

**K945107 POLY-WIRE PISTON**Nov 22, 1994  
35 days to decisionK945107 · Product code: **ETB** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k945107/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Oct 18, 1994
Decision date	Nov 22, 1994
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Micromed Development Corp.</b>
Location	Clearwater, FL, US
Contact	DAN H TRACE
510(k) history	14 submissions · 14 cleared · 1994-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945107/> 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 July 5, 2026