FDA 510(k) Premarket Notification

K834031 FACTOR II DEFICIENT SUBSTRATE PLASMA

CLEARED

Dec 16, 1983
24 days to decision

K834031 · Product code: **GGP** · Hematology
Source: https://www.510kdatabase.net/k834031/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 22, 1983
Decision date	Dec 16, 1983
Days to decision	24 days
Third-party review	No

APPLICANT

Company	**Helena Laboratories**
Location	Mchenry, IL, US
510(k) history	280 submissions · 280 cleared · 1978-2013