

**K050734 COOL.CLICK**Jun 3, 2005  
74 days to decisionK050734 · Product code: **KZE** · General Hospital  
Source: <https://www.510kdatabase.net/k050734/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector, Fluid, Non-electrically Powered (KZE)
Date received	Mar 21, 2005
Decision date	Jun 3, 2005
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bioject, Inc.</b>
Location	Portland, OR, US
Contact	MELANIE TALBERT
510(k) history	9 submissions · 9 cleared · 1987-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050734/> 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 June 23, 2026