FDA 510(k) Premarket Notification

K854376 HEMOTEC CITRATED WHOLE BLOOD COAGULATION CONTROLS

CLEARED

Dec 4, 1985
35 days to decision

K854376 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k854376/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Oct 30, 1985
Decision date	Dec 4, 1985
Days to decision	35 days
Third-party review	No

APPLICANT

Company	**Hemotec, Inc.**
Location	Mchenry, IL, US
Contact	WILLIAM A MORTON
510(k) history	15 submissions · 15 cleared · 1980-1990