FDA 510(k) Premarket Notification

K883690 ORTHO FACTOR X DEFICIENT PLASMA

CLEARED

Nov 1, 1988
64 days to decision

K883690 · Product code: **GJT** · Hematology
Source: https://www.510kdatabase.net/k883690/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Aug 29, 1988
Decision date	Nov 1, 1988
Days to decision	64 days
Third-party review	No

APPLICANT

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