

K891299 MID-LEVEL IGG KIT CAT. NO. 9315Mar 22, 1989
9 days to decisionK891299 · Product code: **DAQ** · Immunology
Source: <https://www.510kdatabase.net/k891299/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igg (fd Fragment Specific), Antigen, Antiserum, Control (DAQ)
Date received	Mar 13, 1989
Decision date	Mar 22, 1989
Days to decision	9 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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