

K894366 REP HDL-8 KIT, NO. 3188, REP HDL-16 KIT, NO. 3187Aug 31, 1989
48 days to decisionK894366 · Product code: **LBT** · Chemistry
Source: <https://www.510kdatabase.net/k894366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoresis, Cholesterol Via Esterase-oxidase, Hdl (LBT)
Date received	Jul 14, 1989
Decision date	Aug 31, 1989
Days to decision	48 days
Third-party review	No

APPLICANT

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

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