

**K945117 DELTA**Feb 28, 1997  
864 days to decisionK945117 · Product code: **FLE** · General Hospital  
Source: <https://www.510kdatabase.net/k945117/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Oct 18, 1994
Decision date	Feb 28, 1997
Days to decision	864 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Pelton &amp; Crane Co.</b>
Location	Mchenry, IL, US
Contact	KRISTI KUNKEL
510(k) history	14 submissions · 14 cleared · 1976-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945117/> 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 20, 2026