

**K885149 NEEDLE INSERT FOR SOFT TISSUE BIOPSY DEVICE**Jan 26, 1989  
42 days to decisionK885149 · Product code: **DWO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k885149/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Biopsy, Cardiovascular (DWO)
Date received	Dec 15, 1988
Decision date	Jan 26, 1989
Days to decision	42 days
Third-party review	No

**APPLICANT**

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Company	<b>Hart Enterprises, Inc.</b>
Location	Wyoming, MI, US
Contact	ALAN TAYLOR
510(k) history	4 submissions · 4 cleared · 1988-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k885149/>; 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 26, 2026