FDA 510(k) Premarket Notification

K897136 PROTEIN C ANTIGEN ROCKET EID METHOD NO. 5357

CLEARED

Feb 5, 1990
40 days to decision

K897136 · Product code: **GGP** · Hematology
Source: https://www.510kdatabase.net/k897136/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Dec 27, 1989
Decision date	Feb 5, 1990
Days to decision	40 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k897136/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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