

**K851902 MODEL U-1000 ULTRASONIC SCANNER**Sep 27, 1985  
150 days to decisionK851902 · Product code: **HEM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k851902/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Imager, Ultrasonic Obstetric-gynecologic (HEM)
Date received	Apr 30, 1985
Decision date	Sep 27, 1985
Days to decision	150 days
Third-party review	No

**APPLICANT**

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Company	<b>Fukuda Denshi USA, Inc.</b>
Location	Mchenry, IL, US
Contact	DON ANDRESEN
510(k) history	68 submissions · 68 cleared · 1984-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k851902/>; 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