

**K904583 SONO-VU US(TM)**Jun 24, 1991  
258 days to decisionK904583 · Product code: **HIO** · Radiology  
Source: <https://www.510kdatabase.net/k904583/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sampler, Amniotic Fluid (amniocentesis Tray) (HIO)
Date received	Oct 9, 1990
Decision date	Jun 24, 1991
Days to decision	258 days
Third-party review	No

**APPLICANT**

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Company	<b>E-Z-Em, Inc.</b>
Location	Mchenry, IL, US
Contact	GEORGANNE BROWN
510(k) history	56 submissions · 56 cleared · 1977-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k904583/>; 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 May 18, 2026