FDA 510(k) Premarket Notification

K894585 REP TM SPE (PONCEAU S) PROCEDURES

CLEARED

Sep 13, 1989
51 days to decision

K894585 · Product code: **CEF** · Chemistry
Source: https://www.510kdatabase.net/k894585/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic, Protein Fractionation (CEF)
Date received	Jul 24, 1989
Decision date	Sep 13, 1989
Days to decision	51 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/k894585/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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