

**K911745 SIMPLATE PEDIATRIC**Aug 9, 1991  
113 days to decisionK911745 · Product code: **JCA** · Hematology  
Source: <https://www.510kdatabase.net/k911745/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Bleeding Time (JCA)
Date received	Apr 18, 1991
Decision date	Aug 9, 1991
Days to decision	113 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Organon Teknika Corp.</b>
Location	Mchenry, IL, US
Contact	ANN M QUINN
510(k) history	130 submissions · 129 cleared · 1980-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911745/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 22, 2026