

**K811695 HELENA FETAL-TEK 200 MARKER**Jul 1, 1981  
15 days to decisionK811695 · Product code: **JJY** · Chemistry  
Source: <https://www.510kdatabase.net/k811695/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Jun 16, 1981
Decision date	Jul 1, 1981
Days to decision	15 days
Third-party review	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k811695/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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