

**K000194 DIGITAL INFLECTION RIGIDOMETER (DIR)**Apr 10, 2000  
80 days to decisionK000194 · Product code: **LIL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k000194/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Penile Tumescence (LIL)
Date received	Jan 21, 2000
Decision date	Apr 10, 2000
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Uroan Xxi Electromedicina</b>
Location	Baleares, ES
Contact	VICTORIA GAYA
510(k) history	1 submissions · 1 cleared · 2000-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000194/> 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 30, 2026