FDA 510(k) Premarket Notification

K854938 COASCREENER/DIASCREENERBLOOD PLASMA TIMING INST.

CLEARED

Mar 12, 1986
92 days to decision

K854938 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k854938/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Dec 10, 1985
Decision date	Mar 12, 1986
Days to decision	92 days
Third-party review	No

APPLICANT

Company	**Diatech, Inc.**
Location	Mchenry, IL, US
Contact	BETTY L WHITE
510(k) history	17 submissions · 17 cleared · 1984-1988