

**K901643 ISOFLO(TM) AMNIOCENTESIS TRAY**Jul 25, 1990  
107 days to decisionK901643 · Product code: **HIO** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k901643/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sampler, Amniotic Fluid (amniocentesis Tray) (HIO)
Date received	Apr 9, 1990
Decision date	Jul 25, 1990
Days to decision	107 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/k901643/>; 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