FDA 510(k) Premarket Notification

CLEARED

K242952 INNOVANCE Antithrombin

Mar 28, 2025
184 days to decision

K242952 · Product code: **JBQ** · Hematology
Source: https://www.510kdatabase.net/k242952/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antithrombin Iii Quantitation (JBQ)
Date received	Sep 25, 2024
Decision date	Mar 28, 2025
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Healthcare Diagnostic Products GmbH**
Location	Marburg, DE
Contact	Martina Pfeiff
510(k) history	4 submissions · 4 cleared · 2016-2025

CLINICAL EVIDENCE - NCT03754790

Long-term Safety and Efficacy Study of Fitusiran in Patients With Hemophilia A or B, With or Without Inhibitory Antibodies to Factor VIII or IX

Status	Active not recruiting - *No results published to ClinicalTrials.gov*
Enrollment	281 patients (actual)
Study sites	79 sites
Condition studied	Hemophilia
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Nov 5, 2026
Sponsor	Genzyme, a Sanofi Company (Industry)

Primary outcome

Number of participants with treatment emergent adverse events (TEAEs)

Secondary outcome

Annualized bleeding rate (ABR)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03754790