

**K051985 BIOVALVE MINI-JECT NEEDLEFREE INJECTOR**Aug 17, 2005  
26 days to decisionK051985 · Product code: **KZE** · General Hospital  
Source: <https://www.510kdatabase.net/k051985/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector, Fluid, Non-electrically Powered (KZE)
Date received	Jul 22, 2005
Decision date	Aug 17, 2005
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biovalve Technologies, Inc.</b>
Location	Worcester, MA, US
Contact	SCOTT HUIE
510(k) history	3 submissions · 3 cleared · 2004-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051985/> 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 July 2, 2026