FDA 510(k) Premarket Notification

K853198 ADDITIONAL HEMOTEC ACT COAGULATION CARTRIDGES

CLEARED

Oct 4, 1985
66 days to decision

K853198 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k853198/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Jul 30, 1985
Decision date	Oct 4, 1985
Days to decision	66 days
Third-party review	No

APPLICANT

Company	**Medical Device Consultants, Inc.**
Location	N. Attleboro, MA, US
Contact	WILLIAM A MORTON
510(k) history	14 submissions · 14 cleared · 1982-2002