

**K032425 INVISIJECT RESUSABLE AUTO-INJECTOR**Nov 5, 2003  
91 days to decisionK032425 · Product code: **KZH** · General HospitalSource: <https://www.510kdatabase.net/k032425/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Syringe Needle (KZH)
Date received	Aug 6, 2003
Decision date	Nov 5, 2003
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biogen</b>
Location	Cambridge, MA, US
Contact	Michael Poirier
Website	<a href="http://www.biogenidec.com">http://www.biogenidec.com</a>
510(k) history	2 submissions · 2 cleared · 2003-2004

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k032425/> 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