FDA 510(k) Premarket Notification

K900017 REP GLYCO CONTROL NORMAL(3209) AND ABNORMAL(3210)

CLEARED

Jan 29, 1990
27 days to decision

K900017 · Product code: **JPK** · Hematology
Source: https://www.510kdatabase.net/k900017/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Jan 2, 1990
Decision date	Jan 29, 1990
Days to decision	27 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/k900017/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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