

**K014248 DND 202 MANUAL UROLOGICAL DIGITAL NEEDLE DRIVER**Mar 21, 2002  
85 days to decisionK014248 · Product code: **KNA** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k014248/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Manual, Specialized Obstetric-gynecologic (KNA)
Date received	Dec 26, 2001
Decision date	Mar 21, 2002
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Urogyn , Ltd.</b>
Location	Natick, MA, US
Contact	EREZ ADIV
510(k) history	2 submissions · 2 cleared · 2000-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k014248/> 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