FDA 510(k) Premarket Notification

K896572 REP(TM) SPE PLUS-30 PROCEDURES

CLEARED

Jan 11, 1990
52 days to decision

K896572 · Product code: **CFP** · Chemistry
Source: https://www.510kdatabase.net/k896572/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Immunoreactive Insulin (CFP)
Date received	Nov 20, 1989
Decision date	Jan 11, 1990
Days to decision	52 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/k896572/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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