K930068 HEMOCHRON MODEL 8000/FACTOR VI PREMIER COAGULATION

CLEARED

Sep 2, 1993
239 days to decision

K930068 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k930068/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Jan 6, 1993
Decision date	Sep 2, 1993
Days to decision	239 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Technidyne Corp.**
Location	Edison, NJ, US
Contact	MATT LESNIESKI
510(k) history	2 submissions · 2 cleared · 1993-1993