

K974609 REP CHOLESTEROL PROFILE CONTROL-IIJan 6, 1998
27 days to decisionK974609 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k974609/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Dec 10, 1997
Decision date	Jan 6, 1998
Days to decision	27 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974609/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026