

K771894 LDH ISOENZYME CONTROLDec 22, 1977
77 days to decisionK771894 · Product code: **CEX** · Chemistry
Source: <https://www.510kdatabase.net/k771894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chromatographic Separation, Lactate Dehydrogenase Isoenzymes (CEX)
Date received	Oct 6, 1977
Decision date	Dec 22, 1977
Days to decision	77 days
Third-party review	No

APPLICANT

Company	Bio-Reagents & Diagnostics, Inc.
Location	Mchenry, IL, US
510(k) history	4 submissions · 4 cleared · 1976-1978

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Device record: <https://www.510kdatabase.net/k771894/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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