

**K961290 IUP - TIP TRANS, IUP - PROXI TRANS**Oct 15, 1996  
194 days to decisionK961290 · Product code: **KXO** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k961290/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Pressure, Intrauterine (KXO)
Date received	Apr 4, 1996
Decision date	Oct 15, 1996
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Scientific Device Manufacturer, LLC</b>
Location	San Rafael, CA, US
Contact	RICHARD C BALL
510(k) history	6 submissions · 6 cleared · 1995-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k961290/> 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 29, 2026