

**K003864 INJEX 50 SYSTEM**Mar 6, 2001  
83 days to decisionK003864 · Product code: **KZE** · General Hospital  
Source: <https://www.510kdatabase.net/k003864/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector, Fluid, Non-electrically Powered (KZE)
Date received	Dec 13, 2000
Decision date	Mar 6, 2001
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Equidyne Systems, Inc.</b>
Location	San Clemente, CA, US
Contact	JIM BARLEY
510(k) history	5 submissions · 5 cleared · 1995-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003864/> 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