FDA 510(k) Premarket Notification

K940840 ACT CONTROL SET

CLEARED

Jul 19, 1994
146 days to decision

K940840 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k940840/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Feb 23, 1994
Decision date	Jul 19, 1994
Days to decision	146 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Sigma Diagnostics, Inc.**
Location	Mchenry, IL, US
Contact	DANIEL E LAWSON, PH.D
510(k) history	164 submissions · 164 cleared · 1984-2002