

**K111947 DUET MAGNA**Mar 1, 2012  
237 days to decisionK111947 · Product code: **LNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k111947/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotripter, Extracorporeal Shock-wave, Urological (LNS)
Date received	Jul 8, 2011
Decision date	Mar 1, 2012
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Direx Systems Corp.</b>
Location	Natick, MA, US
Contact	LARISA GERSHTEIN
510(k) history	22 submissions · 22 cleared · 2003-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111947/> 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 17, 2026