FDA 510(k) Premarket Notification

K760594 AUTO-FI COAGULATION INSTRUMENT

CLEARED

Nov 24, 1976
78 days to decision

K760594 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k760594/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Sep 7, 1976
Decision date	Nov 24, 1976
Days to decision	78 days
Third-party review	No

APPLICANT

Company	**Dade, Baxter Travenol Diagnostics, Inc.**
Location	Mchenry, IL, US
510(k) history	44 submissions · 44 cleared · 1976-1980