FDA 510(k) Premarket Notification

K832225 ORTHO ABNORMAL COAGULATION LEVEL I/II

CLEARED

Aug 12, 1983
35 days to decision

K832225 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k832225/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Jul 8, 1983
Decision date	Aug 12, 1983
Days to decision	35 days
Third-party review	No

APPLICANT

Company	**Ortho Diagnostic Systems, Inc.**
Location	Carpinteria, CA, US
510(k) history	126 submissions · 126 cleared · 1981-1997