

K010617 SPIFE IFE CALIBRATOR AND CONTROL KITMar 15, 2001
14 days to decisionK010617 · Product code: **DEW** · Immunology
Source: <https://www.510kdatabase.net/k010617/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igg, Antigen, Antiserum, Control (DEW)
Date received	Mar 1, 2001
Decision date	Mar 15, 2001
Days to decision	14 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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