

**K033696 PERSONAL INJECTOR**Feb 16, 2005  
449 days to decisionK033696 · Product code: **KZH** · General Hospital  
Source: <https://www.510kdatabase.net/k033696/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Syringe Needle (KZH)
Date received	Nov 25, 2003
Decision date	Feb 16, 2005
Days to decision	449 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Union Medico Aps</b>
Location	Copenhagen, DK
Contact	MICHAEL PERTHU
510(k) history	1 submissions · 1 cleared · 2005-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033696/> 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