FDA 510(k) Premarket Notification

K840329 RISTOCETIN COFACTOR ASSAY

CLEARED

Apr 5, 1984
71 days to decision

K840329 · Product code: **GGP** · Hematology
Source: https://www.510kdatabase.net/k840329/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Jan 25, 1984
Decision date	Apr 5, 1984
Days to decision	71 days
Third-party review	No

APPLICANT

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