrolled	registry based
Patient Follow-up Rate	registry based
Final Safety Findings	K-M Adverse Event Rates: All-cause mortality: 1.3% at 30 days; 3.7% at 1 year Any Stroke: 2.8% at 30 days; 4.1% at 1 year Aortic Valve Re-intervention: 1.0% at 30 days; 2.2% at 1 year

Low Risk Real World Use Surveillance Reporting Schedule

Reporting Schedule	Report Date Due	FDA Receipt Date	Applicant's Reporting Status
1 year report	01/17/2022	01/14/2022	On Time
2 year report	01/17/2023	01/17/2023	On Time
3 year report	01/17/2024		
4 year report	01/17/2025		
5 year report	01/17/2026		
6 year report	01/17/2027		
7 year report	01/17/2028		
8 year report	01/17/2029		
9 year report	01/17/2030		
10 year report	01/17/2031		
11 year report	01/17/2032		
12 year report	01/17/2033		
13 year report	01/17/2034		
14 year report	01/17/2035		
15 year report	01/17/2036		

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

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