FDA 510(k) Premarket Notification

K900019 ROCKET REFERENCE PLASMA, CAT NO. 5188

CLEARED

Jan 25, 1990
23 days to decision

K900019 · Product code: **GGN** · Hematology
Source: https://www.510kdatabase.net/k900019/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Jan 2, 1990
Decision date	Jan 25, 1990
Days to decision	23 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/k900019/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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