

**K901382 ISOFLO(TM) HIGH PRESSURE INJECTION LINES**Jul 19, 1990  
119 days to decisionK901382 · Product code: **DXT** · CardiovascularSource: <https://www.510kdatabase.net/k901382/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Mar 22, 1990
Decision date	Jul 19, 1990
Days to decision	119 days
Third-party review	No

**APPLICANT**

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Company	<b>Healthdyne Cardiovascular, Inc.</b>
Location	Costa Mesa, CA, US
Contact	BILL WELCH
510(k) history	5 submissions · 4 cleared · 1989-1990

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k901382/>; 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 30, 2026