FDA 510(k) Premarket Notification

CLEARED

K896174 PROTEIN S ANTIGEN ROCKET EID KIT, CAT. NO. 5359

Mar 15, 1990
141 days to decision

K896174 · Product code: **GGP** · Hematology
Source: https://www.510kdatabase.net/k896174/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Oct 25, 1989
Decision date	Mar 15, 1990
Days to decision	141 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/k896174/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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