FDA 510(k) Premarket Notification

K905673 AB-TROL II COAGULATION CONTROL PLASM CAT. NO. 5183

CLEARED

Feb 11, 1991
55 days to decision

K905673 · Product code: **GGN** · Hematology
Source: https://www.510kdatabase.net/k905673/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Dec 18, 1990
Decision date	Feb 11, 1991
Days to decision	55 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/k905673/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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