

K013397 PACIFIC HEMOSTASIS REFERENCE EMULSIONFeb 15, 2002
123 days to decisionK013397 · Product code: **JIX** · Hematology
Source: <https://www.510kdatabase.net/k013397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Oct 15, 2001
Decision date	Feb 15, 2002
Days to decision	123 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fisher Diagnostics
Location	Mchenry, IL, US
Contact	JERALD P STEINER
510(k) history	16 submissions · 16 cleared · 1983-2017

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