

K940679 REP HDL/LDL-30 KIT - CAT. NO. 3220,3221,3222Sep 9, 1994
212 days to decisionK940679 · Product code: **JHO** · Chemistry
Source: <https://www.510kdatabase.net/k940679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic Separation, Lipoproteins (JHO)
Date received	Feb 9, 1994
Decision date	Sep 9, 1994
Days to decision	212 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/k940679/> 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