

**K911043 HEMISPHERE MULTIPLANE ENDORECTAL PROBE**Oct 9, 1991  
215 days to decisionK911043 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k911043/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Mar 8, 1991
Decision date	Oct 9, 1991
Days to decision	215 days
Third-party review	No

**APPLICANT**

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Company	<b>Pie Medical Equipment B.V.</b>
Location	Maastricht, NL
Contact	RIKERS
510(k) history	8 submissions · 8 cleared · 1990-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911043/>; 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 19, 2026