FDA 510(k) Premarket Notification

K901463 REP(TM) SPE PLUS-16 (PONCEAU S) AND (AMIDO)

CLEARED

Jun 12, 1990
76 days to decision

K901463 · Product code: **JQJ** · Chemistry
Source: https://www.510kdatabase.net/k901463/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Densitometeric, Protein Fractionation (JQJ)
Date received	Mar 28, 1990
Decision date	Jun 12, 1990
Days to decision	76 days
Third-party review	No

APPLICANT

Company	**Helena Laboratories**
Location	Mchenry, IL, US
Contact	ERIC PETERSEN
510(k) history	280 submissions · 280 cleared · 1978-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k901463/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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