

**K812416 MARK 500 SYSTEM**Apr 8, 1982  
227 days to decision

K812416 · Obstetrics &amp; Gynecology

Source: <https://www.510kdatabase.net/k812416/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Aug 24, 1981
Decision date	Apr 8, 1982
Days to decision	227 days
Third-party review	No

**APPLICANT**

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Company	<b>Kallestad Laboratories, Inc.</b>
Location	Mchenry, IL, US
510(k) history	92 submissions · 92 cleared · 1976-1986

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

Device record: <https://www.510kdatabase.net/k812416/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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