

**K061676 RIGIDOMETER, MODEL DIR-4U**Dec 27, 2006  
196 days to decisionK061676 · Product code: **LIL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k061676/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Penile Tumescence (LIL)
Date received	Jun 14, 2006
Decision date	Dec 27, 2006
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Uroan 21</b>
Location	Palma De Mallorca, ES
Contact	ANABEL ROSSELLO
510(k) history	1 submissions · 1 cleared · 2006-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061676/> 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