Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s). If you are using a web page screen reader and are unable to access this document, please contact the Sentinel Operations Center for assistance at info@sentinelsystem.org.

	Inclusion Criteria				Exclusion Criteria				Outcome				Baseline Characteristics	
Scenario	Pre-Existing Condition	Care Setting	Include/ Exclude	Lookback Period (days)	Pre-Existing Condition	Care Setting	Include/ Exclude	Lookback Period (days)	Outcome	Care Setting	Washout (days)	Blackout Period (days)	Characteristics	Evaluation Window (days)
5	Atrial fibrillation	Any	Include	-183, 0	Dialysis, kidney replacement, deep vein thrombosis, pulmonary embolism, joint replacement, mitral stenosis, valve replacement or valve repair	Any, except AV/OA for dialysis	Exclude	-183, 0	Intracranial hemorrhage	IPP	0	1	See Appendix F	-183, 0
6	Atrial fibrillation	Any	Include	-183, 0	Dialysis, kidney replacement, deep vein thrombosis, pulmonary embolism, joint replacement, mitral stenosis, valve replacement or valve repair	Any, except AV/OA for dialysis	Exclude	-183, 0	Intracranial hemorrhage	IPP	0	1	See Appendix F	-183, 0
7	Atrial fibrillation	Any	Include	-183, 0	Dialysis, kidney replacement, deep vein thrombosis, pulmonary embolism, joint replacement, mitral stenosis, valve replacement or valve repair	Any, except AV/OA for dialysis	Exclude	-183, 0	Stroke	IPP	0	1	See Appendix F	-183, 0
8	Atrial fibrillation	Any	Include	-183, 0	Dialysis, kidney replacement, deep vein thrombosis, pulmonary embolism, joint replacement, mitral stenosis, valve replacement or valve repair	Any, except AV/OA for dialysis	Exclude	-183, 0	Stroke	IPP	0	1	See Appendix F	-183, 0

[1]Possible care settings include: Inpatient Hospital Stay in the Primary position (IPP), Inpatient Hospital Stay in the Secondary position (IPS), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA).

International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) codes are provided by Optum360.

National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."