FDA 510(k) Premarket Notification

K050053 HEMORAM/AGGRAM ANALYZER

CLEARED

Jul 11, 2005
182 days to decision

K050053 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k050053/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Jan 10, 2005
Decision date	Jul 11, 2005
Days to decision	182 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Helena Laboratories**
Location	Mchenry, IL, US
Contact	PATRICIA FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013