FDA 510(k) Premarket Notification

K900395 ORTHOKROME* FACTOR VIII

CLEARED

Mar 15, 1990
45 days to decision

K900395 · Product code: **GGP** · Hematology
Source: https://www.510kdatabase.net/k900395/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Jan 29, 1990
Decision date	Mar 15, 1990
Days to decision	45 days
Third-party review	No

APPLICANT

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