FDA 510(k) Premarket Notification

K821983 TITAN GEL LDH ISOENZYME KIT

CLEARED

Dec 22, 1982
169 days to decision

K821983 · Product code: **CEX** · Chemistry
Source: https://www.510kdatabase.net/k821983/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chromatographic Separation, Lactate Dehydrogenase Isoenzymes (CEX)
Date received	Jul 6, 1982
Decision date	Dec 22, 1982
Days to decision	169 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k821983/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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