

K131479 V8 SP NORMAL CONTROL, ABNORMAL CONTROLOct 7, 2013
138 days to decisionK131479 · Product code: **JJY** · Immunology
Source: <https://www.510kdatabase.net/k131479/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	May 22, 2013
Decision date	Oct 7, 2013
Days to decision	138 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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