FDA 510(k) Premarket Notification

K834050 PROTOPATH FACTOR IX ASSAY

CLEARED

Feb 4, 1984
73 days to decision

K834050 · Product code: **GGP** · Hematology
Source: https://www.510kdatabase.net/k834050/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 23, 1983
Decision date	Feb 4, 1984
Days to decision	73 days
Third-party review	No

APPLICANT

Company	**American Dade**
Location	Mchenry, IL, US
510(k) history	149 submissions · 149 cleared · 1980-1987