

K964471 REP FLUR CHOLESTEROL-60 KITDec 23, 1996
46 days to decisionK964471 · Product code: **JHO** · Chemistry
Source: <https://www.510kdatabase.net/k964471/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic Separation, Lipoproteins (JHO)
Date received	Nov 7, 1996
Decision date	Dec 23, 1996
Days to decision	46 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

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