

**K924915 SCALE SET SOLUTIONS/405NM CAT#1480-650NM
CAT#1479**

Dec 18, 1992
80 days to decision

K924915 · Product code: **JJY** · Hematology
Source: <https://www.510kdatabase.net/k924915/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Sep 29, 1992
Decision date	Dec 18, 1992
Days to decision	80 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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Device record: <https://www.510kdatabase.net/k924915/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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