

**K862365 NEEDLE FOR AMNIOCENTESIS AND CYST PUNCTURE**Jul 7, 1986  
13 days to decisionK862365 · Product code: **HIO** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k862365/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sampler, Amniotic Fluid (amniocentesis Tray) (HIO)
Date received	Jun 24, 1986
Decision date	Jul 7, 1986
Days to decision	13 days
Third-party review	No

**APPLICANT**

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Company	<b>Swemed Laboratories, Inc.</b>
Location	Sweden, SE
Contact	GORAN ITSKOWITZ
510(k) history	2 submissions · 1 cleared · 1986-1986

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k862365/>; 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