FDA 510(k) Premarket Notification

CLEARED

K896170 REP CK ISOFORMS KIT CAT. NO. 3081, 3082, 3083

Feb 16, 1990
114 days to decision

K896170 · Product code: **JHT** · Chemistry
Source: https://www.510kdatabase.net/k896170/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chromatographic Separation, Cpk Isoenzymes (JHT)
Date received	Oct 25, 1989
Decision date	Feb 16, 1990
Days to decision	114 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/k896170/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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