Validation of CardioMEMS HF System Cardiac Output Algorithm IDE Clinical Investigation Plan

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

- at least 18 years old - have a CardioMEMS Pulmonary Artery Sensor for a minimum of 3 months - able to undergo several cardiac Magnetic Resonance Imaging scans (MRI's) - able to upload Pulmonary Artery pressure information daily

Exclusion Criteria:

- likely to receive mechanical circulatory support or cardiac transplant in the next 6 months - pregnant or planning to become pregnant in the next 6 months - other cardiac conditions such as unrepaired congenital heart defect, valve disease, heart attack (study staff will review)

Conditions & Interventions

Conditions:
Heart & Vascular
Keywords:
CardioMEMS

More Information

Description: There are two primary objectives of this clinical investigation. The first objective is to finalize development of the algorithm estimating CO by collecting paired cMRI measurements of CO, as well as other parameters of heart function, and CardioMEMS HF System readings in the same subject. The second objective of this clinical investigation is to use data collected during the validation phase, distinct from the subjects within the development phase, to evaluate the agreement between the CardioMEMS HF System-derived CO and the CO values from cMRI in patients previously implanted with the commercially available CardioMEMS HF System.
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