

K820319 FETAL-TEK CONTROL MATUREMar 25, 1982
48 days to decisionK820319 · Product code: **JJS** · Chemistry
Source: <https://www.510kdatabase.net/k820319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controls For Blood-gases, (assayed And Unassayed) (JJS)
Date received	Feb 5, 1982
Decision date	Mar 25, 1982
Days to decision	48 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k820319/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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