

K013466 SPIFE 2000/3000 LIPOPROTEINDec 21, 2001
64 days to decisionK013466 · Product code: **JHO** · Chemistry
Source: <https://www.510kdatabase.net/k013466/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic Separation, Lipoproteins (JHO)
Date received	Oct 18, 2001
Decision date	Dec 21, 2001
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement
Other names	MODEL# 3340, 3341, 3342, 3343

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k013466/> 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