

**K862364 NEEDLE GUIDE (FOR ULTRASOUND TRANSDUCERS)**Aug 19, 1986  
56 days to decisionK862364 · Product code: **HEM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k862364/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Imager, Ultrasonic Obstetric-gynecologic (HEM)
Date received	Jun 24, 1986
Decision date	Aug 19, 1986
Days to decision	56 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/k862364/>; 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