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...[6]

Actual Conditions of Use Study (STAR 2)

General	
Study Status	**Delayed**
Application Number / Requirement Number	P050050 / PAS002
Date Original Protocol Accepted	05/27/2009
Date Current Protocol Accepted	05/06/2022
Study Name	Actual Conditions of Use Study (STAR 2)
Device Name	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE)
General Study Protocol Parameters	
Study Design	Prospective Cohort Study
Data Source	New Data Collection
Comparison Group	Historical Control
Analysis Type	Analytical
Detailed Study Protocol Parameters	
Study Objectives	This is a retrospective, Real-World Evidence multi-center study. The purpose of this study is to examine the safety and survivorship of the STAR™ Ankle under actual conditions of use, employing the approved instructions for use, labeling, and instrumentation. This study will enroll a minimum of 500 on-label subjects across approximately 5 sites in the United States, consecutively implanted per site, who are to be assessed in this clinical investigation. Each site will have a minimum of fifty patients, with subject patient primary surgery dates taking place between 2015-2019.
Study Population	A minimum of 500 adult male or female subjects, who meet all the study criteria (listed in 4.6), that received treatment with the STAR ankle implant for ankle replacement for treatment of a painful arthritic ankle joint due to osteoarthritis, posttraumatic arthritis or rheumatoid arthritis. Patients sets at each site will be on-label and consecutive. The study plan is to enroll all on-label, consecutive patients per site with primary STAR surgery dates betweer 2015 and 2019. With this surgery date range, the potential patient follow-up period should be between approximately two years at a minimum to seven years maximum. With this new patient follow-up range, the longer time periods for this subject study will be between the PAS2 and PAS8 study bounds.

Sample Size	No. of subjects: 500 on-label subjects No. of sites: 5 (Each site will have a minimum of 50 patients). Sites location: US
Key Study Endpoints	Primary Objective: To examine the safety and survivorship of the STAR™ Ankle under actual conditions of use, employing the approved instructions for use, labeling, and instrumentation. The primary endpoint consists of evaluating key safety and survivorship parameters associated with the STAR™ Ankle, with specific elements listed below. 1. Reoperations - incidence rates and times to event will be collected. 2. Revisions - incidence rates and times to event will be collected. 3. Removals - Incidence rates and times to event will be collected. 4. Occurrence and types of serious device-related adverse events. Secondary Objective: Information regarding the following patient and treatment parameters will be gathered and assessed in the course of evaluation: Nature/reason for revision, onset, duration, severity, relationship to the device, relationship to the operative procedure, and outcome of any adverse event
Follow-up Visits and Length of Follow-up	Duration of follow-up will vary based upon date of primary STAR surgery. All available patient records through the present will be collected per patient, such that patients with surgery dates in 2015 may have up to seven years of follow-up, while those patients with surgery dates in 2019 may have approximately two years of follow-up.

Interim or Final Data Summary

Interim Results	Safety Results: 137 adverse events were reported. AEs were associated with 66 of the 142 enrolled patients, such that 46.48% of patients had one or more AEs. Twenty-one (21) reoperations, fifteen (15) revisions, and five (5) removals were recorded in the current 142-patient data set.
Actual Number of Patients Enrolled	142
Actual Number of Sites Enrolled	Four (4)
Patient Follow-up Rate	28.4%

Actual Conditions of Use Study (STAR 2) Reporting Schedule

Reporting Schedule	Report Date Due	FDA Receipt Date	Applicant's Reporting Status
6 month report	03/29/2010	03/29/2010	On Time
1 year report	05/27/2010	05/28/2010	Overdue/Received
18 month report	11/25/2010	11/18/2010	On Time
2 year report	05/27/2011	05/27/2011	On Time
3 year report	05/26/2012	05/25/2012	On Time
4 year report	05/27/2013	05/28/2013	Overdue/Received
5 year report	06/26/2014	06/27/2014	Overdue/Received
6 year report	06/26/2015	06/26/2015	On Time
7 year report	06/26/2016	06/24/2016	On Time
8 year report	11/28/2017	11/28/2017	On Time
interim report	05/25/2018	05/25/2018	On Time
9 year report	10/31/2019	10/31/2019	On Time
10 year report/final	02/26/2021	02/26/2021	On Time

Contact Us
Mandated Studies Program
Food and Drug Administration
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Silver Spring, MD 20993-0002
Email: MandatedStudiesPrograms@fda.hhs.gov

Additional Resources

- Guidance Document: "Procedures for Handling Post-Approval Studies Imposed by PMA Order"[7]
- PAS Program Background[8]

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